**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | ) | MDL No. 1456 |
| | ) | CIVIL ACTION: 01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO ALL CLASS ACTIONS | ) | Judge Patti B. Saris |

# REVISED FIFTH AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT

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Plaintiffs, by and through their counsel, upon personal knowledge as to their own acts and beliefs, and upon information and belief as to all other matters based upon the investigations of counsel, allege as follows:

## I. INTRODUCTION

1. This case is brought by Plaintiffs as a proposed class action on behalf of consumers, self-insured employers, health and welfare plans, health insurers and other end payors for prescription drugs (the "Class") against certain pharmaceutical companies (referred to as the "Defendant Drug Manufacturers").

2. For the last decade, the Defendant Drug Manufacturers have conspired with others in the pharmaceutical distribution chain, including but not limited to physicians and hospitals (hereafter "medical providers" or "providers"), pharmacy benefit managers ("PBMs") and various publishing entities, to collect inflated prescription drug payments from Plaintiffs and the Class.

3. More specifically, the Defendant Drug Manufacturers report to trade publications a drug price – the Average Wholesale Price (or "AWP") – that for many drugs is deliberately set far above the prices that these drugs are available in the marketplace. The AWPs for these drugs are deliberately false and fictitious and created solely to cause Plaintiffs and the Class members to overpay for drugs. Because all drugs administered under Medicare Part B are priced based on the published AWPs, the Defendant Drug Manufacturers inflate AWP reimbursement rates to enable providers and others to make secret profits through overcharges to patients, their insurers and other end payors. This, in turn, motivates the providers to sell and administer the drugs with the most inflated AWPs, resulting in increased market share and profit for the Defendant Drug Manufacturers and inflated payments for drugs by individual patients (through co-pays or direct payments), health plans and insurers.

4. For drugs reimbursed by Medicare Part B (which generally, but not always, require administration in a provider's office), the health care providers administer the drugs and are reimbursed by Medicare based on the inflated AWP. Thus, the providers benefit by pocketing the "spread" between the AWP and the actual cost that they pay for the drugs, and the Defendant Drug Manufacturers benefit by increasing the sales of their drugs that are covered by Medicare Part B ("Covered Drugs") and by increasing their market share. In some cases, the Defendant Drug Manufacturers also provide chargebacks, rebates, hidden price discounts and/or other unlawful financial inducements, including free samples, to further increase the provider's spread and, therefore, their incentive to prescribe a particular Defendant Drug Manufacturer's product. Those discounts are not used by the Defendant Drug Manufacturers in calculating the published AWPs, resulting in their inflation.

5. The use of AWP is not limited to Medicare reimbursement. Rather, AWP is a benchmark from which hundreds of drug prices are derived in transactions throughout the pharmaceutical distribution chain. For "Part B covered drugs" administered outside of the Medicare Part B context, non-Medicare patients and health plans pay for these drugs based on the inflated AWP with an intermediary (for example, a pharmacy benefit manager) pocketing the "spread" between the AWP and the actual cost that the intermediaries pay for these drugs. And similar to the benefit that the Defendant Drug Manufacturers obtain through the AWP scheme for Part B drugs, the Defendant Drug Manufacturers also benefit from the AWP scheme with respect to these drugs by increasing the sales of their particular AWP-inflated drugs and their market share for those drugs. The use of AWP as a benchmark for reimbursement is also not limited to Part B drugs being administered outside of Medicare, but extends to thousands of other drugs as well. And again, with respect to these non-Part B drugs, it is the end payor, be it a health plan or private insurer, that pays the inflated amount. All others in the distribution chain,

be they wholesalers, pharmacies or pharmacy benefit manufacturers, benefit from the spread between AWP and actual costs.

6. Thus, in a perversion of the type of competitive behavior expected in a market not subject to illegal manipulation, the Defendant Drug Manufacturers often promote their drugs not based on lower prices, but by the use of reimbursement rates based on a fictitious and inflated AWP that allows purchasers and intermediaries (including providers and PBMs) to make inflated profits – and the Defendant Drug Manufacturers to increase their market share – at the expense of Plaintiffs and the Class. The Class, as further defined below, consists of all purchasers of drugs whose AWPs were inflated ("AWP End Payor Class").

7. The Defendant Drug Manufacturers also caution providers and other intermediaries that the success of the high profit scheme will be jeopardized if anyone discloses the significantly lower prices actually paid for the drugs (allowing the scheme to be concealed and to continue). All Defendants actively conceal, and caused others to conceal, information about the true pricing structure for the prescription drugs, including the fact that the AWPs for the drugs are deliberately overstated. And, all those in the distribution chain also conceal the rebates, free samples, educational grants and other economic rewards which they receive, but which are not reflected in calculating AWP.

8. In response to the Court's Order on the motion to dismiss, plaintiffs have prepared a list of each of the specific drugs that are the subject of the claims herein. This list is attached as Exhibit A to the Complaint. The drugs identified in Exhibit A will be referred to herein as the AWP Inflated Drugs ("AWPID" or "AWPIDs"). And, in Appendix A, plaintiffs identify the AWP that is the subject of this Complaint for each drug currently at issue pursuant to this Court's Order. Appendix B details which AWPIDs were purchased by each plaintiff.[1]

[1] Plaintiffs incorporate by reference all Appendices attached to the previously filed complaint.

## II. JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the laws of the United States, 18 U.S.C. § 1964(c), and because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-1968. The Court also has diversity jurisdiction on Counts IX and X pursuant to 28 U.S.C. § 1332(a) as there is diversity between plaintiff Board of Trustees of Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund and each Defendant, and the amount in controversy exceeds $75,000. Those claims are asserted only on behalf of this plaintiff as the named plaintiff.

10. The Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367. To the extent necessary, the District Court should retain jurisdiction over all parties pursuant to 28 U.S.C. § 1367 as the claims against all parties are related to the claims upon which original jurisdiction is based.

11. A substantial part of the events or omissions giving rise to the claims in this action occurred in this judicial District, and Defendants may be found within this judicial District. Venue is proper in this jurisdiction under 28 U.S.C. § 1391 and 18 U.S.C. § 1965. Defendants implemented their fraudulent marketing scheme in this District, as well as nationwide, through providers and sales representatives who reside or transact business in this District and thereby affected Class Members, who similarly reside or transact business in this District.

12. The Judicial Panel on Multidistrict Litigation has, by Order dated April 30, 2002, ordered all related cases in the *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL Docket Number 1456, transferred to the District of Massachusetts for coordinated or consolidated pre-trial proceedings.

## III. PARTIES

### A. Plaintiffs

13. With the exception of the Public Interest Group Plaintiffs, each of the Plaintiffs identified below have, upon information and belief, were charged for the drugs noted based on a formula incorporating AWP.

#### 1. Proposed Class 1 Representatives (Medicare Part B Beneficiaries)

14. Plaintiff Leroy Townsend is a resident of Naples, Florida. During the time period relevant to this Complaint, he was a Medicare recipient who took Zoladex and paid a 20% co-payment.

15. Plaintiff Susan Aaronson resides in Matthews, North Carolina. Mrs. Aaronson, the wife of a local minister, is a Medicare beneficiary with supplemental insurance coverage through her church. Mrs. Aaronson lives with breast cancer and is currently being treated for ovarian cancer. During the applicable time period, Ms. Aaronson was prescribed, and was charged for, the following physician-administered drugs, based in whole or in part on AWP: albumin (manufactured by co-conspirators Aventis Group and Baxter), albuterol sulfate (Dey, the GSK Group, and the Schering-Plough Group), bacitracin (Pfizer), bupivacaine (Abbott), carboplatin injectable (Baxter, the BMS Group), cefazolin sodium (Baxter, and the GSK Group), cisplatin (Baxter, the BMS Group, and the Sicor Group), darbepoetin alfa (Amgen), dexamethasone sodium phosphate (Baxter, the Fujisawa Group, the Sicor Group, and Watson), dextrose injectable (Abbott, AstraZeneca, and Baxter), dextrose sodium chloride (Abbott), diltiazem hydrochloride injectable (Abbott, Baxter and the Sicor Group), diphenhydramine injectable (Baxter, Pfizer, and the Pharmacia Group), enoxaparin sodium (the Aventis Group), epinephrine (Abbott, Dey and the Sicor Group), epoetin alfa (the Johnson & Johnson Group and Amgen), famotidine (Abbott and Baxter), fentanyl citrate (Abbott, AstraZeneca, Baxter, and the Johnson & Johnson Group), furosemide (Abbott, the Aventis Group, and Baxter), glycopyrrolate injectable (Abbott, Baxter, the Sicor Group, and the Wyeth Group), heparin sodium (Abbott,

Baxter, Pfizer, and the Pharmacia Group), hetastarch sodium chloride injectable (Baxter and the BMS Group), hydromorphone injectable (Abbott, AstraZeneca and Baxter), ipratopium bromide (Dey), lidocaine hydrochloride injectable (Abbott, AstraZeneca and Baxter), magnesium sulfate injectable (Abbott and the Sicor Group), midazolam hydrochloride (Abbott, Baxter and Hoffman-La Roche), morphine sulfate injectable (Abbott, AstraZeneca and the BMS Group), neostigmine methylsulfate (Abbott, Baxter, and the Sicor Group), odansetron (the GSK Group), paclitaxel, (the BMS Group), pegfilgrastim (Amgen), phenylephrine (Baxter and the Sicor Group), plicamycin (Bayer), potassium chloride (Abbott and Baxter), promethazine injectable (Abbott, Baxter, the Sicor Group, and Watson), ringers lactated with dextrose injectable (Abbott and Baxter), propofol injectable (Abbott, AstraZeneca, Baxter, Pfizer, and the Sicor Group), sodium chloride (Abbott, the Aventis Group, Baxter, the Schering-Plough Group, and the Sicor Group), succinylcholine chloride injectable (Abbott), and vercuronium bromide injectable (Abbott, Baxter and the Sicor Group). To date, Mrs. Aaronson has paid several thousands of dollars for these and other prescription drug medications. Although Mrs. Aaronson had supplemental insurance coverage, the coverage required her to make percentage co-payments. Mrs. Aaronson is a proposed class representative for, among other defendants, Aventis, Baxter, BMS, Dey, Fujisawa, GSK, Johnson & Johnson, Sicor and Watson.

16. Plaintiff Harold Carter resides in Austin, Texas, and is a 74 year-old, retired wholesale florist. He is a Medicare beneficiary who currently receives partial assistance from Sterling to help defray a portion of his co-insurance obligations under Medicare Part B for his medical care and treatment. Mr. Carter takes prescription drugs for coronary artery disease and other medical conditions, including prostate cancer. During the applicable time period, Mr. Carter was prescribed, and was charged for, the following physician-administered prescription drugs, based in whole or in part on AWP: adenosine (Abbott and Fujisawa), darbepoetin alfa (Amgen), and epoetin alfa (Amgen and the Johnson & Johnson Group). It has been difficult for

Mr. Carter to pay for the high cost of these and other medications, as his supplemental insurance required him to make percentage payments. On a least one occasion Mr. Carter's doctor did not prescribe a medication because Mr. Carter could not pay for it. Mr. Carter is a proposed class representative for Abbott, Amgen and Fujisawa.

17. Plaintiff Roger Clark is representing the estate of his father, David E. Clark. Mr. Clark resided in Tonto Basin, Arizona, and was a Medicare beneficiary with secondary insurance through the Operating Engineers American Benefit Plan. Before he died, Mr. Clark was treated for prostate cancer and inoperable brain cancer. During the applicable time period, Mr. Clark was prescribed, and was charged for, among others, the following physician-administered prescription drugs, based in whole or in part on AWP: cefazolin (Baxter, the BMS Group, and GSK), cefotetan disodium (the BMS Group), ciprofloxacin hydrochloride (Abbott, Baxter, Bayer, and the Schering-Plough Group), cisplatin (Baxter, the BMS Group, and the Sicor Group), dexamethasone acetate (Watson), dexamethasone sodium phosphate (Baxter, Fujisawa, the Sicor Group, and Watson), dextrose injectable (Abbott, AstraZeneca and Baxter), enalaprilat injectable (Abbott, Baxter and the Sicor Group), epoetin alfa (Amgen and the Johnson & Johnson Group), etoposide (Bedford, Genesia), famotidine (Abbott and Baxter), fentanyl citrate (Abbott, AstraZeneca, Baxter, and the Johnson & Johnson Group), granisetron (the GSK Group and Hoffman-LaRoche), hetastarch sodium chloride injectable (Baxter and the BMS Group), hydromorphone injectable (Abbott, AstraZeneca and Baxter), labetalol injectable (Abbott and Baxter), lidocaine hydrochloride injectable (Abbott, AstraZeneca and Baxter), methylsulfate (the Fujisawa Group), midazolam hydrochloride (Abbott, Baxter and Hoffman-La Roche), morphine sulfate injectable (Abbott, AstraZeneca and the BMS Group), potassium chloride (Abbott, Baxter and Pfizer), ranitidine (the GSK Group), and sodium chloride (Abbott, the Aventis Group, Baxter, the Schering-Plough Group, and the Sicor Group). Mr. Clark has made payments for the foregoing drugs totaling nearly $10,000.00 to date, as his supplemental insurance required him to

make percentage payments for his drugs. Mr. Clark is a proposed class representative for, among other defendants, Abbott, Aventis, Baxter, GSK, J&J and Sicor.

18. Plaintiff Robert Howe resides in Mapleton, Oregon, and is a 79 year-old Medicare beneficiary, with supplemental insurance coverage through United Health Care of Utah. Before he died, Mr. Howe was treated for prostate cancer. During the applicable time period, Mr. Howe was prescribed, and was charged for, among others, the following physician-administered drugs, based in whole or in part on AWP: dexamethasone sodium phosphate (Baxter, the Fujisawa Group, the Sicor Group, and Watson), docetaxel (the Aventis Group), gentamicin sulfate (Abbott, Baxter, the Fujisawa Group, and Watson), goserelin acetate (AstraZeneca), granisetron (the GSK Group and Hoffman-LaRoche), novatrone (Immunex) and pegfilgrastim (Amgen). Mr. Howe has made payments for the foregoing drugs, as his supplemental insurance required him to make percentage payments for his drugs. Mr. Howe is a proposed class representative for, among other defendants, Amgen, AstraZeneca, Aventis, GSK, Sircor and Watson.

19. Plaintiff James Monk resides in Lake Village, Arkansas and is a 81 year old Medicare recipient with supplemental insurance. During the applicable time period, Mr. Monk was prescribed, and was charged for, among others, the following physician-administered drugs, based in whole or in part on AWP: casodex (AstraZeneca), eligard (Aventis). Mr. Monk has made payments for the foregoing drugs, as his supplemental insurance requires him to make percentage payments. Mr. Monk is a proposed class representative for, among other defendants, Aventis.

20. Plaintiff James Shepley resides in Reno, Nevada, and is an 85 year-old Medicare beneficiary, with secondary insurance coverage through United American. Mr. Shepley is living with prostate cancer. During the applicable time period, Mr. Shepley was prescribed, and was charged for, the following physician-administered prescription drugs, based in whole or in part on AWP: epoetin alfa (Amgen and the Johnson & Johnson Group), goserelin acetate

(AstraZeneca). Mr. Shepley has made payments for the foregoing drugs. Although Mr. Shepley had supplemental insurance coverage, the coverage required him to make percentage co-payments. Mr. Shepley is a proposed class representative for, among other defendants, AstraZeneca and J&J.

21. Plaintiff Larry Young is representing the Estate of Patricia K. Young, his late wife. Before she died, Mrs. Young resided in Enid, Oklahoma where her husband still resides. She was a Medicare beneficiary as a result of a longstanding disability, with supplemental insurance through United Healthcare that covered only a portion of her co-insurance obligation for prescription drugs under Medicare Part B. She received medication for rheumatoid arthritis, Hepatitis C, and lymphoma, the disease that ultimately caused her death. During the applicable time period, Mrs. Young was prescribed, and was charged for, among others, the following physician-administered prescription drugs manufactured and sold by the defendant companies, based in whole or in part on AWP: anzemet (Aventis), aristocort (Fujisawa), cytoxan (the BMS Group, Pfizer, and the Pharmacia Group), dexamethasone acetate (Abbott, Bayer and Watson), dexamethasone sodium phosphate (Baxter, the Fujisawa Group, the Sicor Group, and Watson), dolasetron mesylate (the Aventis Group), dopamine hydrochloride (Abbott, Baxter, and the BMS Group), epirubicin (Pfizer and the Pharmacia Group), epoetin alfa (Amgen), fentanyl citrate (Abbott, AstraZeneca, Baxter, and the Johnson & Johnson Group), filgrastim (Amgen), heparin sodium (Abbott, Baxter, Pfizer, and the Pharmacia Group), hydrocortisone sodium succinate (Pfizer and the Pharmacia Group), infliximab (the Johnson & Johnson Group), ketorolac tromethamine (Abbott and Baxter), levofloxacin (Abbott and the Johnson & Johnson Group), lidocaine hydrochloride injectable (Abbott, AstraZeneca and Baxter), lorazepam injectable (Abbott, Baxter, and Watson), methotrexate sodium injectable (Baxter, Immunex, and the Wyeth Group), midazolam (Abbott, Baxter and Hoffman-LaRoche), moxifloxacin injectable (Bayer and the Schering-Plough Group), oprelvekin (the Wyeth Group), promethazine (Abbott, Baxter, the

Sicor Group, and Watson), protonix injectable (the Wyeth Group), solucortef (Pharmacia), triamcinolone acetonide (the BMS Group), vancomycin sulfate (Abbott, Baxter, and Watson), vincristine sulfate (the Pharmacia Group and the Sicor Group), and warfarin sodium injectable (the BMS Group). At various times throughout the course of Mrs. Young's treatment, the Youngs' made payments via credit card to meet their payment obligations to their various medical providers. To date, the Youngs made many payments for the foregoing drugs, as their supplemental insurance requires them to make percentage payments. The Estate of Patricia Young is a proposed class representative for, among other defendants, Abbott, Amgen, Aventis, Baxter, BMS, Fujisawa, J&J, Pfizer, Sicor and Watson.

22. Plaintiff Virginia Newell is representing the Estate of William Newell. Mr. Newell was a resident of Mooresville, North Carolina. Mr. Newell took prescription drug medications for diabetes and osteoparothis. He was a Medicare recipient with supplemental insurance through the American Association of Retired Persons. During the applicable time period, Mr. Newell was prescribed, and was charged for, among others, the following physician-administered drugs, based in whole or in part on AWP: epoetin alfa (Amgen and the Johnson & Johnson Group), viadur (the Johnson & Johnson Group), taxotere (Aventis) and levaquin (the Johnson & Johnson Group). The Newells made payments for the foregoing drugs, as their supplemental insurance did not cover the full cost of their drugs. The Estate of William Newell is a proposed class representative for, among other defendants, Amgen, AstraZeneca, BMS, J&J and Aventis.

23. Plaintiff Oral Ray Roots resides in Wichita, Kansas and is an 82 year old Medicare recipient with supplemental insurance through AETNA. During the applicable time period, Mr. Roots was prescribed, and was charged for, among others, the following physician-administered drugs, based in whole or in part on AWP: albuterol sulfate (Dey, the GSK Group, and the Schering-Plough Group) and depo-provera (Pfizer). Mr. Roots has made payments for

the foregoing drugs because his supplemental coverage required him to make payments for them. Mr. Roots is a proposed class representative for, among other defendants, Dey, Pfizer and Schering-Plough.

24. Plaintiff Hunter G. Walters resides in Bandalia, Michigan and is a Medicare recipient with no supplemental insurance. Mr. Walters receives medication for emphysema and prostate cancer. During the applicable time period, Mr. Walters was prescribed, and was charged for, among others, the following physician-administered drugs, based in whole or in part on AWP: albuterol sulfate (Dey, the GSK Group, and the Schering-Plough Group) and ipratropium bromide (Dey). Mr. Walters has made payments for the foregoing drugs. Mr. Walters is a proposed class representative for, among other defendants, Dey and Schering Plough.

24A. Plaintiff Muriel Tonacchio is the representative of the Estate of Wilma Mort. Ms. Mort was a resident of Weirton, West Virginia. Ms. Mort took prescription drug medications for the treatment of cancer and was a Medicare recipient at the time of her cancer treatments. During the applicable time period, Ms. Mort was prescribed and was charged for the physician-administered drug Anzamet based in whole or in part on AWP. Ms. Mort made one or more payments for this drug. Ms. Tonacchio, as the representative of the Estate of Wilma Mort, is a proposed class representative, for among other Track Two Defendants, Aventis.

**2. Proposed Class 2 Representatives (MediGap Payors)**

25. Plaintiff United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") is an employee welfare benefit plan and employee benefit plan maintained pursuant to Section 302(c)(5) of the LMRA, and is an employee welfare benefit plan established and maintained pursuant to ERISA, for the purpose of providing health benefits to eligible participants and beneficiaries. UFCW maintains its principal place of business in Cook County, Illinois. During the Class Period, UFCW has been billed for and paid charges for AWPIDs, including: Abbott's sodium chloride, gentamicin sulfate, furosemide, heparin lock

flush and dextrose; Baxter's sodium chloride and dextrose; Bedford's leucovorin calcium; Sicor's leucovorin calcium; Pharmacia's methylprednisolone sodium; Aventis' Furosemide; Immunex' leucovorin calcium and Johnson & Johnson's Remicade. UFCW also made payments for drugs outside of the Medicare Part B context based on published AWPs. All of UFCW drugs that are at issue in the Complaint are identified in Appendix B. From December 2000 to the present, UFCW has contracted with a PBM to administer its prescription drug benefit for its beneficiaries. For brand name drugs its contract expressly provides that reimbursement is at "AWP less 13%." For generic drugs its reimbursement is also based on AWP. Prior to December 2000, UFCW contracted with pharmacies for the payment of purchases of pharmaceutical drugs by its members and beneficiaries at an estimated acquisition cost based on the AWPs (less a specified percentage) published by the manufacturers in Medispan.

26. UFCW's beneficiaries began to and have continued to be reimbursed for their purchases of physician-administered drugs pursuant to UFCW's comprehensive medical expense benefit, its major medical plan. *See* United Food and Commercial Workers Unions and Employers Midwest Health Benefits Plan, P001294-1417. UFCW made payments for physician-administered drugs based on published AWPs. Since November 1, 1994, UFCW's comprehensive medical expense benefit has been administered by Blue Cross Blue Shield of Illinois ("BCBS"). Until January 1, 2005, when BCBS' payments for physician-administered drugs began to be established considering ASP, BCBS' payments were based on a negotiated allowance which was established considering a percentage above AWP. For physician-administered drugs not covered by Medicare Part B, UFCW paid 80% or 85% of BCBS' payments, and the UFCW member paid the remainder. Further, UFCW has made co-payments under Medicare Part B throughout the Class Period. A member's 20 percent co-payment under Medicare Part B is, and has been, an eligible expense under UFCW's plans during the Class

Period. If Medicare pays a portion of a Fund member's claim under Medicare Part B, UFCW reimburses the remainder of the claim.

27. For transactions that occurred after October 31, 2004, Plaintiff UFCW is able to determine for which drugs it reimbursed and by how much it reimbursed by performing a computer search of its claims files. Such files also show which of its covered members had an amount due and owing after UFCW made its reimbursement of the claim.

28. Plaintiff Pirelli Armstrong Tire Corporation Retiree Medical Benefits Trust ("PMBT") is a voluntary employee benefits association maintained pursuant to the federal Employee Retirement Security Act, 29 U.S.C. § 1132, *et seq.*, and to the settlement of a federal court action (Case No. 3:94-0573) brought in the United States District Court for the Middle District of Tennessee against Pirelli Armstrong Tire Corp. ("Pirelli") in the early 1990's by many Pirelli retirees, for the purpose of providing health and medical benefits to eligible participants and beneficiaries. PMBT maintains its principal place of business in Goodlettsville, Sumner County, Tennessee.

29. During the Class Period, PMBT also reimbursed its members for portions of pharmaceutical bills (including physician-administered drugs) that were covered in the first instance by Medicare Part B. The plan expressly states that it pays 20 percent of all covered Medicare Part B claims. The fund notified that Medicare Part B has covered a given drug or procedure and has paid 80 percent of the cost. The fund then pays the identified "coinsurance" amount, or 20 percent of the total cost Medicare has paid. Numerous drugs fall into this category. Based on a recent review of a small number of our files, PMBT has determined that, with respect to drugs manufactured by the Track 1 Defendants (Astra-Zeneca, Bristol-Myers-Squibb, Glaxo-Smith-Kline and Johnson & Johnson), PMBT made Medicare co-payments with respect to at least the following drugs: Zovirax (Glaxo Smith Kline), Zoladex (Astra-Zeneca), Cytoxan (Bristol-Myers-Squibb), and Procrit (Johnson & Johnson). Because the fund is

composed of retirees, about two-thirds of whom are eligible for Medicare, and because the search was only of a relatively small number of files, plaintiffs are confident that further investigation will show that other drugs were paid for in the Medicare Part B context with respect to the various companies known in this case as "Track 1" and "Track 2" Defendants. Our investigation is continuing.

30. Plaintiff Sheet Metal Workers National Health Fund ("SMW Health Fund") is a Taft-Hartley trust administered pursuant to the requirements of 29 U.S.C. § 186 by an equal number of trustees appointed by labor representatives and union representatives. Its Fund Office is in Goodlettsville, Tennessee. The SMW Health Fund is also a multiemployer welfare fund subject to ERISA. The SMW Heath Fund provides a Supplemental Medicare Wraparound Plus ("SMW+") program that covers the Medicare Part B co-payments of its beneficiaries. There are over 15,000 retirees and covered beneficiaries who receive benefits under the SMW+ program. During the Class Period, the SMW Health Fund has paid for portions of pharmaceutical bills that were covered in the first instance by Medicare Part B. The drugs for which payments were made include Cytoxan (BMS), Etopophos (BMS), Kytril (GSK), Levaquin (J&J), Nevelbine (GSK), Paraplatin (BMS), Procrit (J&J), Remicade (J&J), Rubex (BMS), Taxol (BMS), Vepesid (BMS) and Zoladex (AstraZeneca), and drugs manufactured by Abbott, Amgen, Aventis, Baxter, Bayer, Dey, Fujisawa, Genesia, Immunex, Pfizer, Pharmacia, Sicor and Watson.

31. Plaintiff Blue Cross and Blue Shield of Massachusetts, Inc. ("BCBSMA") is a not-for-profit hospital and medical services corporation organized under the laws of Massachusetts, and has its principal place of business in Boston, Massachusetts and is a proposed class representative for Class 2 as against Track 1 defendants. At all times relevant to this action, BCBSMA has been, and is, licensed to do, and is doing, business in the state of Massachusetts. During the Class Period BCBSMA has made co-payments under Medicare Part B for AWPIDs for Track 1 Defendants, including: BMS's Cytoxan, Etopophos, Rubex,

Belnoxane, Paraplantin, Vepesid, and Taxol; GSK's Kytril, Zofran, Zantac, Alkeran, Nalvelbine; Shearing's Procrit and Intron-A; AstraZeneca's Zoladex and Pulmicort; and Johnson & Johnson's Remicade, as part of its medigap insurance product known as Medex.

**3. Proposed Class 3 Representatives (TPPs and Consumers for AWP-Based Charges on Physician Administered Drugs Outside of Medicare)**

32. UFCW is also a proposed representative for this Class.

33. Plaintiff Board of Trustees of Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund ("CMHV") is an employee welfare benefit plan and employee benefit plan established and maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. § 186(c)(5), and as defined by §§ 1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001, *et seq*., for the purpose of providing health benefits to eligible participants and beneficiaries. As such, CMHV is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). CMHV maintains its principal place of business at 9555 West Sam Houston Parkway South, Suite 400, Houston, Texas. During the Class Period, Carpenters Welfare Trust Fund has been billed for and paid charges for Covered Drugs and otherwise made payments for drugs outside of the Medicare Part B context based on published AWPs. These drugs are identified in Appendix B. During the period relevant to the complaint, CMHV used an administrator to provide medical and drug benefits to its members. CMHV's administrator contracted directly with a PBM to provide pharmacy services to CMHV participants. By contract, all of CMHV's drug purchases were directly and expressly tied to AWP. CMHV paid for brand named drugs in both the retail and mail order context based on AWP minus a fixed percentage. For generic drugs in the retail context CMHV paid based upon MAC, which itself was tied to AWP and in the mail order context CMHV's generic purchases were made at either MAC or AWP minus a fixed percentage. By contract, the AWP used to determine prices was based on that published by "First Databank Blue Book."

34. Plaintiff Teamsters Health & Welfare Fund of Philadelphia and Vicinity ("THWF") is an employee welfare benefit plan and employee benefit plan established and maintained pursuant to Section 302(c)(5) of the LMRA, and is an employee welfare benefit plan established and maintained pursuant to §§ 1002(1) and (3) of ERISA, for the purpose of providing health benefits to eligible participants and beneficiaries. As such, THWF is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. 1132(d). THWF maintains its principal place of business at Fourth & Cherry Streets, Philadelphia, Pennsylvania 19106. It provides comprehensive health coverage for over 28,000 participants and beneficiaries in parts of Pennsylvania, New Jersey and Delaware. During the Class Period, THWF has been billed for and paid charges for AWPIDs. THWF also made payments for drugs outside of the Medicare Part B context based on published AWPs. All drugs covered by this Complaint purchased by this plaintiff are identified in Appendix B. THWF uses the services of a PBM to administer its prescription drug program. Based upon its contracts it pays for brand name drugs at AWP minus a fixed percentage, and pays for generics based on MAC, which is itself based on AWP. It also pays for certain drugs outside the PBM context and does so based on AWP.

35. Plaintiff Twin Cities Bakery Workers Health and Welfare Fund ("TCBW") is a jointly administered Taft-Hartley Fund established and maintained pursuant to Section 302(c)(5) of the LMRA, and is an employee welfare benefit plan established and maintained pursuant to ERISA, for the purpose of providing health benefits to eligible participants and beneficiaries. TCBW maintains its principal place of business in Eagan, Minnesota. As such, TCBW is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). TCBW provides health benefits, including prescription drug benefits, to approximately 2000 active participants, and their spouses and dependants. During the Class Period, TCBW has been billed for and paid charges for AWPIDs. TCBW also made payments for drugs outside of the Medicare Part B context based on published AWPs. The drugs purchased by TCBW at issue in this litigation are

identified in Appendix B. TCBW contracts with a third-party administrator for administration of its pharmacy and medical benefits programs. This administrator in turn contracts with pharmacies and reimburses the pharmacies based upon published AWPs. For example, a typical agreement with a pharmacy providing services to TCBW members provides that reimbursement is at "AWP minus 10%." It further provides that the AWP is determined by Medispan. As for generics, reimbursement is based on MAC, which in turn is derived from AWP.

36. Plaintiff Philadelphia Federation of Teachers Health and Welfare Fund ("PFTHW") is a voluntary employee benefits plan organized pursuant to § 501(c) of the Internal Revenue Code for the purpose of providing health benefits to eligible participants and beneficiaries. PFTHW maintains its principal place of business in Philadelphia, Pennsylvania. PFTHW provides health benefits, including prescription drug benefits, to approximately 20,000 active participants, and their spouses and dependents. During the class period, PFTHW has been billed for and paid charges for covered drugs and otherwise made payments for drugs outside of the Medicare Part B context based on published AWPs. These drugs are identified in Appendix B. During the period relevant to this Complaint PFTHW used a PBM to provide prescription services for its members. At all times its payment formula for both brand name and generic drugs was expressly tied to AWP.

37. Plaintiff Man-U Service Contract Trust Fund ("Man-U Service Fund") is a trust fund established and maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act, 29 U.S.C. § 186(c)(5), and is an employee benefit plan established and maintained pursuant to the Employee Retirement Income Security Act, 29 U.S.C. § 1001, *et seq.*, for the purpose of providing health benefits, including prescription drug coverage, to eligible participants and beneficiaries. The Man-U Service Fund maintains its principal place of business at 4600 Powder Mill Road, Suite 100, Beltsville, Maryland 20705. The Manu-U Service Fund provides comprehensive health coverage, including prescription drug coverage, for

approximately 1,200 participants and beneficiaries located in Maryland, Delaware, Virginia, North Carolina, Pennsylvania and Washington, D.C. All of Man-U Service Fund's drugs at issue in the Complaint are identified in Appendix B. Plaintiff Man-U Service Fund utilizes the services of a PBM and all of its contracts provide that its drug purchases are directly based on AWP. For example, for drugs purchased through the pharmacy, its contract provides for payment at "AWP – 16%," and for mail-order drugs, "AWP – 23%."

38. BCBSMA is also a proposed representative for Class 3 as against Track 1 defendants. During the Class Period, BCBSMA made payments for drugs outside of the Medicare Part B context based on published AWPs from Track 1 Defendants. All of BCBSMA drugs that are at issue in the Complaint are identified in Appendix A. BCBSMA contracts to reimburse providers based on fee schedules generated by BCBSMA which fee schedules relating to physician administered drugs are based on the AWP for those drugs.

39. Pipefitter's Local Union 357 ("Pipefitters") is an employee welfare benefit plan and employee benefit plan maintained pursuant to Section 302(c)(5) of the LMRA and is an employee welfare benefit plan established and maintained pursuant to ERISA, for the purpose of providing health benefits to eligible participants and beneficiaries. Pipefitters maintains its principal place of business in Allston, Massachusetts. During the Class Period, Pipefitters has been billed for and paid charges for AWPIDs outside of the Medicare Part B context based on published AWPs. All of Pipefitters drugs that are at issue in the Complaint are identified in Appendix A. During the Class Period Pipefitters contracted with a third-party administrator, BCBSMA, to administer its prescription drug benefit for its beneficiaries. Pipefitter's Reimbursement for AWPIDs is based on fee schedules generated by BCBSMA which fee schedules relating to physician administered drugs are based on the AWP for those drugs.

39a Plaintiff Health Care For All ("HCFA") is a consumer health advocacy organization that has led the fight in Massachusetts to expand access to affordable, quality health

care since 1985. HCFA maintains its principal place of business in Boston, Massachusetts. During the Class Period, HCFA's members have been billed for and paid charges for AWPIDs outside of the Medicare Part B context based on published AWPs.

40. In addition, from 2002 through 2003, plaintiff William Barnewolt paid out-of-pocket amounts for Procrit (J&J), Arenesp (Amgen), Furosemide (Abbott), and Infed (Watson). Plaintiff William Barnewolt is represented in this action by plaintiff Bonnie Barnewolt, as a successor in interest to William Barnewolt. The amounts Mr. Barnewolt paid were based on AWP. Mr. Barnewolt was a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

41. Plaintiff Cheryl Barreca is a resident of Schaumburg, Illinois. In 1997, 1998, and 2001, Ms. Barreca paid out-of-pocket amounts for Procrit (J&J), Rubex (BMS), Cytoxan (BMS), Kytril (GSK), and Dexamethasone Sodium. Kytril (granisetron HCL) is a physician administered injectable drug marketed by GSK, which is used to relieve suffering from nausea and vomiting as a result of chemotherapy and radiation therapy. The amounts she paid were based on AWP. Ms. Barreca is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

42. Plaintiff Cynthia Byrski is a resident of Chicago Heights, Illinois. In 2002, Ms. Byrski paid out-of-pocket amounts for Rubex (BMS), Kytril (GSK), Cytoxan (BMS), and Dexamethasone Sodium. The amounts she paid were based on AWP. Ms. Byrski is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

43. Plaintiff Mary Cauble is a resident of Granite City, Illinois. In 2004, Ms. Cauble paid out-of-pocket amounts for Rubex (BMS), Dextrose, Dexamethasone Sodium, and Heparin Sodium. The amounts she paid were based on AWP. Ms. Cauble is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

44. Plaintiff Anna Choice is a resident of Chicago, Illinois. From 2000 through 2005, Ms. Choice paid out-of-pocket amounts for Rubex (BMS), Zofran (GSK), Cytoxan (BMS), Heparin, Dexamethasone Sodium, and Taxotere (Aventis). Taxotere (docetaxel) is a physician administered injectable drug marketed by Aventis, which is used to treat locally advanced cancers following the failure of chemotherapy. The amounts she paid were based on AWP. Ms. Choice is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting co-insurance amounts paid by plan participants, are based on AWP.

45. Plaintiff Joyce Dison is a resident of Toulon, Illinois. In 2000 and 2001, Ms. Dison paid out-of-pocket amounts for Rubex (BMS), Cytoxan (BMS), Dexamethasone Sodium, and Anzemet (Aventis). The amounts she paid were based on AWP. Ms. Dison is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

46. Plaintiff Tracy Garcia is a resident of Oak Lawn, Illinois. In 2004 and 2005, Ms. Garcia paid out-of-pocket amounts for Rubex (BMS), Cytoxan (BMS), Albuterol (Schering-Plough), Neulasta (Amgen), Heparin, Sodium Chloride, Anzemet (Aventis), and Dexamethasone Sodium. The amounts she paid were based on AWP. Ms. Garcia is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for

physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

47. Plaintiff Donna Kendall is a resident of Decatur, Illinois. From 2002 to 2004, Ms. Kendall paid out-of-pocket amounts for Cytoxan (BMS), Kytril (GSK), Rubex (BMS), Procrit (J&J), Dexamethasone Sodium, Sodium Chloride, Lorazepam (Abbott), and Taxotere (Aventis). The amounts she paid were based on AWP. Ms. Kendall is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

48. Plaintiff Sandra Leef is a resident of Chicago, Illinois. In 2001, Ms. Leef paid out-of-pocket amounts for Cytoxan (BMS), Dexamethasone Sodium, Anzemet (Aventis), Lorazepam (Abbott), and Fluorouracil (Fujisawa). The amounts she paid were based on AWP. Ms. Leef is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

49. Plaintiff Gerald Miller is a resident of Peoria, Illinois. In 2004 and 2005, Mr. Miller paid out-of-pocket amounts for Paraplatin and Dexamethasone Sodium manufactured by BMS. The amounts he paid were based on AWP. Mr. Miller is a beneficiary of the UFCW Fund, which is administered by Blue Cross/Blue Shield of Illinois, which charges for physician-administered drugs based on AWP, and any co-payments are based upon AWP.

50. Plaintiff Joseph Miller is a resident of Merrillville, Indiana. In 1997 and 1998, Mr. Miller paid out-of-pocket amounts for Zofran (GSK), Heparin Sodium, Cisplatin (Baxter), Furosemide (Abbott), and Dexamethasone Sodium. The amounts he paid were based on AWP. Mr. Miller is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue

Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

51. Plaintiff Constance Nelson is a resident of McHenry, Illinois. In 2000 and 2002, Ms. Nelson paid out-of-pocket amounts for Rubex (BMS), Zofran (GSK), Cytoxan (GSK), Heparin, Procrit and Dexamethasone Sodium. The amounts she paid were based on AWP. Ms. Nelson is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

52. Plaintiff Andrea Palenica is a resident of Oak Lawn, Illinois. In 2000 and 2005, Ms. Palenica paid out-of-pocket amounts for Cytoxan (BMS), Kytril (GSK), Dexamethasone Sodium (Watson), Leucovorin Calcium (Sicor), and Dextrose (Baxter). Upon information and belief, the amounts Ms. Palenica paid were based on AWP. Ms. Palenica is a beneficiary of the UFCW Fund, which is administered by Blue Cross/Blue Shield of Illinois, which has previously testified that its charges for physician-administered drugs, and the resulting co-insurance amounts paid by plan participants, are based on AWP.

53. Plaintiff Regina Shoemaker is a resident of Crown Point, Indiana. In 1996 and 1997, Ms. Shoemaker paid out-of-pocket amounts for Cytoxan (BMS) and Dextrose. The amounts she paid were based on AWP. Ms. Shoemaker is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

54. Plaintiff Scott Tell is a resident of Freeport, Illinois. In 1999, 2000 and 2004, Mr. Tell paid out-of-pocket amounts for his wife Rhonda's medications, including Kytril (GSK), Paraplatin (BMS), Heparin and Dexamethasone Sodium. The amounts he paid were based on AWP. Mr. Tell is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue

Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

55. Plaintiff Kenneth Vanderwal is a resident of Dyer, Indiana. In 2003 and 2004, Mr. Vanderwal paid out-of-pocket amounts for Remicade (J&J). The amounts he paid were based on AWP. Mr. Vanderwal is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

56. Plaintiff Pauline Vernick is a resident of Buffalo Grove, Illinois. In 2002, Ms. Vernick paid out-of-pocket amounts for Cytoxan (BMS), Rubex (BMS), Sodium Chloride, Heparin, Anzemet (Aventis), and Dexamethasone Sodium. The amounts she paid were based on AWP. Ms. Vernick is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

57. Plaintiff Mardolyn Vescovi is a resident of Shorewood, Illinois. In 2002, Ms. Vescovi paid out-of-pocket amounts for Cytoxan (BMS), Rubex (BMS), Procrit (J&J), Heparin, Dexamethasone Sodium and Anzemet (Aventis). The amounts she paid were based on AWP. Ms. Vescovi is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

58. Plaintiff Susan Wessels is a resident of Rock Falls, Illinois. In 2004 and 2005, Ms. Wessels paid out-of-pocket amounts for Zoladex (AstraZeneca). The amounts she paid were based on AWP. Ms. Wessels is a beneficiary of the UFCW Fund. The UFCW Fund is administered by Blue Cross/Blue Shield of Illinois whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

59. Plaintiff Kathleen Weaver-Zech is a resident of Chicago, Illinois. In 2003, Mrs. Weaver-Zech paid out-of-pocket amounts for Remicade. The amounts she paid were based on AWP. Mrs. Weaver-Zech was a beneficiary of the UFCW Fund, which is administered by Blue Cross Blue Shield of Illinois, whose charges for physician-administered drugs, and the resulting amounts paid by plan participants, are based on AWP.

60. Rebecca Hopkins resides in North East, Pennsylvania, and is a 49 year-old who has been privately insured through Blue Cross/Blue Shield of Pennsylvania for most of the applicable time period. However, for a portion of her medical care and treatment, Mrs. Hopkins had no insurance coverage and had to pay 100% of the cost of her care, amounting to thousands of dollars, which care included physician-administered drugs for which she paid out of pocket. Mrs. Hopkins received medication for ovarian cancer. During the applicable time period, Mrs. Hopkins was prescribed, and was charged for, the following physician-administered drugs, based in whole or in part on AWP: azithromycin (Pfizer), bleomycin sulfate (the BMS Group and the Pharmacia Group), carboplatin injectable (the BMS Group and Baxter), cefuroxime (Baxter), cisplatin (Baxter, the BMS Group, and the Sicor Group), doxycycline (Pfizer), etoposide phosphate (the BMS Group, the Pharmacia Group, and the Sicor Group), minocycline (the Wyeth Group), paclitaxel (the BMS Group), tamoxifen (AstraZeneca), and vancomycin sulfate (Abbott, Baxter, and Watson). Mrs. Hopkins has made payments for the foregoing drugs. Mrs. Hopkins is a proposed class representative for, among other defendants, BMS.

61. George Baker Thomson resides in Gulfport, Florida, and is a 78 year-old who is privately insured through Wellcare. Mr. Thomson is living with prostate cancer. During the applicable time period, Mr. Thomson was prescribed, and was charged for, the following physician-administered drugs, based in whole or in part on AWP: goserelin acetate (AstraZeneca) and triptorelin pamoate (Pfizer and the Pharmacia Group). Mr. Thomson has made payments for the foregoing drugs. Although Mr. Thomson had insurance coverage, the

coverage required him to make percentage co-payments. Mr. Thomson is a proposed class representative for, among other defendants, AstraZeneca.

62. Each of the plaintiffs is either producing complete documentation or is in the process of obtaining medical records.

**4. Public Interest Group Plaintiffs**

63. Plaintiff Vermont Public Interest Research Group ("VPIRG") has been Vermont's leading watchdog and advocacy group since 1972. It is located at 141 Main Street, Ste. 6, Montpelier, Vermont. During the Class Period, VPIRG's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers and made inflated payments or co-payments based in whole or in part on published AWPs, and were injured by the illegal conduct alleged herein. For example, Ms. Elizebeth Ryan Cole of Thetford, Vermont, an active VPIRG member, purchased the Johnson & Johnson Group's drug Retin-A based in whole or in part upon the published AWP and Ms. Dawn Taylor of Hinesburg, Vermont, an active VPIRG member, purchased BMS's drug Plavix in whole or in part based upon Defendants' published AWP. As an unincorporated association, VPIRG has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). VPIRG appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, § 16 of the Clayton Act and any other applicable statute.

64. Plaintiff Wisconsin Citizen Action ("WCA") is the state's premiere public interest organization with 53,000 individual members and 250 affiliate organizations. It is located at 1202 Williamson St., Suite B, Madison, Wisconsin. During the Class Period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers and made inflated payments or co-payments based in whole or in part upon the published AWP, and were injured by the illegal conduct alleged herein. For example, Ms. Ida Johnson of Oconomowoc, Wisconsin, and active WCA member, purchased

Pfizer's drug Lipitor in whole or in part based upon Defendants' published AWP. As an unincorporated association, WCA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). WCA appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, §16 of the Clayton Act and any other applicable statute.

65. Plaintiff New York StateWide Senior Action Council ("StateWide") is a grassroots membership organization made up of individual senior citizens and senior citizen clubs from all parts of New York State. It is located at 275 State Street, Albany, New York. During the Class Period, StateWide's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments based in whole or in part upon published AWPs, and were injured by the illegal conduct alleged herein. For example, Ms. Mary Jane Snyder of Clifton Park, New York, an active StateWide member, purchased AstraZeneca's drugs Prilosec and Nexium, BMS's drug Tequin, and Schering's drugs Clarinex and K-Dur based in whole or in part on Defendants' published AWPs. As an unincorporated association, StateWide has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). StateWide appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, §16 of the Clayton Act and any other applicable statute.

66. Plaintiff Citizen Action of New York ("CANY") is a coalition of labor, senior citizen, women's, student, tenant and community organizations that works with community activists for social and economic justice. It is located at 94 Central Avenue, Albany, New York. During the Class Period, CANY's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefore based in whole or in part on published AWPs, and were injured by the illegal conduct alleged herein. For example, Ms. Marilyn Gourley of Binghamton, New York,

an active CANY member, purchased Pfizer's drug Zoloft based in whole or in part upon Defendants' published AWPs. As an unincorporated association, CANY has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). CANY appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, §16 of the Clayton Act and any other applicable statute.

67. Plaintiff Citizens for Consumer Justice ("CCJ") is a Pennsylvania nonprofit umbrella organization that promotes affordable, quality health care. It is located at Architects Building, 117 South 17th Street, Suite 311, Philadelphia, Pennsylvania. During the Class Period, CCJ's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or copayments based in whole or in part on published AWPs, and were injured by the illegal conduct alleged herein. For example, Ms. Patricia Pudyk of Aliquippa, Pennsylvania, an active CCJ member, purchased AZ's drug Nexium in whole or in part based upon Defendants' published AWP. As an unincorporated association, CCJ has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). CCJ appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, § 16 of the Clayton Act and any other applicable statute.

**B. Defendants**

68. The acts charged in this Complaint as having been done by the Defendants were authorized, ordered, or done by their officers, agents, employees, or representatives while actively engaged in the management of the Defendants' business or affairs.

69. Various other individuals, partnerships, sole proprietors, business entities, companies and corporations, presently unknown to Plaintiffs and not named as Defendants in this Complaint, participated as co-conspirators in the violations alleged in this Complaint and performed acts and made statements in furtherance thereof. Such unknown persons or entities

acted as co-conspirators and aided, abetted or participated with Defendants in the commission of the wrongful acts alleged in this Complaint.

**1. Abbott**

70. Defendant Abbott Laboratories ("Abbott") is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott is a diversified health care company that discovers, develops, manufactures, and markets health care products and pharmaceuticals. Abbott's principal businesses are global pharmaceuticals, nutritionals, and medical products. Abbott reported revenues for the year 2000 of approximately $13.7 billion and net earnings of $2.8 billion.

71. Abbott, one of the world's largest pharmaceutical companies, is in the business of manufacturing prescription medications for clinical distribution by Medicare Plan B providers nationwide. The drugs manufactured by Abbott and covered by Medicare Part B include, but may not be limited to: acetylcysteine, acyclovir, amikacin sulfate, calcitriol, cimetidine hydrochloride, clindamycin phosphate, dextrose, dextrose sodium chloride, diazepam, furosemide, gentamicin sulfate, heparin lock flush, metholprednisolone sodium succinate, sodium chloride, tobramycin sulfate, vancomycin, and zemplar.

72. Abbott is also sued herein in its capacity as a participant in the Together Rx conspiracy.

**2. Amgen**

73. Defendant Amgen Inc. ("Amgen") is a Delaware corporation with its principal place of business at One Amgen Drive, Thousand Oaks, California. Amgen is a biotechnology corporation that focuses its research and development efforts on drugs related to nephrology, cancer, inflammation, neurology and metabolism. In 2000, Amgen's revenues exceeded $3.6 billion.

74. Amgen is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by Amgen and covered by Medicare Part B include, but may not be limited to: Epogen® (epoetin alfa) and Neupogen® (filgrastim).

**3. AstraZeneca**

75. Defendant Zeneca, Inc. ("Zeneca") is a Delaware corporation with its principal place of business at Malvern, Pennsylvania. Zeneca is a wholly owned subsidiary of AstraZeneca, PLC, a limited liability company domiciled in the United Kingdom.

76. Defendant AstraZeneca US is a Delaware corporation with its principal place of business at 1800 Concord Pike, Wilmington, Delaware.

77. Defendant AstraZeneca Pharmaceuticals L.P. is a Delaware corporation, with its principal place of business located at 1800 Concord Pike, Wilmington, Delaware. AstraZeneca Pharmaceuticals L.P. is owned and controlled by AstraZeneca PLC, a public limited liability company domiciled in the United Kingdom.

78. AstraZeneca, PLC, Zeneca, Inc., AstraZeneca Pharmaceuticals L.P. and AstraZeneca U.S. are collectively referred to as "AstraZeneca."

79. AstraZeneca maintains research and development and manufacturing facilities worldwide, including in the United States. AstraZeneca reported annual sales of $16.5 billion in 2001, with an operating profit of $4.2 billion.

80. AstraZeneca manufactures and markets several drugs covered by Medicare Part B including, but not limited to: Zoladex® (goserilin acetate implant), Nolvadex® (tamoxifen citrate), Tomudex® (raltitrexed), and Diprivan® (propofol).

81. AstraZeneca is also sued herein in its capacity as a participant in the Together Rx conspiracy.

**4. The Aventis Group (Aventis, Pharma, Hoechst and Behring)**

82. Defendant Aventis Pharmaceuticals, Inc. ("Pharma") is a Delaware corporation with its principal place of business located at 300-400 Somerset Corporate Blvd., Bridgewater, New Jersey. Pharma is a wholly owned subsidiary of Aventis, S.A., a company domiciled in France. Pharma is comprised of the U.S. commercial operations of predecessor companies Rhone-Poulenc Rorer, S.A. and Defendant Hoechst Marion Roussel, Inc. ("Hoechst"). Prior to its acquisition by Pharma, Hoechst was a Delaware corporation with its principal place of business located at 10236 Marion Park Drive, Kansas City, Missouri.

83. Pharma's principal business activities are the discovery, development, manufacture and sale of prescription pharmaceuticals in the areas of cardiology, oncology, infectious diseases, arthritis, allergies and respiratory disorders, diabetes and central nervous system disorders. Pharma reported U.S. net sales of approximately $5.8 billion in 2001.

84. Defendant Aventis Behring L.L.C. ("Behring"), located at 1020 First Avenue, King of Prussia, Pennsylvania, formerly did business as Centeon L.L.C., a 50/50 joint venture between Hoechst and Rhone-Poulenc Rorer, S.A. When Centeon L.L.C.'s parent companies merged to create Aventis in 1996, Behring became its wholly-owned subsidiary.

85. Behring is the plasma protein business of Pharma, producing a line of therapies including coagulation therapies for the treatment of hemophilia, wound healing agents used during major surgical procedures, inhibitor treatments that inhibit the formation of blood clots, immunoglobulins for the prevention and treatment of immune disorders, and plasma expanders for the treatment of a variety of conditions such as shock, burns and circulatory disorders. In 2000, Behring held assets estimated at $1.5 billion.

86. The drugs manufactured by Pharma, Hoechst and Behring (collectively referred to as "The Aventis Group") and covered by Medicare Part B include, but may not be limited to:

Anzemet® (dolasteron mesylate), Bioclate® (antihemo factor viii), Gammar® (immune globulin), Helixate® (antihemo factor viii), Humate-P® (antihemo factor viii), Mononine® (antihemo factor ix complex), Monoclate-P® (antihemo factor viii), and Taxotere® (docetaxel).

87. Aventis is also sued in its capacity as a participant in the Together Card Rx conspiracy.

**5. Baxter**

88. Defendant Baxter International Inc. ("Baxter") is a Delaware corporation with its principal place of business at One Baxter Parkway, Deerfield, Illinois. Baxter manufactures and distributes prescription drugs to clinical administrators. Baxter's annual sales from January 1, 2000 through December 31, 2000 were over $6.8 billion.

89. Defendant Baxter Healthcare Corporation is the principal domestic operating subsidiary of Baxter International. Baxter International and Baxter Healthcare Corporation are collectively referred to as "Baxter."

90. Baxter is a global medical products company that, *inter alia*, develops, manufactures, markets and/or distributes drugs to treat cancer, trauma, hemophilia, immune deficiencies, infectious diseases, kidney disease and other disorders. Baxter reported a year 2000 sales of $6.9 billion.

91. The drugs developed, manufactured, marketed, sold and/or distributed by Baxter that are covered by Medicare Part B include, but may not be not limited to: albumin, Bebulin® (factor ix complex), Buminat® (human albumin), dextrose, dextrose sodium chloride, Gammagard® (immune globulin), Iveegam® (immune globulin), Holoxan® (ifosfanide), Uromitexan® (mesna), Endoxan® (cyclophosphamide), Hemofil M® (antihemo factor viii), Proplex T® (factor ix complex), Recombinate® (antihemo factor viii), cisplatin, sodium chloride, and diazepam.

**6. Bayer**

92. Defendant Bayer Corporation ("Bayer") is an Indiana corporation with its principal place of business located at 100 Bayer Road, Pittsburgh, Pennsylvania. Bayer is a wholly owned United States subsidiary of a German corporation, Bayer AG. Bayer's pharmaceutical division is located at 400 Morgan Lane, West Haven, Connecticut.

93. Bayer is a highly diversified health care company whose principal business includes the development, manufacture, marketing, sale and/or distribution of healthcare products and services, including pharmaceuticals. Bayer reported sales in the United States of $10.1 billion in 2001 and $8.9 billion in 1999.

94. Bayer is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. The pharmaceutical drugs manufactured by Bayer and covered by Medicare Part B include, but may not be limited to: Kogenate® (antihemo factor viii), FS/Kogenate® (antihemo factor viii), and Koate-DVI® (antihemo factor viii) and Gamimune® (immune globulin), all used to treat hemophilia, and Gamimune® which is used in the treatment of immunodeficiency and autoimmune disorders.

**7. The BMS Group (Oncology Therapeutics; Apothecon)**

95. Defendant Bristol-Myers Squibb Co. ("Bristol-Myers") is a Delaware corporation with its principal place of business located at 345 Park Avenue, New York, New York. Bristol-Myers is a multi-national health care company specializing in the manufacturing, marketing and sale of pharmaceuticals and medical devices. For the year 2000, Bristol-Meyers reported revenues of approximately $20 billion and net earnings of $4.7 billion.

96. Defendant Oncology Therapeutics Network Corp. ("OTN") is a Delaware corporation with its principal place of business located at 395 Oyster Point Boulevard, Suite 405, South San Francisco, California. OTN has been a wholly-owned subsidiary of Bristol-Myers since its acquisition in 1996. Prior to 1996, OTN was an independent company. In 2001, OTN reported revenues of over $1.4 billion.

97. OTN is a healthcare services and distribution firm that directly sells Bristol-Myers' infusion oncology drugs and related products to approximately 2,300 office-based oncology practices in the United States. At the time of its acquisition by Bristol-Myers, OTN was the leading distributor of chemotherapeutic drugs and related products for the treatment of cancer. Bristol-Myers paid OTN a commission for marketing and selling its drugs. Both prior to and after Bristol-Myers acquired OTN, Bristol-Myers marketed and sold its drugs directly to medical providers across the country, and thus Bristol-Myers and OTN employed and maintained extensive marketing and sales departments.

98. Defendant Apothecon, Inc. ("Apothecon") is a Delaware corporation with its principal place of business located in Princeton, New Jersey. It is a subsidiary of Bristol-Myers specializing in small to mid-size niche brand and generic products.

99. Bristol-Myers, OTN and Apothecon are collectively referred to herein as the "BMS Group."

100. The BMS Group manufactures and distributes prescription drugs that are clinically distributed by Medicare Plan B providers nationwide. The drugs manufactured by the BMS Group and covered by Medicare Part B include, but may not be not limited to: Blenoxane® (bleomycin sulfate), Paraplatin® (carboplatin), Cytoxan® (cyclophospamide), Rubex® (doxorubicin hydrochloride), Etopophos® (etoposide), Vepesid® (etoposide), Taxol V (paclitaxel), and Fungizone® (amphotericin B).

101. Bristol-Myers is also sued herein in its capacity as a participant in the Together Rx conspiracy.

102. The BMS Group engages in an organization-wide and deliberate scheme to inflate AWPs. The BMS Group has stated fraudulent AWPs for all or almost all of its drugs including Amikacin Sulfate, Amphotercin B, Bleomycin Sulfate, Cyclophospamide, Vespid (Etoposide),

Carboplatin (Paraplatin), Taxol (paclitaxel), and Blenoxane. The specific drugs of the BMS Group for which relief is sought in this case are set forth in Appendix A.

**8. Dey, Inc.**

103. Defendant Dey, Inc. ("Dey") is a Delaware corporation with its principal place of business at 2751 Napa Valley Corporate Drive, Napa, California. Dey is a unit of Merck KGaA, a German pharmaceutical conglomerate.

104. Dey is a specialty pharmaceutical company that primarily develops, manufactures and markets generic drugs used in the treatment of selected respiratory diseases and allergies. Dey, one of the largest U.S. manufacturers of such pharmaceuticals, had net sales of $266 million in 1998.

105. The drugs manufactured by Dey and covered by Medicare Part B include, but may not be not limited to: albuterol sulfate, acetylcysteine, cromolyn sodium, ipratropium bromide, and metaproterenol sulfate.

106. Defendant Dey, Inc. f/k/a Dey Laboratories, Inc. ("Dey") is a corporation organized under the laws of Delaware with its principal offices in Napa, California.

107. Dey is a specialty pharmaceutical company focusing on drug products for respiratory diseased and related allergies. The products it manufactures and publishes AWPs on include: Ipratropium Bromide; Metaproterenol Sulfate, and Accuneb.

**9. The Fujisawa Group (Fujisawa Healthcare, Fujisawa USA)**

108. Defendant Fujisawa Healthcare, Inc. ("Fujisawa Healthcare") is a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois, 60015. Fujisawa Healthcare is a wholly-owned subsidiary of Fujisawa Pharmaceutical Co. Ltd., a Japanese corporation. Fujisawa Healthcare focuses its efforts in the therapeutic areas of immuno-suppression and transplantation, cardiovascular care, skin care, oncology, and antifungal and anti-infective treatment.

109. Defendant Fujisawa USA, Inc. ("Fujisawa USA") is a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois. Fujisawa USA was a wholly-owned subsidiary of Fujisawa Pharmaceutical Co. Ltd. In 1998, Fujisawa Healthcare assumed responsibility for Fujisawa USA's portfolio of proprietary products

110. The drugs manufactured by Fujisawa Healthcare and Fujisawa USA (collectively referred to as "The Fujisawa Group") and covered by Medicare Part B include, but may not be limited to: Acyclovir Sodium, Dexamethasone Sodium Phosphate, Doxorubicin Hydrochloride, Fluorouracil, Gentamicin Sulfate, Pentamidine Isethionate, and Vancomycin Hydrochloride.

**10. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)**

111. Defendant GlaxoSmithKline, P.L.C. ("GlaxoSmithKline") is a public limited company incorporated under the laws of England and Wales, with its corporate headquarters located at 980 Great West Road, Brentford, Middlesex, United Kingdom TW8 9GS. GlaxoSmithKline was created through the December 27, 2000, merger of GlaxoWellcome, P.L.C. and SmithKline Beecham, P.L.C. GlaxoSmithKline's operational headquarters are located at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania.

112. Defendant SmithKline Beecham Corporation ("SKB"), a wholly-owned U.S. subsidiary of the former SmithKline Beecham P.L.C., is a Pennsylvania corporation with its principal place of business at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania.

113. Defendant GlaxoWellcome, Inc. ("Glaxo"), a wholly-owned subsidiary of GlaxoSmithKline, is a North Carolina corporation with its principal place of business at 5 Moore Drive, P.O. Box 13398, Research Triangle Park, North Carolina. Cerenex Pharmaceuticals ("Cerenex"), a division of Glaxo prior to the merger, was responsible for Glaxo's central nervous system drugs, including Zofran.

114. Defendants GlaxoSmithKline, SKB and Glaxo are referred to collectively as the "GSK Group."

115. The GSK Group is a diversified pharmaceutical company which controls an estimated 7 percent of the world's pharmaceutical market. In 2001, the GSK Group reported pharmaceutical sales of $24.8 billion.

116. The drugs manufactured by the GSK Group and covered by Medicare Part B include, but may not be limited to: Hycamtin® (topotecan hydrochloride), Ventolin® (albuterol) and Zofran® (ondansetron hydrochloride). Pierre Fabré Médicament licenses another Medicare Part B drug, Navelbine® (vinorelbine tartrate), to the GSK Group. SmithKline Beecham P.L.C. manufactured and sold Kytril® (granisteron hydrochloride), another drug covered by Medicare Part B (and a competitor to Zofran®), prior to the merger. To secure regulatory approval for the merger, SmithKline Beecham P.L.C. sold Kytril®'s global rights to the Roche Group in December of 2000.

117. GSK is also sued herein as a member of the Together Rx conspiracy.

**11. Immunex**

118. Defendant Immunex Corporation ("Immunex"), a wholly owned subsidiary of Defendant Amgen, Inc., is a Washington corporation with its principal place of business at 51 University Street, Seattle, Washington. Immunex is a company that develops products for the treatment of cancer, asthma, rheumatoid arthritis, inflammatory diseases, infectious diseases, and cardiovascular diseases. In 1999, its total revenues were $542 million.

119. Immunex is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceutical drugs that are manufactured by Immunex and covered by Medicare Part B include, but may not be limited to: Leucovorin Calcium, Enbrel® (etanercept), Novantrone® (mitoxane hydrochloride), Leukine® (sargramostim), and Thioplex®(thiotepa).

120. Defendant Immunex has been a wholly owned subsidiary of Defendant Amgen, since Immunex' acquisition in July 2002.

**12. The Johnson & Johnson Group (J&J, Centocor, Janssen, NcNeil, Ortho)**

121. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. In 2001, pharmaceutical sales represented 45% of J&J's worldwide sales and 19% of its operational growth. J&J is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

122. Defendant Centocor, Inc. ("Centocor") is a Pennsylvania corporation and has been a wholly owned subsidiary of Defendant J&J since its acquisition by J&J in October 1999. Centocor's principal place of business is located at 200 Great Valley Parkway, Malvern, Pennsylvania. Centocor manufactures, markets and distributes prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

123. Defendant Janssen Pharmaceutica Products, L.P. ("Janssen") is a New Jersey limited partnership with a principal place of business located at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Janssen is a subsidiary of Johnson & Johnson. Janssen is sued for its role in the Together Rx conspiracy.

124. Defendant McNeil-PPC, Inc., is a New Jersey corporation. McNeil-PPC, Inc. is a subsidiary of Johnson & Johnson. McNeil Consumer & Specialty Pharmaceuticals is a division of McNeil-PPC, Inc. and has a principal place of business located at 7050 Camp Hill Road, Fort Washington, Pennsylvania 19034. McNeil-PPC is sued for its role in the Together Rx conspiracy.

125. Defendant Ortho Biotech ("Ortho") is New Jersey corporation and has been a wholly owned subsidiary of Defendant J&J since its formation by J&J in 1990. Ortho's principal place of business is located at 700 U.S. Highway 202, Raritan, New Jersey. Ortho manufactures

and distributes prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

126. The drugs manufactured by J&J, Centocor, Ortho, McNeil-PPC and Janssen (collectively referred to as "J&J Group") and covered by Medicare Part B include, but may not be limited to: ReoPro® (abciximab), an anti-blood clotting medication, Retavase® (reteplase), an anti blood clotting agent, Procrit® (epoetin alfa), for the treatment of anemia, Leustatin® (cladribine), for the treatment of leukemia, Orthoclone® (muromonab-CD3), used to prevent organ transplant rejection, Sporanox® (itraconazole), used in the treatment of fungal infections, and Remicade® (infliximab), an anti-inflammatory drug.

**13. Pfizer, Inc.**

127. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is one of the largest pharmaceutical companies in the United States, whether measured by number of prescriptions written, revenues, or market capitalization.

128. Pfizer is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by the Pfizer Group and covered by Medicare Part B include, but may not be limited to: Cerebyx® (fosphenytoin sodium injection), Dilatin® (phenytoin), Diflucan® (fluconazole), Zithromax® (azithromycin), Trovan® (trovafloxacin mesylate), and Unasyn® (ampicillin sodium/sulbactam sodium).

129. In addition to manufacturing and marketing drugs that are reimbursed by Medicare Plan B, the Pfizer Group also manufactures and distributes other named brand drugs for which it publishes, or causes to be published, an AWP in various industry compendia.

**14. The Pharmacia Group (Pharmacia and Pharmacia & Upjohn)**

130. Defendant Pharmacia Corporation ("Pharmacia") is a Delaware corporation with its principal place of business located at 100 Route 206, North Peapack, New Jersey. Pharmacia was created through the merger of Defendant Pharmacia and Upjohn, Inc. and Monsanto Company on March 31, 2000.

131. Defendant Pharmacia & Upjohn, Inc. ("P&U") is a subsidiary of Pharmacia Corp. In 1995, P&U was formed through the merger of Pharmacia AB and The Upjohn Company. P&U became a global provider of human healthcare products, animal health products, diagnostics and specialty products. In 1998, Pharmacia & Upjohn relocated its global headquarters from the United Kingdom to New Jersey. In September 1999, the company established its global headquarters on a 70-acre campus in Peapack, New Jersey. This site is now the management and pharmaceutical headquarters for Pharmacia.

132. Pharmacia is a highly diversified health care company whose business focuses on the discovery, development, manufacture and sale of a broad and diversified line of health care products and services, including pharmaceuticals, diagnostics and hospital products. Pharmacia's Prescription Pharmaceuticals business segment is involved in researching, developing, registering, manufacturing and selling prescription pharmaceutical products, including general therapeutics, ophthalmology, and hospital products, which include oncology products and diversified therapeutics. Pharmacia reported sales of $18.1 billion for the fiscal year ended December 31, 2000. Pharmacia also reported $12.0 billion in prescription pharmaceuticals sales for the year 2001, and $10.8 billion in prescription pharmaceuticals sales for the year 2000. Prescription pharmaceuticals sales account for over 85 percent of Pharmacia's overall pharmaceutical sales. According to its Annual Report, Pharmacia's oncology drugs generated more than $1 billion in sales in 2001.

133. The drugs manufactured by Pharmacia and P&U (collectively referred to as "The Pharmacia Group") and covered by Medicare Part B include, but may not be limited to:

Adriamycin PFS® (doxorubicin hydrochloride), Adrucil® (fluorouracil), Amphocin® (amphotericin), Aromasin® (bleomycin), Camptosar® (irinotecan hydrochloride), Cleocin Phosphate® (clindamycin phosphate), Neosar ® (cyclophosphamide), Cytosar-U (cytarabine), Depo-Testosterone® (testosterone cypionate), Adriamycin PFS® (doxorubicin HCL), Ellence® (epirubicin HCL), Toposar® (etoposide), Adrucil® (fluorouracil), Solu-Cortef® (hydrocortisone sodium succinate), Idamycin® (idarubicin hydrochloride), Medrol® (methylprednisolone), and Vincasar® (vincristine sulfate).

**15. The Schering-Plough Group (Schering Plough & Warrick)**

134. Defendant Schering-Plough Corporation ("Schering-Plough") is a New Jersey corporation with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey.

135. Schering-Plough's primary business involves prescription products in core product categories, including allergy and respiratory, anti-infective and anticancer, cardiovasculars, dermatologicals and central nervous systems and other disorders. Schering-Plough's revenues in 2001 totaled $9.8 billion.

136. Defendant Warrick Pharmaceuticals Corporation ("Warrick"), is a Delaware corporation with its principal place of business at 12125 Moya Boulevard, Reno, Nevada. Warrick is a wholly-owned subsidiary of Defendant Schering-Plough and has been since its formation in 1993. Warrick manufactures generic pharmaceuticals.

137. The drugs manufactured by Schering-Plough and Warrick (collectively at times referred to as "The Schering-Plough Group") and covered by Medicare Part B include, but may not be limited to: Proventil® (albuterol sulfate), Integrelin® (eptifibatide), Intron A® (interferon alfa-2b recombinant), and Temodar® (temozolomide). The Schering-Plough Group's Albuterol sulfate sales alone totaled $154 million in 2000.

**16. The Sicor Group (Sicor and Gensia)**

138. Defendant Sicor, Inc. ("Sicor") is a Delaware corporation with its principal place of business located at 19 Hughes, Irvine, California. Sicor was the result of the 1997 merger between Defendant Gensia, Inc. ("Gensia"), a finished dosage manufacturer, and Rakepoll Holding, a Europe-based supplier of active pharmaceutical ingredients.

139. Sicor markets itself as a vertically-integrated specialty pharmaceutical company with expertise in the development, manufacturing and marketing of injectable pharmaceutical products, primarily used worldwide by hospitals. Sicor's finished dosage products manufacturing operations account for 32% of its total revenue, and is comprised of a portfolio of products that includes oncology, anesthesiology, and critical care. Sicor's 2001 revenues totaled nearly $370 million. According to its website, Sicor operates its business through several subsidiaries.

140. Defendant Gensia Sicor Pharmaceuticals, Inc. ("Gensia Sicor"), a Delaware corporation, is a wholly-owned subsidiary of Sicor with its principal place of business located at 17 Hughes, Irvine, California. Gensia Sicor focuses on acute-care multisource products in the fields of oncology, cardiology, and anesthesiology. Gensia Sicor's injectable drug business includes more than 60 products.

141. In 1999, Gensia Sicor entered into a sales distribution agreement with Abbott Laboratories under which the two companies formed a strategic alliance for the marketing and distribution of oncology products in the U.S. The agreement was restructured in March 2002. In 1999, Gensia Sicor also amended an earlier agreement with Baxter Pharmaceutical Products, Inc. Notably, Abbott (6%) and Baxter (34%) accounted for nearly 40% of Sicor's total product sales in 2001.

142. The drugs manufactured by Sicor, Gensia, and Gensia Sicor (collectively referred to as "The Sicor Group") and covered by Medicare Part B include, but may not be not limited to: amikacin sulfate and tobramycin sulfate.

### 17. Watson

143. Defendant Watson Pharmaceuticals, Inc. ("Watson") is a Delaware corporation with its principal place of business at 311 Bonnie Circle, Corona, California. Watson develops, manufactures and markets brand and generic pharmaceuticals. Watson is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

144. The pharmaceuticals manufactured by Watson and covered by Medicare Part B include, but may not be limited to: albuterol sulfate, dexamethasone acetate, diazepam, gentamicin sulfate, iron dextran, testosterone enanthate, vancomycin hydrochloride, and cytarabine.

## IV. GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

145. The allegations contained herein apply generally to all Defendants.

### A. The AWP System

146. There are approximately 65,000 different drug products in the United States market, including different dosages of the same drug. Prescription drugs are dispensed to patients by or through different types of medical providers, including but not limited to: (a) physicians who administer the drug in an office, (b) retail pharmacies, (c) home infusion pharmacies, and (d) other medical providers.

147. Providers regularly submit claims for reimbursement, seeking payment for the drugs from Medicare, insurers and patients. During the Class Period, the Defendants were aware that the Medicare program and virtually all end payors (the latter are included as members of the Class) use published AWPs to reimburse providers for drugs. Use of the published AWPs to establish reimbursement rates for drugs is an industry-wide practice and exists with respect to all classes of drugs, brand name and generic and is used for Part B drugs and non-Part B drugs.

148. There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWPs for the tens of thousands of drugs on the market, including the *Drug Topics Red Book* (the "*Red Book*"), *American Druggist First Databank Annual Director of Pharmaceuticals* and *Essential Director of Pharmaceuticals* (the "*Blue Book*") and Medi-Span's *Master Drug Database* (collectively referred to herein as the "Publishers"). These Publishers publish AWPs for the various dosage forms for drugs. And the AWPs are published for Part B, non-Part B, brand name and generic drugs.

149. In periodically announcing the AWP for each drug, during the time period relevant to this Complaint the Publishers publish the prices that are supplied to them by the Defendant Drug Manufacturers for their respective drugs. For instance, the forward to the 1999 edition of the *Red Book* states that "all pricing information is supplied and verified by the products' manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted." In addition, a June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the *Red Book*, stated that it only publishes prices that are faxed directly from the manufacturer. Thus, the Defendant Drug Manufacturers control the prices listed as the AWPs for each drug listed by the Publisher.

150. A system that bases its reimbursement rates for drugs on the published AWP is thus dependent on the honesty of the drug manufacturers. The Defendant Drug Manufacturers knew they could directly control and fabricate the AWP for their drugs at any time by forwarding to the Publishers a phony AWP. The Defendant Drug Manufacturers also knew that actual transaction price data – the amounts charged to providers and others for their drugs – was not publicly available, and they kept this information (on which AWPs should have been calculated) highly confidential and secret.

151. As detailed, the AWPs for the drugs at issue here bore little relationship to the drugs' pricing in the marketplace. They were simply fabricated and overstated in furtherance of

Defendants' scheme to generate the profit spread to providers, PBMs and others and to increase Defendants' profits at the expense of Plaintiffs and the Class members.

152. Plaintiffs and the members of the Class paid for the drugs based on the inflated AWPs reported by the Defendant Drug Manufacturers.

153. The Defendant Drug Manufacturers' pattern of fraudulent conduct in artificially inflating the AWPs for their drugs (sometimes referred to herein as the "AWP Scheme") directly caused Plaintiffs and the members of the Class to substantially overpay for those drugs.

154. As detailed below, this overpayment manifested itself in two contexts, both of which were well known and understood by the Defendant Drug Manufacturers: (i) all drugs administered under Medicare Part B and (ii) drugs administered outside of the Medicare context whose reimbursement was established by use of AWP as a benchmark.

## B. The Defendant Drug Manufacturers Commit AWP Fraud to Increase Market Share For Their Drugs Covered by Medicare Part B

### 1. The Medicare Insurance Program

155. In 1965, Congress enacted Title XVIII of the Social Security Act ("Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care.

156. The United States Department of Health & Human Services ("HHS") is responsible for the funding, administration and supervision of the Medicare Program. The Centers for Medicare and Medicaid Services ("CMMS"), formerly known as the Health Care Financing Administration ("HCFA"), is a division of HHS and is directly responsible for the administration of the Medicare Program.

157. The Medicare Program generally does not cover the cost of prescription drugs that a Medicare beneficiary self administers (*e.g.*, by swallowing the drug in liquid or pill form). However, Medicare Part B does cover some drugs, including injectables administered directly by a doctor, certain oral anti-cancer drugs, and drugs furnished under a durable medical equipment benefit. Approximately 450 drugs are covered by Medicare Part B.

158. In determining the amount it will pay, Medicare calculates the "allowed" amount for the drug. During the period 1992 through 1997, Medicare's reimbursement for Covered Drugs was set at the lesser of the estimated acquisition cost or national average wholesale price. For generic drugs (where more than one company sells a certain drug, sometimes called multiple-source drugs), payment was based on the lower of the estimated acquisition cost or the wholesale price that was defined as the median price for all sources of the generic form of the drug. This payment methodology was set forth in 42 C.F.R. § 405.517, a regulation first published in the Federal Register on November 25, 1991 and which became effective on or about January 1, 1992.

159. The estimated acquisition cost for a drug could be determined by the Medicare Program "based on surveys of the actual invoice prices paid for the drug" taking into consideration the estimated acquisition cost, including "factors such as inventory, waste and spoilage." However, historically it has been the AWP published in the *Red Book* or other compendia that has been used as a ceiling for Medicare reimbursement.

160. On January 1, 1998, 42 C.F.R. § 405.517 was amended to provide that the allowed amount would be based upon the lower of the billed charge on the Medicare claim form or 95 percent of AWP.

161. The Medicare Program has publicly announced that it would use the AWP published in pharmaceutical industry magazines as the basis for reimbursement. Specifically, Program Memorandum AB-99-63 (dated September 1999 but re-issuing PM AB-98-76 dated in December 1998), a publicly available Medicare Program bulletin, confirmed that reimbursement for certain Medicare Part B drugs and biologicals "are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in sources such as the *Red Book*, *Blue Book*, or Medi-Span."

162. Pursuant to PM AB-99-63, the AWP for a single-source drug or biological equals the AWP of the single product. For a multi-source drug or biological, the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP.

163. Medicare Part B reimburses medical providers 80% of the allowable amount for a drug. The remaining 20% is paid by the Medicare Part B beneficiary, and is called the "co-payment" amount. All medical providers are required by law to bill the 20% co-payment and make attempts beyond merely billing to collect that amount. In addition, beneficiaries under Part B are required to pay an annual deductible amount before Part B benefits are payable.

164. Some Medicare beneficiaries are able to purchase private Medigap insurance, which covers, among other things, all or part of the 20% co-payment for Covered Drugs.

165. In setting reimbursement rates, the Medicare Program uses the AWPs generated by the pharmaceutical industry. There are no regulations describing how AWPs are to be calculated, nor any regulatory process for approving them. Pharmaceutical companies do not report AWPs directly to the federal government, but instead send their pricing information to independent publishing companies that compile the data and publish the AWPs in trade publications, which are then used by the government, as well as private health plans.

166. The importance of an accurate AWP was recently reconfirmed by the Office of the Inspector General ("OIG") in an April 2003 report: "Compliance Program Guidance for Pharmaceutical Manufacturers." The OIG report found that the "government sets reimbursement with the expectation that the data provided are complete and accurate." The OIG report made it clear that the AWP must be a meaningful figure that is not artificially inflated:

> Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar

> benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

167. And, the OIG rejected the notion that purposeful AWP manipulation was a lawful practice:

> The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.
>
> Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.
>
> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.
>
> In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. ***The conjunction of manipulation of the AWP to***

> ***induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute***. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product. [Emphasis added.]

**2. Congressional and Other Federal Investigations and Actions**

168. The United States Department of Justice ("DOJ"), the United States General Accounting Office ("GAO"), the Office of the Inspector General at the United States Department of HHS ("OIG"), and certain Congressional subcommittees have been investigating the Defendant Drug Manufacturers and other pharmaceutical manufacturers for questionable practices regarding the industry's calculation of AWPs and for offering illegal incentives to providers.

169. In a letter dated September 28, 2000, sent from the House of Representatives Committee on Ways and Means, Subcommittee on Health to the President of the trade organization known as the Pharmaceutical Research and Manufacturers of America (most of the Defendant Drug Manufacturers are members of this association), Congressman Stark identified the improper scheme of manipulating AWPs and noted:

> This corruptive scheme is perverting financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit.

170. In his September 28 letter, Congressman Stark made the following five "shocking conclusions":

> First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.
>
> Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.
>
> Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded

> health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.
>
> Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.
>
> Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

171. The DOJ and Congressional investigations are ongoing.

### 3. Certain of the Defendants Drug Manufacturers' Fraudulent Conduct Within the Medicare Part B Program

172. As set forth below, certain of the Defendants Drug Manufacturers each perpetrated the alleged fraudulent scheme by using some and/or all of the following practices:

#### a. Artificially Inflating AWPs

173. Each Defendant Drug Manufacturer provided AWPs for each of its drugs to the *Red Book*, the *Blue Book*, Medi-Span and other pharmaceutical compendia for Covered Drugs and non-Part B drugs, both brand name and generic.

174. During the Class Period, the Defendant Drug Manufacturers deliberately and intentionally published AWPs for Covered Drugs that did not reflect the actual pricing structure of the drugs, but was created solely to cause Plaintiffs and the Class members to overpay for the Covered Drugs. The Defendant Drug Manufacturers created and perpetuated this scheme so that the medical providers who purchased these drugs at a low cost would bill patients and their insurers at the inflated AWPs and earn a substantial profit from the "spread" between the real cost and the various AWP-related reimbursement rates.

175. The Defendant Drug Manufacturers knew and understood that Medicare and Plaintiffs and the Class members used the *Red Book* and other publications to determine the

AWPs of the drugs. Because the Defendant Drug Manufacturers controlled the AWPs published in the *Red Book* and other compendia, the Defendant Drug Manufacturers knew and understood that they could manipulate the providers' profits from Plaintiffs and the Class. The purpose of artificially inflating the providers' profits was to create an illegal kickback to the providers, funded by Plaintiffs' and the Class members' overpayments.

176. As part of their scheme, the Defendant Drug Manufacturers specifically instructed and expected the providers to charge the inflated AWPs for Covered Drugs to Medicare, Plaintiffs and the Class members.

**b. Improper Use of Free Samples**

177. The Defendant Drug Manufacturers, through their sales personnel and marketing representatives, also provided free samples of their drugs to providers as a means of lowering the price. The free samples were used to offset the total cost associated with the purchases of the drugs, thereby increasing the "spread." Moreover, the Defendant Drug Manufacturers specifically told providers to bill Plaintiffs and the members of the Class for the free samples, which Defendants knew was unlawful.

178. Every free sample of a drug for which a provider bills a patient or insurer effectively reduces that provider's overall cost for that drug. However, the full cost of the Covered Drug was charged to the Plaintiffs and the Class members, and the free sample is not used by the drug company in calculating the AWP, which in turn inflates the AWP.

179. Although the Defendant Drug Manufacturers provided free samples and marketed them as a way to lower the providers' actual cost of the Covered Drugs, they did not include the value of the free samples in calculating the AWPs for those drugs. Thus, the Defendant Drug Manufacturers effectively and improperly passed on the cost of the free samples directly to Plaintiffs and the members of the Class.

### c. Other Hidden and Improper Inducements and Price Reductions

180. The Defendant Drug Manufacturers also have provided and/or arranged for many other non-public financial inducements to stimulate sales of their Covered Drugs at the expense of Plaintiffs and the members of the Class. Such inducements included volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and educational and promotional grants. All of these incentives were designed to lower the providers' net cost of purchasing the Defendant Drug Manufacturers' Covered Drugs. And again, the value of these services was kept "off the book," so as to not be reflected in the AWP, which in turn inflates the AWP.

## C. The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain the Price of Drugs Outside of the Medicare Part B Context

181. The Defendant Drug Manufacturers' AWP fraud strikes well beyond Medicare Part B, adversely impacting health plans and their participants with respect to reimbursements for scores of other drugs. As described below, one such area is the use of AWPs by PBMs.

182. Health plans typically contract with intermediaries called pharmacy benefit managers ("PBMs") so that a health plan's participants can obtain brand name drugs from pharmacies or, via mail order, directly from the PBMs. In these contracts, the brand name drugs are priced at the AWP less a certain percentage "discount."

183. Pharmacy benefit managers – or "PBMs" – are fiscal intermediaries that specialize in the administration and management of prescription benefit programs. PBM clients include HMOs, employers, preferred provider organizations and other health insurers. Collectively, four PBMs comprise the significant market share of the PBM market. They are: AdvancePCS; Caremark; Express Scripts; and Medco Health. These four companies handle the drug benefits of 210 million people in the United States, or 70 percent of the nation's population.

184. For brand name drugs, PBMs use inflated "Average Wholesale Price" – or "AWP" – set by drug manufacturers as the basis for reimbursement (i) made by health plans to

the PBMs for their members' drug purchases; and (ii) from the PBMs to the pharmacies for the purchases made by health plans' members. The PBMs typically contract with retail pharmacies to reimburse an amount equal to each drug's AWP, less a specified discount, plus a dispensing fee. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies. However, the PBM frequently pockets a "spread" or differential between charges paid to pharmacies and collected from clients. So, for example, clients may be charged the AWP minus 13 percent, but the retail pharmacy may only receive the AWP minus 15 percent, generating an undisclosed 2 percent spread for the PBM. Furthermore, as the example presented demonstrates, PBMs are motivated to, and do place on their formulary those drugs with inflated AWPs: the greater the AWP inflation, the greater the profit to the PBM based on the 2 percent spread. A similar situation occurs for generic drug pricing based on Maximum Acquisition Cost ("MAC") lists, as the PBM uses one MAC list to charge clients and another MAC list to reimburse pharmacies. Further, with respect to mail order prescriptions, PBMs do business with companies that have the right to repackage drugs; they are called repackagers. These repackagers assign a new NDC number to a drug and publish a higher AWP. The PBM then negotiates with the repackager a discount off the AWP and tells the health plan it has saved a certain percentage off the AWP. But because the repackager's AWP is higher, the health plan pays more and the PBM pockets the spread between the AWP and the price paid to the repackager. PBMs also have mail order services in which case they act as the pharmacy. In this situation, the PBM keeps the spread between the AWP and the list price as there is no intermediary, like a pharmacy dispensing the drug. The PBMs keep this spread knowing that the AWPs are inflated and not the true AWP.

185. The Defendant Drug Manufacturers knew and understood that the PBM Defendants used the *Red Book* and other publications to determine the AWPs of the drugs.

Because the drug manufacturers controlled the AWPs published in the *Red Book* and other compendia, the drug manufacturers knew and understood that they could help manipulate the PBMs' profits from Plaintiffs and the classes. The purpose of artificially inflating the PBMs' profits was to create an illegal kickback to the PBMs, funded by health plan and subscriber overpayments.

186. PBMs use the inflated AWPs set by drug manufacturers as the basis for the payments (i) made by health plans to the PBMs for their members' drug purchases, and (ii) from the PBMs to the pharmacies for the purchases made by health plans' members.

187. The PBMs typically contract with retail pharmacies to reimburse in an amount equal to each drug's AWP, less a specified discount, plus a dispensing fee. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies.

188. However, the PBMs frequently pockets a secret "spread" or differential between charges paid to pharmacies and collected from clients. So, for example, clients may be charged the AWP minus 13 percent, but the retail pharmacy may only receive the AWP minus 15 percent, generating an undisclosed 2 percent spread for the PBMs.

189. Furthermore, as the example presented demonstrates, PBMs are motivated to place on their formulary those drugs with inflated AWPs: the greater the AWP inflation, the greater the profit to the PBM based on the 2 percent spread.

190. A similar situation occurs for generic drug pricing based on MAC lists, as the PBM uses one MAC list to charge clients and another MAC list to reimburse pharmacies.

191. The PBMs deliberately utilize the inflated AWP to overcharge health plans for brand name drugs purchased by their participants and beneficiaries at retail pharmacies. An example of this practice was recently reported in the WALL STREET JOURNAL on March 30, 2003. According to the JOURNAL article, the AWP for fluoxetine is $2.66 a pill. With a 60 percent

discount off the AWP, that brings the price to $1.06 a pill the PBM collects from the plan. Express Scripts pays the pharmacy 25 cents a pill and keeps the rest as profit. Express Scripts claims that currently its client pays 60 cents a pill, but since Express Scripts pays a pharmacy 25 cents per pill, it receives almost a 100 percent profit. And at the same time it was making this profit, Express Scripts was notifying its clients it was saving them money by having switched to fluoxetine, instead of Prozac.

### D. The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain Volume and Market Share For Generic and Multi-Source Drugs

192. The Defendant Drug Manufacturers' AWP fraud is most exacerbated for generic drugs or for brand name drugs for which there are biological or therapeutic equivalents.

193. Health plans and other sponsors of drug benefits contract with PBMs both so that the plan's participants can obtain ***brand name*** drugs from pharmacies or mail order distribution, but also so that they might receive ***multi-source***, or ***generic, drugs***. As with brand name drugs, reimbursement for multi-source, or generic, drugs is also related to a published average wholesale price for each generic drug manufactured and/or distributed by a generic drug company.

194. In the private payor arena, generic drug reimbursement is determined either in the same manner for brand name drugs (*i.e.*, a certain percentage "discount" off of the AWP), or is based on the amount specified as the maximum allowable cost or "MAC." MAC prices or reimbursements rates are a schedule of pricing for generically equivalent drugs based upon the listed average wholesale prices (AWPs) of competing generic drug manufacturers. The federal government originally introduced the concept of MAC reimbursement for generic medications. The CMS issues a MAC price list for generic products that have three or more manufacturers or distributors on the market. Because of this limitation, not all generics have a corresponding CMS MAC price.

195. PBMs often utilize this government-issued MAC reimbursement publication as a basis for their proprietary MAC list and supplement the list with other generic products or modify it for a variety of purposes. Sometimes, to stabilize the cost variance of different generic products of the same compound, pharmacy benefit administrators calculate a maximum allowable cost based on the list average wholesale prices of competing generic drug manufacturers (indeed, this is termed in the industry as the average average wholesale price or "AAWP"). The resulting proprietary MAC generic drug reimbursement lists are typically based on the AAWP and, in turn, the AWP.

196. Accordingly, in the private payor arena generic drug reimbursement is closely tied to the published AWP for a generic drug. Generic drug makers are able to push market share for their generic drugs by intentionally increasing the published AWP for a generic drug with the intention to create a profit margin for others in the distribution chain. That profit margin is taken advantage of either directly (through reimbursement based upon the AWP for some plans and in some channels) or indirectly on the AWP based upon the establishment of a MAC tied to the AWP.

197. In the public payor arena under Medicare Part B, multi-source drugs or biologicals are also reimbursed on the basis of AWP. For multi-source drugs or biologicals, under Medicare Part B the AWP is equal to the lessor of the median AWP of all of the generic forms of the drug or biological, or the lowest brand name product AWP. Because reimbursement is pegged to the AWP, drug makers act in unison by elevating the AWP for all generic drugs, thereby inflating the amount of the reimbursement that occurs through Medicare Part B, including the Medicare co-payment through Part B.

198. As stated by one industry consultant:

> . . . This situation is more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by substantially inflating their published AWPs.. . . [T]he system allows a retailer to acquire a drug at a low cost $2.50 per 100

> tablets, for example) while relying on a published AWP ($20.00 or more) for its own pricing. It is not uncommon that the $25.00 retail price for a generic drug renders a gross profit well above $20.00 for the retailer. It is also common for the AWP of a generic product to remain stable while the actual selling price declines. . . .It is obvious that AWP is not an accurate measure of the prices manufactures charge. It must also be noted that not all generic products will be priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing decisions and an artificially high AWP provides the retailer with greater profits.

199. The raising of an individual Defendant's reported AWP for a multi-source drug raises the median AWP at which the generic drug is reimbursed. As a result, the publication and reporting of fraudulent AWPs by Defendants for generic drugs squarely fits generic drugs in which the cure of unlawful AWP inflation within the activity complained of in the MCC. Moreover, while any one generic manufacturer can only effect the median generic reimbursement AWP for a product, Defendants can and do create a spread between the median AWP and the actual prices paid by reporting AWPs that are far in excess of the actual wholesale prices while simultaneously maintaining or lowering actual wholesale prices.

200. Documents produced by Defendant generic manufacturers show that they are aware of the AWPs reported by their competitors and of the actual sales price of their generic competitors and that they manipulate their own AWPs in order to gain or maintain a competitive advantage in the market for their generic products. Each Defendant generic maker or distributor competes by inflating its AWP and thereby inflating the median AWP. The natural and expected result of this "leap frogging" of increasing AWPs is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs. A few examples are set forth below:

| **Defendant** | **Multisource Drug** | ***RedBook* AWP** | **DOJ Determined Actual AWP** | **Percentage Spread** |
|---|---|---|---|---|
| Abbott | Sodium Chloride | $670.89 | $3.22 | 20,735% |

| Defendant | Multisource Drug | *RedBook* AWP | DOJ Determined Actual AWP | Percentage Spread |
|---|---|---|---|---|
| Baxter | Dextrose | $928.51 | $2.25 | 41,167% |
| Baxter | Sodium Chloride | $928.51 | $1.71 | 54,199% |
| BMS Group | Etoposide (Vepesid) | $136.49 | $34.30 | 298% |
| Dey | Albuterol Sulfate | $30.25 | $9.17 | 230% |
| Immunex | Leucovorin Calcium | $137.94 | $14.58 | 846% |
| Pharmacia | Etoposide | $157.65 | $9.47 | 1,565% |
| Sicor Group | Tobramycin Sulfate | $342.19 | $6.98 | 4,802% |
| Watson | Vancomycin HCL | $70.00 | $3.84 | 1,567% |

201. In summary, generic or multi-source drugs are subject to fraudulent AWP manipulation as set forth in this Amended MCC.

202. The importance of AWPs to generic drugs was recently revealed in a lawsuit filed by Dey and two of the Publishers. In this lawsuit, Dey's allegations can be summarized as follows:

(a) Dey is a generic manufacturer, and generic manufacturers largely compete on price because they market products that contain the same active ingredients and are predominantly therapeutically interchangeable. (¶ 9 of Dey Complaint.)

(b) A large segment of the generic marketplace for respiratory drugs is comprised of a relatively small number of entities controlling purchase decisions. (¶ 12 of Dey Complaint.)

(c) The vast majority of prescription drug transactions – as much as 85% – are covered, in whole or in part, by third-party payor reimbursement arrangements such as managed care plans and Medicaid. (¶ 13 of Dey Complaint.) Both Medicaid and the private insurance system rely on reimbursement formulas that utilize the AWP. (¶¶ 14-16 of Dey Complaint.) ***This allegation confirms Plaintiffs' allegations in this Complaint that the AWP fraud impacts private markets, not just Medicaid***.

(d) Dey has an agreement with First DataBank and Medi-Span to provide the reporting services with AWP pricing information. Pursuant to this agreement (and in order to make Dey's products eligible for reimbursement through Medicaid Programs), Dey has reported WACs and AWPs. (¶¶ 26-32 of Dey Complaint.)

> In each case, until the events that have resulted in the present crisis, First DataBank has (except for some inadvertent errors) selected for listing in its published reports the AWP as suggested by Dey. For over ten years, until April 2003, no prices other than those submitted by Dey have been listed by First DataBank as AWP for Dey products in its databases [even though Dey also reported declining WACs for the products]."

(¶ 32 of Dey Complaint; *see also* ¶ 36 of Dey Complaint for similar allegation against Medi-Span.) This has also been the course of dealings between the Publishers and Dey's competitors:

> Virtually every drug manufacturer who participates in these reimbursement programs, and against whom Dey competes also communicates their suggested AWP prices to the reporting services. To the best of Dey's knowledge, with few, if any exceptions, First DataBank and Medi-Span have selected and reported the AWP pricing exactly as suggested by these competing manufacturers.

(¶ 37 of Dey Complaint.) *See also* ¶ 47 of Dey Complaint (recounting testimony of First DataBank representative who admits that First DataBank had always accepted the AWPs suggested by the manufacturers).

(e) Providers who dispense generic drugs "are cognizant of, and are highly attentive to, AWPs as reported by the recognized industry compendia published by First DataBank and Medi-Span because of the direct relationship between the level of reimbursement anticipated for the drugs selected and the reported AWPs of those drugs." (¶ 38 of Dey Complaint.) Indeed, Dey admits that it has relied on the publishers' practice of treating all manufacturers equally by simply reporting whatever AWP a manufacturer submitted. Consequently, First DataBank and Medi-Span have frustrated Dey's "reasonable expectations" by ***independently reporting*** an AWP different than that submitted by Dey. (¶ 39 of Dey

Complaint.) These allegations become even more emphatic in a section of the Complaint titled "The Immediate Consequences of the Arbitrary Changes:"

> Since reimbursement to Dey's customers is, in Medicaid program in many states and in and [sic] insurance programs, most frequently based on the AWP as reported by the reporting services, this arbitrary and capricious reduction by First DataBank and Medi-Span in AWP would result in a drastic reduction in the reimbursement to drug providers who choose to dispense Dey's product. Since there has not been a comparable reduction in the AWP for Dey's competitors, there would be no comparable reduction in the reimbursement the purchasers of competitive products receive.
>
> Because reimbursement for Dey products would be significantly reduced, but reimbursement for those competing products would remain as they have been, Dey is prevented, by First DataBank's and Medi-Span's arbitrary and capricious acts, from effectively competing in the marketplace.
>
> In fact, within one day of learning that First DataBank and Medi-Span had arbitrarily changed Dey's AWP, Dey has already been contacted by at least nine of its customers complaining about the drastic changes and indicating that, because of those changes, the customers would not be able to purchase Dey products since they could not earn a reasonable profit from the sale of such products.
>
> Further, at least one customer has already indicated that he had canceled all of his purchases presently on order from Dey and was, instead, buying those products from Dey's direct competitors.
>
> ….. These providers will cease to purchase and dispense Dey's drugs if the reimbursement for those drugs is a fraction of those obtained from competing companies. Because purchasing decisions are highly concentrated in this industry among wholesalers and group purchasing organizations, this scenario is playing out across the country and threatens to eliminate sales of Dey's products that are covered by Medicaid and insurance reimbursement programs.

(¶¶ 50-54 of Dey Complaint.)

203. ***These allegations confirm the allegations herein that medical providers rely on spreads in dispensing (and, consequently, so do the manufacturers in order to move market share).*** Further, these allegations are akin to saying: "We all committed fraud on an even basis, but now only my competitors can commit fraud; consequently, I have now suffered damage."

**E. Defendants' Concealment of the Truth**

204. Each Defendant concealed its fraudulent conduct from the Plaintiffs and the Class by controlling the process by which the AWPs for Covered Drugs and brand name drugs were set. Defendants prevented Plaintiffs and the Class Members from knowing what the actual pricing structures for these drugs were, and failed to inform them of the usage of free samples and the provision of other financial incentives to providers and other intermediaries to lower their respective costs for the drugs. Moreover, Defendants' fraudulent conduct was of such a nature as to be self-concealing.

205. Each Defendant closely guarded its pricing structures and sales figures for their Covered Drugs and brand name drugs. CMS Health Care Industry Market Update (dated January 10, 2003) stated that drug "price discounts are closely guarded as competitive information." *See* p. 39.

206. Each Defendant also concealed its fraudulent conduct by instructing providers and others not to report the prices they paid for the Covered Drugs and brand name drugs, respectively.

207. Each Defendant also worked with and motivated provider and intermediary trade associations to halt any investigations or change in the AWP system.

208. Each Defendant's efforts to conceal its pricing structures for Covered Drugs and brand name drugs is evidence that it knew that its conduct was fraudulent.

209. Thus, each Defendant concealed that (i) its AWPs were highly-inflated (and were inflated solely to cause Plaintiffs and the Class to overpay for the AWPIDs), (ii) it was manipulating the AWPs of the AWPIDs, and (iii) the AWPs bore no relationship to the prices paid for, or the pricing structure of, the AWPIDs as they were sold to providers and others.

210. Plaintiffs were diligent in pursuing an investigation of the claims asserted in this Complaint. Through no fault of their own, they did not receive inquiry notice nor learn of the factual basis for their claims in this Complaint and the injuries suffered therefrom until recently.

### F. Tolling of Applicable Statutes of Limitation

211. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs and members of the Class have been kept in ignorance of vital information essential to knowledge of and the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs and members of the Class could not reasonably have discovered the fraudulent nature of the published AWPs.

212. Defendants were and continue to be under a continuing duty to disclose to Plaintiffs and the Class the fact that the published AWPs bore and continue to bear no relationship to the prices or pricing structures for Covered Drugs and brand name drugs. Because of their knowing, affirmative, and/or active concealment of the fraudulent nature of the published AWPs, Defendants are estopped from relying on any statutes of limitations.

## V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

213. Due to acts of concealment by each Defendant, the following examples of the specific unlawful conduct engaged in by each particular Defendant are merely illustrative. They are not intended to be an exhaustive account of all of the unlawful activity engaged in by each Defendant. Instead, these allegations allege the circumstances of the wrongdoing with some detail. Additional detail is peculiarly within the Defendants' control and warrants that further discovery should proceed as to each drug identified in this Complaint as well as other drugs whose AWP is published by any Defendant.

### A. Abbott

214. Abbott engages in an organization-wide and deliberate scheme to inflate AWPs. Abbott has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Abbott for which relief is currently sought in this case are set forth in Appendix A or in the proposed class certification order, and are summarized below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| ABBOTT | A-Methapred | methylprednisolone sodium succinate | Anti-Inflammatory Agent<br>Used to provide relief for inflamed areas of the body. Also used for control of allergic processes |
| | Aminosyn | amino acid | Nitrogen Product<br>Used as a nutritional supplement |
| | Biaxin | clarithromycin | Macrolide (Anti-Infective Agent)<br>Used to treat mild to moderate infections |
| | Calcijex | calcitrol | Hormone<br>Used in the treatment of hypocalcemia |
| | Depakote | divalproex sodium | Anticonvulsant<br>Used in the treatment of complex partial seizures |
| | Ery-tab | erythromycin, enteric-coated | Antibiotic Agent (Anti-Infective Agent)<br>Used in the treatment of various infections |
| | Erythromycin | erythromycin base | Antiacne Agent; Anti-Infective Agent<br>Used in the treatment of various infections |
| | Liposyn II | fat emulsion | Caloric Agent; Nutritional Supplement<br>Used as a nutritional supplement |
| | Prevacid | lansoprazole | Proton Pump Inhibitor (Gastrointestinal Agent)<br>Used in the treatment of duodenal ulcer and erosive esophagitis |
| | | acetylcysteine | Mucolytic (Respiratory Agent: Diagnostic Aid)<br>Used for certain lung conditions when increased amounts of mucus make breathing difficult |
| | | acyclovir sodium | Anti-Infective Agent<br>Used in the treatment of herpes infections |
| | | amikacin sulfate | Antibiotic Agent (Anti-Infective Agent)<br>Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections |
| | | cimetidine hydrochloride | Gastrointestinal Agent<br>Used in the treatment of duodenal ulcer and prevention of ulcer recurrence |
| | | clindamycin phosphate | Anti-Infective Agent<br>Used in the treatment of vaginal infections |
| | | dextrose | Caloric Agent<br>Used to increase intake of calories and fluids |
| | | dextrose sodium chloride | Caloric Agent; Electrolyte Replenisher<br>Used to increase intake of calories and fluids |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | | diazepam | Central Nervous System Agent<br>Used to treat status eplipeticus and anxiety disorders. Also used as an amnesic prior to surgical procedures |
| | | fentanyl citrate | Central Nervous System Agent<br>Used for anesthetic purposes |
| | | furosemide | Diuretic<br>Used in the treatment of edema associated with cirrhosis and kidney disease. Also used to manage hypertension |
| | | gentamicin sulfate | Anti-Infective Agent<br>Used as a general antibiotic to treat serious gastrointestinal, respiratory, bone, skin and soft tissue infections |
| | | heparin sodium or heparin lock flush | Blood Modifier<br>Used to prevent and treat thrombosis and pulmonary embolism. Also used as an anticoagulant in blood transfusions and dialysis procedures |
| | | leucovorin calcium | Antianemic Agent (Blood Modifier)<br>Used in the treatment of anemia |
| | | lorazepam | Central Nervous System Agent<br>Used in the treatment of anxiety disorders |
| | | sodium chloride | Flush; Abortifacient<br>Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion |
| | | tobramycin sulfate | Antibiotic Agent (Anti-Infective Agent)<br>Used to treat severe infection |
| | | vancomycin hydrochloride | Antibiotic Agent (Anti-Infective Agent)<br>Used as a general antibiotic |

**1. Abbott Has Been The Target of Government Investigations**

215. In connection with its scheme to inflate AWPs, Abbott has been investigated by the United States Department of Justice, Commonwealth of Massachusetts, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

216. These investigations confirm that Abbott has engaged in a deliberate scheme to inflate the published AWPs for many of its drugs. According to Representative Pete Stark, the ranking member of the Congressional Ways and Means Committee:

> The price manipulation scheme is executed through Abbott's inflated representations of average wholesale price ("AWP") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is regularly referred to . . . as "the spread." The evidence . . . clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims.

*See* October 31, 2000 letter from U.S. Representative Pete Stark to Miles White, Chief Executive Officer of Abbott. (P007647-78.)

**2. Abbott Controls the Published AWP for Its Products**

217. Abbott has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

**3. Abbott's AWP Manipulation Benefited Providers at the Expense of the Class**

218. The purpose of Abbott's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

a. For example, Abbott anticipated that the spread between AWP and cost would be eliminated by legislative changes in 1997. Accordingly, Abbott looked for ways to maximize the profit spread immediately. In one internal memorandum about a third party's pricing product, Abbott states:

> One of GeriMed's goals of obtaining maximum profitability for its members presents an opportunity for our injectables. They think there is about an 18 month window of opportunity to promote our injectables as more profitable for their members to use because of the bigger spread between AWP and cost. Legislative changes in reimbursement are expected to do away with this spread advantage by mid 1997.

(ABT AWP/MDL 015839) (Highly Confidential).

b. In a second memorandum about this same product, Abbott states:

> The purpose of these programs was to "enhance revenue and decrease cost." *** These suggestions are made to save money through lower contract pricing or increase revenue through better spread between AWP and contract price.… The [distributor's] program identifies the lowest cost product and ***the best spread for the particular state***.

(ABT AWP/MDL 010407-09) (Highly Confidential) (emphasis added).

219. Abbott tried to maximize spread because it understood that its customers routinely engaged in "spread shopping" – comparing Abbott's AWPs with those of its competitors in order to determine the greatest spread (and therefore sell or administer the drug with the greatest spread). An example is a document produced by Abbott, prepared by a customer in late 1993, comparing Abbott's proposed contract price and its published AWPs with that of Baxter's competing generic drugs. (ABT AWP/MDL 028546) (Highly Confidential).

220. Just as Abbott motivates providers to administer drugs based on the AWP, Abbott's 1996 Pricing Guidelines reveal that Abbott rewards PBMs based on the degree of influence they exert to drive utilization of Abbott products. (ABT AWP/MDL 053922-23) (Highly Confidential).

**4. Specific Abbott AWPs Documented by the DOJ**

221. In a report published by the DHHS (the "DHHS Report"; PM Rev. AB-00-86, "An Additional Source of Average Wholesale Price Data In Pricing Drugs and Biologicals Covered by the Medicare Program," Sept. 8, 2000), the DOJ documented at least 81 instances where the published AWPs for various dosages of 16 drugs manufactured by Abbott were

substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 16 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

| Drug | Abbott's 2001 *Red Book* AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|---|---|---|---|---|
| Acetylcysteine | $35.87 | $21.90 | $13.97 | 64% |
| Acyclovir | $1047.38 | $349.05 | $698.33 | 200% |
| Amikacin Sulfate | $995.84 | $125.00 | $870.84 | 697% |
| Calcitriol (Calcijex) | $1,390.66 | $1079.00 | $311.66 | 29% |
| Cimetidine Hydrochloride | $214.34 | $35.00 | $179.34 | 512% |
| Clindamycin Phosphate | $340.52 | $75.35 | $265.17 | 352% |
| Dextrose | $239.97 | $3.91 | $236.06 | 6,037% |
| Dextrose Sodium Chloride | $304.38 | $1.93 | $302.45 | 15,671% |
| Diazepam | $28.50 | $2.03 | $26.47 | 1,304% |
| Furosemide | $74.52 | $14.38 | $60.14 | 418% |
| Gentamicin Sulfate | $64.42 | $.51 | $63.91 | 12,531% |
| Heparin Lock Flush | $38.30 | $13.60 | $24.70 | 182% |
| Metholprednisolone Sodium Succinate | $34.08 | $2.30 | $31.78 | 1,382% |
| Sodium Chloride | $670.89 | $3.22 | $667.67 | 20,735% |
| Tobramycin Sulfate | $150.52 | $2.94 | $147.58 | 5,020% |
| Vancomycin Hydrochloride | $382.14 | $4.98 | $377.16 | 7,574% |

(P006299-316.)

### 5. Additional Evidence Concerning Vancomycin

222. At least one Publisher, Medi-Span, challenged the manner in which Abbott set its AWPs for vancomycin. The following statement appeared in a February 9, 1996 faxed letter to Abbott from a representative of Medi-Span:

> It appears that the only difference between these two products listed is the vial it comes in. If it is, please let us know why the $400 plus difference in AWPs?... [T]his customer claims he can get Vancomycin for $6 or $7 per vial DP as opposed to the $52.94 and $19.50 the Abbott Vancomycin cost.

(ABT AWP/MDL 001215.)

223. The government investigation into Abbott's AWP for vancomycin identified:

> prices that are routinely made available to many providers, but are far below Medicare reimbursement rates. They include 1999 prices for vancomycin, the Abbott Labs-manufactured antibiotic, which a health care provider could buy for $76.00 but for which the AWP upon which Medicare's reimbursement was based on was $261.84.

*See* September 25, 2000 letter from U.S. Rep. Tom Bliley to the Honorable Nancy-Ann Min DeParle, Administrator of the Health Care Financing Administration. (P007015-490.)

224. For other doses of vancomycin, Abbott reported an AWP of $68.77 as of April 2000. The DOJ adjusted it to $8.14.

**6. Additional Evidence for Amikacin**

225. One published report states: "Amikacin, used to treat an infection that HIV+ people get and manufactured by Abbott, had an AWP of $54.56. DOJ said the actual price was $6.75." *See States Mull Suit Against Drug Companies*, www.stateline.org (April 2, 2001) (P011268-70).

**7. Inflated AWPs From Abbott Price Lists**

226. In response to government subpoenas, Abbott produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Abbott has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs (not already referenced above) with spreads in excess of 100% from two specific Abbott customers.

227. Table 1 is an analysis of certain dosages of Abbott drugs from a document entitled "2000 Manufacturer Listing of Pharmaceutical Awards – GeriMed." (ABT AWP/MDL 031024-62) (Highly Confidential).

**Table 1**

| Drug | Contract Price | AWP | $ Diff AWP | % Spread |
|---|---|---|---|---|
| alcohol injection | 30.30 | 78.98 | 48.68 | 160.66 |
| aminosyn (amino acid) | 36.48 | 125.10 | 88.62 | 242.93 |
| aminocaproic acid | 17.75 | 41.88 | 24.13 | 135.94 |
| amphotericin b | 4.65 | 10.94 | 6.29 | 135.27 |
| atacurium besylate | 104.80 | 217.75 | 112.95 | 107.78 |
| bleomycin sulfate inj | 95.00 | 305.78 | 210.78 | 221.87 |
| bretylium tosylate | 215.52 | 567.60 | 352.08 | 163.36 |
| Marcaine (bupivacaine hcl) | 13.40 | 32.01 | 18.61 | 138.88 |
| AbboCath (catheter iv) | 113.00 | 540.00 | 427.00 | 377.88 |
| Chromium TR Meta (chromic chloride) | 12.00 | 30.00 | 18.00 | 150.00 |
| Copper Trace (cupric chloride) | 12.00 | 30.00 | 18.00 | 150.00 |
| Dopamine | 17.00 | 34.88 | 17.88 | 105.18 |
| Doxorubicin hcl inj | 62.50 | 151.25 | 88.75 | 142.00 |
| Epinephrine | 7.00 | 15.94 | 8.94 | 127.71 |
| halothane inhalation anesthetic | 269.94 | 708.75 | 438.81 | 162.56 |
| irrigation set peritoneal dialysis | 103.80 | 245.00 | 141.20 | 136.03 |
| ketorolac tromethamine | 29.50 | 87.38 | 57.88 | 196.20 |
| lidocaine hcl inj | 77.04 | 216.90 | 139.86 | 181.54 |
| mangenese chloride | 10.50 | 30.00 | 19.50 | 185.71 |
| Mannitol | 21.50 | 50.53 | 29.13 | 135.49 |
| Carbocaine (mepivicaine) | 4.67 | 11.34 | 6.67 | 142.83 |
| metoclopramide inj | 27.25 | 98.75 | 71.50 | 262.39 |
| nalbuphine inj | 5.10 | 11.38 | 6.28 | 123.14 |
| Neostigmine methylsul inj | 10.40 | 42.50 | 32.10 | 308.65 |
| pancuronium bromide | 32.63 | 170.94 | 138.31 | 423.87 |
| Pentamidine isethionate inj | 19.00 | 91.84 | 72.84 | 383.37 |
| potassium acetate | 11.50 | 40.00 | 28.50 | 247.83 |
| Novocaine (procaine inj) | 37.25 | 84.95 | 47.70 | 128.05 |
| sodium acetate inj | 12.00 | 42.50 | 30.50 | 254.17 |
| vincristine inj | 3.00 | 36.14 | 33.14 | 1104.67 |
| water for injection bacteriostatic | 6.50 | 13.44 | 6.94 | 106.77 |
| zinc chloride inj | 11.75 | 30.00 | 18.25 | 155.32 |

228. Table 2 is an analysis of a certain dosage of Abbott's drug Toposar from a document entitled "2000 Manufacturer Listing of Pharmaceutical Awards – IVMed." (ABT AWP/MDL 031000-23) (Highly Confidential).

**Table 2**

| Drug | Contract Price | AWP | $ Diff AWP | % Spread |
|---|---|---|---|---|
| Toposar (etoposide inj) | 26.32 | 286.63 | 260.31 | 989.01 |

229. As set forth above, Abbott's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

## B. Amgen

### 1. The Drugs at Issue and Their Competitive Environment

230. Amgen engages in an organization-wide and deliberate scheme to inflate AWPs. Amgen has stated fraudulent AWPs for all or almost all of its drugs, including: Epogen (eportin alfa for ESRD use),[2] Neupogen (filgrastim), Aranesp (darbepoetin alfa), Enbrel (etanercept), Kineret (anakrina), and Neulasta (pegfilgrastim). The specific drugs of Amgen for which relief is sought in this case are set forth in Appendix A and are set forth below and the complaint includes all NDCs for these drugs:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| AMGEN | Aranesp | darbepoetin alfa albumi | Antianemic Agent; Blood Modifier<br>Used in the treatment of anemia associated with chronic renal failure and/or chemotherapy |
| | Enbrel | etanercept | Antirheumatic Agent<br>Used to reduce signs and symptoms of rheumatoid arthritis |

[2] In the Medicare Part B context, reimbursement for Epogen is not based on the AWP, but rather on a specific dollar amount set by statute. However non-Medicare Part B reimbursement for Epogen is based on AWP for many Class members.

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | Epogen | epoetin alfa | Antianemic Agent; Blood Modifier<br>Used in the treatment of anemia associated with chronic renal failure, chemotherapy and/or HIV-infected patients |
| | Kineret | anakrina | Antirheumatic Agent<br>Used in the treatment of moderate to severe rheumatoid arthritis |
| | Neulasta | pegfilgrastim | Antineoplastic; Blood Modifier<br>Used to decrease incidence of infection (neutropenia) in some cancer patients |
| | Neupogen | filgrastim | Antineoplastic; Blood Modifier<br>Used to decrease incidence of infection (neutropenia) in some cancer and leukemia patients |

224A. Amgen introduced EPOGEN® (Epoeitin alfa) in 1989. EPOGEN® is indicated for the treatment of anemia in patients with chronic renal failure on dialysis. In 2001, Aranesp® (darbepoetin alfa), an erythropoietic protein with greater biological activity and a longer half-life than Epoetin alfa, was approved for the treatment of anemia in patients with chronic renal insufficiency. In 2002, Aranesp® was also approved for the treatment of chemotherapy-induced anemia. By 2003 Aranesp had sales of $283 million.

224B. NEUPOGEN® (filgrastim) was approved in 1991. NEUPOGEN® is indicated for decreasing the incidence of infection associated with chemotherapy-induced neutropenia in cancer patients with nonmyeloid malignancies. In 2002, Amgen introduced Neulasta® (pegfilgrastim), a longer-acting form of filgrastim approved for the same use but requiring only one injection per chemotherapy cycle.

231. Since its introduction, Aranesp has been locked into a knock-down competitive battle with Ortho Biotech's Procrit.

225A. A review of their respective websites reveals that Amgen and Ortho are targeting the exact same type of patient with respect to use of Aranesp and Procrit. Amgen describes Aranesp on its website as follows:

> That's where Aranesp® can help. Aranesp® stimulates natural production of red blood cells boosting the number of red blood cells in the body, which can increase the amount of oxygen in your blood and give you more energy. And since you will need fewer shots and doctor visits, you can begin to feel less like a patient and more like a person – and get back to being you again.
>
> Aranesp® is available by prescription only. Aranesp® has been approved by the Food and Drug Administration to treat the anemia associated with chronic renal failure (renal disease) in people with reduced kidney function or on dialysis. People who have uncontrolled high blood pressure should not use Aranesp®.

225B. Ortho promotes and describes Procrit on its website as follows:

> PROCRIT® (Epoetin alfa) is for the treatment of anemia in patients who have chronic kidney disease and are on dialysis. PROCRIT has a proven safety record. Your doctor should carefully monitor your blood pressure and hemoglobin for rapid increases, which should be avoided. PROCRIT is available by prescription only and is administered by your health care provider.

(Emphasis added).

232. Thus, these two companies were targeting the exact same patients and have an incentive to compete based on the spread that they could offer physicians.

226A. Amgen's Neupogen also competed with Immunex's Leukine prior to Amgen's acquisition of Immunex. Both of these drugs are Part B covered drugs and as set forth below this competitive landscape became a breeding ground for competition based on spread or discounts off AWP. Competition also existed between Amgen's Remicade and Immunex's Embrel, which created a climate for using the spread between AWP and acquisition cost as an inducement to wholesalers and other providers.

**2. Amgen's Definition and Understanding of AWP**

226B. Internally, Amgen defines AWP as "the common basis for reimbursement by payors. AWP may not necessarily reflect the actual purchase price" (Press Release, "Data from Study Shows Aranesp …," Dec. 9, 2002 (www.amgen.com)) or "one of the factors used by Medicare to determine payment for drug charges."

**3. Amgen Controls the Published AWP for Its Products**

233. Amgen has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

**4. Amgen Understands the Importance of Reimbursement Rates**

227A. Amgen was well aware that its customers' profits depended on reimbursement rates for drugs, and that Amgen's own sales and profits in turn depended on its customers' reimbursement payments and profits:

> Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement rate could result in decreased sales of our products.
>
> In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payors … ***we believe that sales of Aranesp and Neulasta are and will be affected by government and private payor reimbursement policies***. … If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales or revenues …

(Amgen 2002 Form 10-K at 43-44).

227B. The foregoing references referring to "reimbursement policies" refers to policies that use AWP as the benchmark for reimbursement.

234. Amgen also made sure its sales representatives were focused on reimbursement and customer profit motives. A senior Amgen sales manager has publicly stated:

> Reps need to understand the insurance system flawlessly. They need to understand the money trail in terms of how a drug gets reimbursed, who reimburses it, and coverage or policy limitations – those are fundamental questions."

228A. Part of that "understanding" was an explanation by Amgen sales representatives that was routinely made by sales representatives to physicians concerning profit that a physician could make by purchasing at a discount off AWP. With respect to, for example, Aranesp and

Neupogen, Amgen sales representatives either handed out calculations showing the spread off of AWP that a provider could realize by using Amgen's drugs, or orally reviewed such profits with physicians.

228B. Amgen has also established a website (www.reimbursementconnection.com) to help providers with reimbursement issues, including information on how to calculate reimbursement for Amgen drugs and Sample Reimbursement Sheets detailing how much Medicare will pay for Amgen drugs. In addition, Amgen maintains a telephone Reimbursement Hotline for providers or their office staffs to call to get help with reimbursement questions.

235. Amgen actually promotes the use of AWPs for reimbursement purposes on its website as follows:

**Sample of Reimbursement Payments for Aranesp® Syringe/Vial Strengths**

| | | Medicare | | |
|---|---|---|---|---|
| **Syringe/Vial Strength** | **Average Wholesale Price (AWP)[1/2]** | **85% of Medicare Allowable (AWP)** | **Payment[1] (at 80%)** | **Secondary Insurer or Patient Co-Payment[2] (at 20%)** |
| J0880 – 25 mcg* | $124.69 | $105.99 | $84.79 | $21.20 |
| J0880 – 40 mcg* | $199.50 | $169.58 | $135.66 | $33.92 |
| J0880 – 60 mcg* | $299.25 | $254.36 | $203.49 | $50.87 |
| J0880 – 100 mcg* | $498.75 | $423.94 | $339.15 | $84.79 |
| J0880 – 150 mcg** | $748.13 | $635.91 | $508.73 | $127.18 |
| J0880 – 200 mcg* | $997.50 | $847.88 | $678.30 | $169.58 |
| J0880 – 300 mcg* | $1,496.25 | $1,271.81 | $1,017.45 | $254.36 |
| J0880 – 500 mcg† | $2,493.80 | $2,119.73 | $1,695.78 | $423.95 |

[1] As reported in *Drug Topics Red Book®*, February 2004.
[2] Most private insurers base reimbursements for drugs on a percentage above or below published AWP.
* These strengths are available in either Arenesp® SingleJect® prefilled syringes or vials.
† Available only in Aranesp® SingleJect® prefilled syringe.
** These strengths are available in vials only.

229A. In the above table, Amgen recognizes the impact of an AWP-based price on a "secondary insurer" or patient making copay. Amgen thus promotes AWP all the while knowing that the posted AWP is artificially inflated as described.

**5. Specific Examples of AWP Abuse**

229B. At all relevant times Amgen understood that reimbursement for its drugs was dependent upon AWP. Amgen set the AWPs for its products in an arbitrary manner that rendered AWP to be a fictitious number in that it failed to account for rebates, volume discounts and other incentives provided to physicians and others purchasing Amgen drugs.

236. Both Procrit and Aranesp are Part B covered drugs, hence given the competition between the two, one clear way to increase market share was to increase the spread and hence the profit to providers. Indeed at Aranesp's launch to the oncology market Amgen sales representatives had ready at their fingertips information concerning Aranesp's AWP, the Medicare reimbursement amount, WAC, WAC minus discounts and the "profit" created by the spread between Medicare reimbursement and net acquisition cost.

230A. It was intended by Amgen's top sales executives that its sales force would use this "profit" as a basis for marketing Aranesp.

230B. Examples of the improper use of AWPs by Amgen are set forth below. For example, to increase its market share Amgen in 2003 offered Aranesp to customers with a rebate or discount of up to 30% off of list price, which in itself is 20%-25% off of the published AWP. Thus, Amgen was offering spreads of 50% or more off of the published AWP on Aranesp. These spreads are being offered while Amgen is promoting use of AWP on its own website.

237. On or about July 18, 2003, Amgen extended this discount through July 15, 2004. Thus, even in the face of this litigation, Amgen was offering substantial discounts which rendered the reported AWPs inflated and without basis.

231A. The spread on Aranesp was created at the time of its introduction, and Amgen has published an AWP that created at times at least a 40% spread between the estimated cost to a dispenser and AWP. Given the significant cost of Aranesp this is about $300 per unit for most NDCs. If a typical treatment involves two doses twice a month for a three- to four–month period, the cost of this spread is $1800 - $2400 per patient. For a Medicare patient this could increase co-payments by $360 - $480.

231B. The use of rebates and off-invoice discounts did not start in 2003 but occurred shortly after Aranesp was introduced in 2002. The allegation is based on (a) the fact that the competition between Amgen and Ortho existed before 2003, (b) that Ortho was heavily engaged in its own conduct directed at marketing the spread and Amgen needed to respond in kind, (c) Amgen was offering "introductory" discounts that inflated AWP, and (d) as noted above Amgen sales representatives were armed with calculations showing the profit created by the Aranesp spread. Ortho, at national sales meetings, authorized its sales and marketing representatives to provide free samples as a means of lowering acquisition costs to providers. Ortho also used inducements such as educational and promotional grants to win over clinics and other providers and as credit memos which were inducements for a clinic or provider to use Procrit exclusively. Amgen sales representatives learned of these efforts and reacted to them by offering inducements of their own. These inducements included rebates based upon volume used by the practitioner.

238. Amgen's efforts at using inflated AWPs to increase market share were successful as Aranesp sales have steadily increased.

232A. Amgen's AWP-related manipulation did not stop at Aranesp. Prior to its acquisition of Immunex, Amgen competed with Immunex with respect to its drug Neupogen and Immunex's Leukine. Documents produced by Immunex reveal that Immunex was marketing Leukine based on the spread, promoting its spread of $80.60 per vial as an advantage over

Amgen's $51.61 spread per vial. At the time of this spread marketing by Immunex, Amgen published an AWP for Neupogen of roughly $263.30, and was selling its product to doctors at $201.16. This created a spread of 31% off of AWP which, given the high price of each vial, would have a substantial impact on co-payors and third-party payors, and provided a handsome profit to providers.

232B. Amgen's use of the spread did not go unnoticed by competitors. In an internal memorandum, employees of a competitor, Centecor, wrote in the context of "reimbursement issues" that doctors have a "fear of audit and not being perceived as infusing only for profit," *i.e.*, using infusion where other treatments were available, but noted that Amgen had no issues in encouraging oncologists to choose drugs based on the spread:

> We need to do a stronger job up front driving home the patient benefit of PMP. One of the other reasons I see doctors hitting a point and not moving forward is fear of audit and not being perceived locally as infusing only for profit. An example of what goes on in other specialties might be of benefit – personally I would use an ***Amgen*** or Immunex oncology product and show the AWP versus payment. ***As you know these companies have been telling Rheums it is unethical to receive payment for prescribing an agent but have no problem promoting this concept to oncologists.*** We don't need to make this a big production–if you put the slide up with the product and company the attendees can connect the dots.

239. The foregoing e-mail is in effect competitor intelligence confirming that Amgen was marketing the spread on its products sold to oncologists, which include Aranesp, Neulasta and Neupogen.

233A. Spreads created for Neupogen are set forth below for a 300ml dose. Not only are the spreads sizable, but reported AWPs increased faster than the real AWP, thus making the reported AWPs in later years even more inflated. This increase in spread is the direct result of an effort to induce physicians to use Neupogen due to the increase in the spread:

| Year | Reported AWP | Real AWP | Spread in Dollars | Percentage |
|---|---|---|---|---|
| 1997 | $161.30 | $125.09 | $36.21 | 28 |
| 1998 | $165.30 | $130.02 | $35.28 | 27 |
| 1999 | $180.40 | $134.81 | $45.91 | 34 |
| 2000 | $188.50 | $140.49 | $39.88 | 28 |
| 2001 | $197.80 | $148.62 | $49.18 | 33 |
| 2002 | $207.50 | $149.60 | $57.90 | 38 |

233B. Spreads for the 10,000 u/ml ten pack for Epogen were historically approximately 33%, but beginning in January 2000 Amgen implemented a series of AWP increases so that by 2002 the spread increased to 42%. The increase in spread was designed to increase market share.

240. AWPs for the 4,000 units/ml of Epogen were also inflated with spreads between 92% and 105%. AWPs for this drug/dose increased while costs to the provider decreased. Similarly, the ten pack 4,000 units/ml dose started in 1997 with a spread of 26% that increased to 47% over time.

234A. Amgen has also caused artificially inflated AWPs to be published for its top-selling drug Enbrel. Originally, the spread between AWP and acquisition cost was 25%. This spread has steadily increased over time such that for some doses, the spread is 32% to 40%. Amgen has created this spread to encourage promotion and use of Enbrel by those in the distribution chain.

**6. Amgen Rebates on Epogen**

234B. In addition to marketing the spread, Amgen has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price.

241. A 1993 OIG Report detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epogen. The report noted that Medicare and Medicare beneficiaries did not receive the benefit of any rebates; all monies remained with the provider.

There was no way to provide for any rebates on Medicare claim forms, and Amgen's rebates were not provided until year-end:

> [T]he effect of the rebates is that it reduces the actual cost of EPO to a dialysis facility, thus increasing their gross profit. Presently, the rebates represent price reductions which benefit the facilities exclusively.

("Review of Epogen Reimbursement," (OIG A-01-02-00506 at 7-8)).

235A. By utilizing hidden inducements, Amgen provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

242. Amgen's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of hidden rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

**7. Amgen Concealed Its AWP Manipulation**

236A. Amgen deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, as noted above, Amgen gave rebates to its Epogen customers which effectively lowered the true price charged. When OIG asked Amgen for data on its total sales or the total amount of Epogen rebates, Amgen refused to provide such data. ("Review of Epogen Reimbursement," (OIG A-01-02-00506 at 7-8)).

243. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services.

237A. As set forth above, Amgen's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

**C. AstraZeneca**

244. AstraZeneca has engaged in an ongoing deliberate scheme to inflate AWPs. The drugs at issue for this defendant are identified in Appendix A and summarized below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| ASTRAZENECA | Accolate | zafirlukast | Leukotriene Antagonist (Respiratory Agent)<br>Used in the treatment of asthma |
| | Armidex | anastrozole | Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist)<br>Used in the treatment of breast cancer in postmenopausal women |
| | Atacand | candesartan cilexetil | Angiotension II Receptor Antagonist (Cardiovascular Agent)<br>Used in the treatment of hypertension |
| | Atacand HCT | candesartan cilexetil-hydrocholorothiazide | Angiotension II Receptor Antagonist With Diuretic (Cardiovascular Agent)<br>Used in the treatment of hypertension |
| | Casodex | bicalutamide | Antineoplastic<br>Used in the treatment of prostate cancer |
| | Diprivan | propofol | General Anesthetic<br>Used in the induction or maintenance of anesthesia as part of balanced anesthetic technique |
| | Entocort | budesonide | Glucocorticoid<br>Used in the treatment of Crohn's disease |
| | Nexium | esomeprazole magnesium | Proton Pump Inhibitor (Gastrointestinal Agent)<br>Used in the treatment of heartburn and erosive esophagitis |
| | Nolvadex | tamoxifen citrate | Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist)<br>Used in the treatment or prevention of breast cancer |
| | Prilosec | omeprazole | Proton Pump Inhibitor (Gastrointestinal Agent)<br>Used in the treatment of gastric and duodenal ulcers, gastroesophageal reflux disease and erosive esophagitis |
| | Pulmicort | budesonide (inh) | Glucocorticoid<br>Used for maintenance treatment of asthma |
| | Rhinocort | budesonide (nasal) | Glucocorticoid<br>Used in the treatment of allergic rhinitis |
| | Seroquel | quetiapine fumarate | Antipsychotic Agent (Psychotherapeutic Agent)<br>Used in the treatment of schizophrenia |
| | Toprol | metoprolol succinate | Beta Adrenergic Blocking Agent (Cardiovascular Agent)<br>Used in the treatment of hypertension, angina pectoris and heart failure |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | Zestril | lisinopril | Angiotension Converting Enzyme Inhibitor (Cardiovascular Agent)<br>Used in the treatment of hypertension and heart failure |
| | Zoladex | goserelin acetate | Gonadotropin Releasing Hormone Analogue (Antineoplastic: Hormonal Agonist/Antagonist)<br>Used in the treatment of prostate and advanced breast cancer |
| | Zomig | zolmitriptan | Serotonin Receptor Agonist (Migraine Preparation)<br>Used in the treatment of migraines |

**1. AstraZeneca Has Been the Target of a Government Investigation**

245. In connection with its scheme to inflate AWPs, AstraZeneca has been investigated by the United States Department of Justice. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex® that AstraZeneca sales representatives had given the doctor. The indictment alleges that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.

246. In response to the government's subpoena, AstraZeneca appears to have produced documents related to Zoladex only.

**2. AstraZeneca's Definition and Understanding of AWP**

247. In AstraZeneca's Guide to Coverage and Reimbursement, AstraZeneca defines AWP as follows:

> Average Wholesale Price (AWP): The composite wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book. AWP is often used by third-party payers as a basis for reimbursement.

(AZ0052597) (Confidential). Thus, by its own definition, AstraZeneca recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWPs directly affect the payments made by the Class.

**3. AstraZeneca Controls the Published AWP for Its Products**

248. AstraZeneca has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one internal marketing memorandum, AstraZeneca recommended:

> We take a price increase in December 1995. By doing this, we can inform the Red Book of this increase and it will go into the Red Book for January 1996. This is critical, so that the state Medicare carriers can recognize our new price in January. Typically, the state carriers use the January Red Book and the July Red Book for their reimbursement price of Medicare reimbursed products. Last year when we took the price increase in February there were some Medicare carriers who did not change their reimbursement price until September. Also TAP notifies Red Book 1 month before the price change. We are at a competitive disadvantage with our audience.

(AZ0021838) (Highly Confidential).

**4. AstraZeneca's AWP Manipulation Benefited Providers at the Expense of the Class**

249. The purpose of AstraZeneca's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

a. In one internal marketing memorandum, AstraZeneca recognized the profits to providers from the inflation of AWPs: "The market we are in wants a more expensive Zoladex, because the doctor can make more money." (AZ0021838) (Highly Confidential).

b. Similarly, in its agreements with PBMs, AstraZeneca guaranteed that it would maintain a spread between AWP and AWC (average wholesale cost) in order to ensure a profit to PBMs at the expense of the Class. (AZ0036207) (Highly Confidential). For example, in its agreement with Caremark, AstraZeneca stated:

> ZENECA WILL REIMBURSE CAREMARK FOR THE DIFFERENCE BETWEEN THE AMOUNT COLLECTED BY CAREMARK ON EACH PATIENT UNIT SOLD AND AWP AT THE TIME THE UNIT WAS DISPENSED. CAREMARK WILL HAVE EXERCISED BEST EFFORTS TO COLLECT THE FULL AWP FROM THE 3RD PARTY PAYER AND THE PATIENT PRIOR TO SUBMISSION TO ZENECA.

(AZ0036208) (Highly Confidential).

c. AstraZeneca recognized that its practices were at the expense of the Class:

> BECAUSE OF OUR STEEP DISCOUNTING, NEARLY HALF THE PROFIT TO BE REALIZED WITH ZOLADEX IS PAID BY MEDICARE. AND SINCE MEDICARE IS THE QUICKEST AND MOST DEPENDABLE PAYOR, THIS WAS SEEN AS AN ENORMOUS BENEFIT. THE OTHER HALF OF THE PROFIT WAS FROM THE PATIENT CO PAY OR SECONDARY INSURANCE . . . .

(AZ0037011) (Highly Confidential).

**5. AstraZeneca Manipulated and Marketed the AWP for Zoladex**

250. AstraZeneca stated an inflated AWP for Zoladex and marketed the resulting spread during the Class Period. AstraZeneca's documents reveal an intense competition with TAP Pharmaceuticals and its drug Lupron, focusing primarily on the spreads available to physicians between Zoladex and Lupron.

251. For instance, one internal chart touts the greater spread that can be reaped from the inflated AWP for Zoladex over the AWP for Lupron:

| | AWP | AWP minus 5% | Current Cost (1 depot) | Return to Practice 1 depot | Current Max Discount 29.5% vs 50% | Return to Practice at Max. |
|---|---|---|---|---|---|---|
| Lupron 3-month depot | $1,622.68 | $1,541.55 | $1,297.50 | $244.05 | $915.00 | $626.55 |
| Zoladex 3-month depot | $1,231.53 | $1,169.95 | $985.22 | $184.73 | $492.61 | $677.34 |

(AZ 0055816) (Highly Confidential).

252. Another document announcing new pricing for Zoladex states:

> With a purchase of 72+ depots of ZOLADEX and the additional 2% for paying within 30 days yields the doctor a $133.67 profit

> margin with ZOLADEX vs $133.50 with a purchase of 101+ depots of Lupron. For those offices that purchase between 60-100 depots of Lupron monthly, they can increase their profit margin greatly by purchasing ZOLADEX.

(AZ 0037019) (Highly Confidential).

253. Moreover, AstraZeneca repeatedly tried to educate providers regarding the Medicare reimbursement system and the benefits to the providers for Zoladex utilization. For example in a document sent to providers AstraZeneca states:

The following is a cost comparison of Zoladex® vs Lupron® 7.5 mg where Zoladex® is purchased under the buying power of the Urology Purchasing Group, St. Louis, Mo. The calculations reflect prices/discounts effective as of 2/1/94.

| | ZOLADEX | LUPRON | | | |
|---|---|---|---|---|---|
| Quantity | 1 | 1-11 | 12-25 | 26-50 | Your Office |
| Direct Drug Cost | $245.97 | $371.00 | $360.99 | $352.50 | $ |
| Medicare $ Claim<br><br>Medicare Payment to MD | $344.76<br>x 80.%<br><br>$275.81 | $463.75<br>x 80%<br><br>$371.00 | $463.75<br>x 80%<br><br>$371.00 | $463.75<br>x 80%<br><br>$371.00 | $463.75<br>x 80%<br><br>$371.00 |
| Patient / 3rd Party Payment* | $344.76<br>-275.81<br><br>$ 68.95 | $463.75<br>-371.00<br><br>$ 92.75 | $463.75<br>-371.00<br><br>$ 92.75 | $463.75<br>-371.00<br><br>$ 92.75 | $463.75<br>-371.00<br><br>$ 92.75 |
| Medicare Claim Direct Drug Cost<br><br>Total Profit Per Injections | $344.76<br>-245.97<br><br>$ 98.79 | $463.75<br>-371.00<br><br>$ 92.75 | $463.75<br>-360.00<br><br>$103.75 | $463.75<br>-352.50<br><br>$111.25 | $463.75<br>-_____ |
| Difference | | $ 6.04 | $ 4.96 | $ 12.46 | $_____ |
| Percent Profit per Injection | 40% | 25% | 29% | 32% | __% |
| Additional Cost outlay of Lupron vs Zoladex (Direct Cost vs Direct Cost) | | $125.03 | $114.03 | $106.53 | $_____ |

ILLUSTRATION: If your office uses between 12 and 25 Lupron® units per month, your total "profit" per injection, over Zoladex, is $4.96 but your additional outlay per Lupron injection is $114.03. This represents and unnecessary tie up of corporation monies. Based on 12 Lupron injections per month, your office has "tied up" $1,368.36 to achieve a "profit" of $59.52. In this example, Zoladex represents a 40% return on investment vs. 29% for Lupron.

* Calculations assume a 100% collection of monies from patient or 3rd party. If Lupron® is used instead of Zoladex® and the 20% is not collected, then the office has lost $23.80 per injection ($92.75 - $68.95 = $23.80).

01-25-0418

(AZ0046085) (Highly Confidential).

254. Internal AstraZeneca documents reveal that AstraZeneca was directly marketing the spread to physicians. A memo announcing price changes for Zoladex states:

> We have raised AWP and AWC by 7% and have increased our discount level higher at all purchasing tiers.
>
> Pricing on Zoladex 3-month is as follows:

| Discount | | AWP | Cost |
|---|---|---|---|
| 1-5 depots | 0 | 1206.49 | 966.79 |
| 6-11 depots | 11 | 1206.49 | 860.44 |
| 12-23 depots | 15 | 1206.49 | 821.77 |
| 24-47 depots | 17 | 1206.49 | 802.44 |
| 48-59 depots | 20 | 1206.49 | 773.43 |
| 60-71 depots | 22 | 1206.49 | 754.10 |
| 72-96 depots | 24 | 1206.49 | 734.76 |
| 96-191 depots | 25 | 1206.49 | 725.09 |
| 192 + | 30 | 1206.49 | 676.75 |

> Zoladex AWP has been priced at a 5% premium above 3 times the Zoladex 1-month depot. The discount levels have been increased also.

(AZ 0024566-67.)

255. Thus, at the same time AstraZeneca was raising the AWP for Zoladex, it was lowering the real price to providers (by giving bigger discounts), which served to widen the spread.

256. Another document sets forth the difference between the purchase price and the AWP at various volume levels. Note that even with no volume discount, a provider is still making at least a $71.00 profit per unit on Zoladex ($358.55 - 286.84 = 71.71):

> NEW LOWER CASE QUANTITY DISCOUNT
> ZOLADEX PRICING

| UNITS | AWP | COST | DISCOUNT | LESS 2% |
|---|---|---|---|---|
| 1-5 | $358.55 | $286.84 | 0% | $281.10 |
| 6-11 | $358.55 | $269.63 | 6% | $264.24 |
| 12-23 | $358.55 | $261.02 | 9% | $255.80 |
| 24-47 | $358.55 | $252.42 | 12% | $247.37 |
| 48-59 | $358.55 | $243.81 | 15% | $238.93 |
| 60-71 | $358.55 | $235.21 | 18% | $230.50 |
| 72+ | $358.55 | $229.47 | 20% | $224.88 |

(P003060.)

257. The same document goes on to tout the practice's ability to make more profit, or return on investment, by exploiting the AWP scheme:

> Thank you for your time and listening ear on Monday, April 17. As discussed, I am offering a proposal to switch Lupron patients to Zoladex. Zeneca Pharmaceuticals now has new volume pricing, with a 20% maximum discount, for Zoladex. What this will offer the practice is an opportunity to save money, realize a better return on investment, achieve the same profit you currently have with our competitor and free up a substantial amount of working capital. Zoladex will also save the patient money and the system money.
>
> Based on a comparison of Zoladex and Lupron, if 480 depots are used annually Zoladex will save the practice $57,177.60 a year. Your dollar return to the practice is now slightly higher with Zoladex. This rate of return for Zoladex is now 59% compared to Lupron's 39%

(P003058.)

258. Another AstraZeneca document even more explicitly demonstrates to providers how they can profit from the AWP scheme, in excess of $64,000 per year:

ZOLADEX

| Direct Pricing | Medicare AWP | $$Return / % Return |
|---|---|---|
| 72+ $224.88 | $358.55 | $133.67 59% |
| 72x$224.88=$16,191.38 | 72x$358.55=$25,815.60 | $9,624.24 59% |
| *based on your use of 480 depots annually, with our 2% discount these are the comparisons* | | |
| $107,942.40 | $172,104.00 | $64,161.60 59% |

(P003058.)

259. According to a September 2001 GAO report, the discount from AWP for medical providers who purchased AstraZeneca's Zoladex and billed Medicare was between 21.9% and 22.3%. ("Payments for Covered Outpatient Drugs Exceed Providers' Cost, Sept. 2001" (P005546-78).)

260. AstraZeneca, through its employees and agents, also provided millions of dollars worth of free samples of its drugs to providers. The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. Moreover, at least as to Zoladex®, AstraZeneca sales representatives specifically told providers that they could and should bill for the free samples.

261. A written proposal from AstraZeneca Sales representative Randy Payne dated July 17, 1995 encourages a urology practice to switch all of their patients to Zoladex and states: "AS AN ADDED INCENTIVE, ZENECA WILL PROVIDE YOU WITH 50 FREE DEPOTS (over $11,900 worth of product) FOR THE INITIAL CONVERSION TO ZOLADEX." (P003059.)

262. As set forth above, AstraZeneca's scheme to inflate its reported AWPs for Zoladex, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

**D. The Aventis Group (Aventis, Pharma, Hoechst and Behring)**

263. Aventis engages in an organization-wide and deliberate scheme to inflate AWPs. Aventis has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Aventis for which relief is sought in this case are set forth in Appendix A or in the proposed class certification order, and are summarized below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| AVENTIS GROUP (Aventis, Pharma, Hoechst and Behring) | Allegra | fexofenadine | Antihistamine<br>Used for the relief of symptoms of seasonal allergic rhinitis |
| | Allegra-D | fexofenadine pseudoephedrine | Antihistamine<br>Used for the relief of symptoms of seasonal allergic rhinitis |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | Amaryl | glimepiride | Antidiabetic<br>Used to lower blood glucose in Type II diabetes patients |
| | Anzemet | dolasetron mesylate | Antineoplastic<br>Used to prevent nausea and vomiting after chemotherapy or operation |
| | Arava | leflunomide | Antirheumatic<br>Used in the treatment of active rheumatoid arthritis |
| | Azmacort | triamcinolone aceonide (inh) | Steroidal Anti-Inflammatory Agent (Respiratory Agent)<br>Used for maintenance treatment of asthma |
| | Calcimar | calcitonin salmon | Parathyroid Agent<br>Used in the treatment of blood calcium levels and to increase the level of calcium in the bones |
| | Carafate | sucralfate | Duodenal Ulcer Adherent Complex (Gastrointestinal Agent)<br>Used in the treatment and maintenance therapy of duodenal ulcer |
| | Cardizem | diltiazem | Calcium Channel Blocker (Cardiovascular Agent)<br>Used in the treatment of angina and hypertension |
| | Gammar PI.V. | immune globulin | Immunizing Agent<br>Used as a maintenance therapy in patients with compromised immune systems |
| | Intal | cromolyn sodium | Antiasthmatic<br>Used to treat allergic rhinitis and severe perennial bronchial asthma |
| | Nasacort | triamcinolone acetonide (nasal) | Steriodal Anti-Inflammatory Agent (Nasal Preparation)<br>Used for nasal treatment of allergic rhinitis symptoms |
| | Taxotere | docetaxel | Antineoplastic<br>Used in the treatment of breast or lung cancer after failed chemotherapy |
| | Trental | pentoxifylline | Blood Viscosity-Reducing Agent (Blood Modifier)<br>Used to improve the flow of blood through blood vessels |

**1. Aventis Has Been the Target of Government Investigations**

264. In connection with its scheme to inflate AWPs, Aventis has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Commerce Committee of the U.S. House of Representatives, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

**2. Aventis' Definition and Understanding of AWP**

265. Internal documents recently produced by Aventis reveal the definition of AWP used and understood by Aventis and its predecessor companies. Specifically, a November 1992 internal newsletter at Armour Pharmaceutical Company (a predecessor company to Centeon LLC, later known as Aventis Behring) states:

> "AWP" is common language among insurance carriers (state, federal and private). The acronym stands for Average Wholesale Price. AWPs are set by manufacturers as a "suggested retail" for the products they produce. ***These figures represent a reasonable profit margin to healthcare providers and as such are widely referenced by insurance carriers when setting reasonable and customary rates of reimbursement***.
>
> Average Wholesale Prices are printed in Red Book Drug Topics and Blue Book. Both serve as data resources to all state Medicaid programs. Each publication lists the drugs by brand name in alphabetical order with its corresponding descriptions.

(ABAWP 008990-91) (Highly Confidential) (emphasis added).

266. Aventis possessed the *Red Book*'s definition of Average Wholesale Price:

> Average wholesale price (AWP) is the standardized cost of a drug, which managed care plans frequently use for determining drug benefits. The AWP is determined through reference to a common source of price information, such as the American Druggist's *Blue Book*, which lists the costs charged for an undiscounted drug to a pharmacy by a large group of pharmaceutical wholesale suppliers. AWP's are set by pharmaceutical manufacturers and supplied to all pricing data banks for publication.

(ABAWP 012067) (Highly Confidential).

**3. Aventis Controls the Published AWP for Its Products**

267. Aventis controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

a. For example, on December 29, 1997, Rhone-Poulenc Rorer (a subsidiary of Rhone Poulenc SA, which merged with Hoechst AG to form Aventis in 1999) submitted a list of AWP price increases effective January 1, 1998 to both Medi-Span and First Data Bank. Aventis instructed Medi-Span and First Data Bank to "change [their] records accordingly to reflect the new prices." (AV-AAA-001054) (Confidential). Similar letters requesting price changes for 1999 were sent to Medi-Span and First Data Bank by Aventis on December 29, 1998. (AV-AAA-001047) (Highly Confidential), (AV-AAA-001050) (Highly Confidential), and price changes for 1997 on December 23, 1996 (AV-AAA-001066) (Highly Confidential).

b. An April 1, 1998 letter from Centeon notifies Medical Economics (the *Red Book*) that effective April 1, 1998, it "has raised AWP pricing" for Bioclate and Monoclate. (ABAWP 005314) (Highly Confidential).

**4. Aventis' AWP Manipulation Benefited Providers at the Expense of the Class**

268. The purpose of Aventis' manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

269. Aventis knew that AWP manipulation, and the related marketing of an AWP spread, was improper. An internal Aventis (Centeon) document, in pertinent part, states – in large, bold print:

> **ATTENTION!**
>
> SELLING AGAINST AWP
>
> This is <u>not</u> an option.
>
> Traditionally, some manufacturers have promoted differences in AWPs as a means to sell their products. Centeon does not do this,

> and we hope to hear from you if you learn that any other manufacturer (sic) are using this tactic.
>
> Some pharmaceutical manufacturers set high AWPs as a means of securing market shares for their drugs. Although not illegal, the intensity of government scrutiny of this and other pharmaceutical manufacturer pricing practices is increasing. The inspector general is looking at prices for big-ticket drugs
>
> ***
>
> At the risk of being redundant it is imperative to stress that AWP can not (sic) be used in the content of selling any of our products. If you are made aware, either orally or through written correspondence, of any manufacturer using this form of sales tactic immediately report such findings to Gene Hull and appropriate steps will be taken.

(ABAWP 000855) (Highly Confidential).

270. Nonetheless, Aventis (Centeon) routinely promoted differences in AWPs in marketing its numerous products. In seminar materials used in conjunction with an "Oncology University Anzemet Workshop" held in 1998, Aventis explained to attendees how its AWP spread could be exploited. Aventis offered the following definition and example of AWP spread:

> **SPREAD**
>
> - Difference between acquisition cost (AC) and reimbursement (Profit, Margin, etc.).
> - Example for Anzemet
>
> -AC = $68 for 100 mg vial
> -AWP = $166.50
> -AWP – 5% = $158.18
> -80/20 = $126.54/$31.64
> -Spread = $58.54 + $31.64 = $90.18

(AV-AAA-02242-56) (Highly Confidential).

271. Aventis, through its employees and agents, also provided free samples of its drugs to providers. (ABAWP 000089) (Highly Confidential) (ABAWP 000811) (Highly Confidential). The free samples would be used to offset the total cost associated with purchases of its drugs,

thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. In fact, a 1995 "SALES AND FREE GOODS STATUS" memo reveals that Aventis (Armour) issued millions of "free goods units" to a single customer alone. (ABAWP 000220-25) (Highly Confidential).

272. Further, just as Aventis motivates providers to administer drugs based on the AWP, Aventis rewards PBMs based on the degree of influence they exert to drive utilization of Aventis products. (AV-AAA-000197-99) (Highly Confidential).

**5. Specific Aventis AWPs Documented by the DOJ**

273. In a report published by the DHHS (AB-00-86), the DOJ documented at least 15 instances where the published AWPs for various dosages of 4 drugs manufactured by Aventis were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 4 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Aventis in the 2001 *Red Book*.

| Drug | 2001 *Red Book* AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|---|---|---|---|---|
| Anzemet Injectable (dolasetron mesylate) | $166.50 | $74.08 | $92.42 | 125% |
| Factor VIII/ Bioclate | $1.25 | $.91 | $.34 | 37% |
| Factor VIII/ Helixate | $1.18 | $.78 | $.40 | 51% |
| Gammar (immune globulin) | $400.00 | $296.67 | $103.33 | 35% |

(P006299-P006316).

274. An OIG report (*see* "Medicare Reimbursement of Prescription Drugs," OEI-03-00-00310, Jan. 2001) further revealed that: (i) the AWP for all immune globulin 5 mg doses listed in the 1997 *Red Book* were inflated by an average spread of 32.21%; (ii) a 10 mg dose of Anzemet had a Medicare Median of $14.82 and a Catalog Median of $8.29, resulting in a spread

of 78.76%; and (iii) a 20 mg dose of Taxotere had a Medicare Median of $283.65 and a Catalog Median of $8.29, resulting in a spread of 18.75%. (P006398-006424).

**6. Additional Evidence Concerning Anzemet**

275. Aventis distributed a "Reimbursement Spreadsheet" to be utilized by its sales personnel to demonstrate to "private practice office" customers the "financial advantages" of its drug, Anzemet, compared to Zofran and Kytril based on Aventis' established AWP and acquisition price (total reimbursement through Medicare). (AV-AAA-001190-93) (Highly Confidential). Aventis also communicated to its sales staff on December 7, 1998 that "Anzemet still [held] the advantage on spread" following a Kytril price increase. (AV-AAA-002291) (Highly Confidential).

276. Another Aventis internal document also addresses how a particular Aventis customer might increase its margin choosing Anzemet over the competition:

> Cost and Reimbursement: OnCare has negotiated a very favorable contract with Hoechst Marion Roussel [an Aventis predecessor company], manufacturer of Anzemet. Our cost from OTN for the Anzemet 100 mg/ml vial is reduced from approximately $70 ea. to $62.50. In addition there will be quarterly rebates further reducing the cost to $61.25. The AWP is $149.88, making the margin $88.63. Additional returns can be realized by using 1.8 mg/kg as recommended in the package insert. For example, for a patient weighing 70Kg, the dose is 126 mg, requiring 2 vials. Since the vial is single use, you may bill for both vials: total cost is $122.50, the AWP is $299.76, the net is $177.26 (assuming reimbursement at AWP). By comparison the current margin for 0.7 of Kytril is $54.89. For 1 mg it is $78.42. If there is a price increase in 1999 (which we expect) our prices are protected, however the AWP will go up, further increasing the margin. The contract makes Anzemet the preferred 5-HT3 antiemetic drug for OnCare.

(AV-AAA-001523) (Highly Confidential). Other customers received promotional materials reflecting a significant spread between the unit price and AWP for Anzemet – and touting a "Reimbursement and Patient Assistance Program Hotline." (AV-AAA-001619-23) (Confidential).

277. A government investigation revealed similar inflated pricing implemented by Aventis with respect to the injectable form of Anzemet. In a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, U.S. Rep. Pete Stark provided a synopsis of the scheme implemented by Aventis (Hoechst):

> The following chart represents a comparison of Hoechst's fraudulent price representations for its injectable form of the drug versus the truthful prices paid by the industry insider. It is [sic] also compares Hoechst's price representations for the tablet form of Anzemet and the insider's true prices. It is extremely interesting that Hoechst did not create a spread for its tablet form of Anzemet but only the injectable form. This is because Medicare reimburses Doctors for the injectable form of this drug and by giving them a profit, can influence prescribing. The tablet form is dispensed by pharmacists, who accept the Doctor's order. And this underscores the frustration that federal and state regulators have experienced in their attempts to estimate the truthful prices being paid by providers in the marketplace for prescription drugs and underscores the fact that, if we cannot rely upon the drug companies to make honest and truthful representations of their prices, Congress will be left with no alternative other than to legislate price controls.

| NDC No: | Unit Size/ Type | Quantity | Net Price as Represented to Florida Medicaid | True Wholesale Price | Variance |
|---|---|---|---|---|---|
| 0088-1206-32 | 100 mg/5 ml Injectable | 1 | $124.90 | $70.00 | Represented price 78% higher than true wholesale price. |

(P007548-007588).

**7. Additional Evidence Concerning Gammar**

278. Similarly, Aventis increased AWPs for its Gammar product line to keep provider and intermediary reimbursement levels competitive with those created by the inflated AWPs of other manufacturers. A May 8, 1996 Aventis (Centeon) Interoffice Correspondence memo states:

> Effective June 1, 1996, we will be revising our AVERAGE WHOLESALE PRICE for our Gammar P iv product line. We are implementing this change based on feedback from the field. Alpha and Bayer have recently increased their AWP pricing on

> Gammimmune 10% and Venoglobulin S 10%. They are presently priced at $75 and $80 per gram respectively. . . . This change will help us maintain a competitive balance in the marketplace.

(ABAWP 004767) (Highly Confidential).

279. Centeon interoffice correspondence, dated June 23, 1999, reveals that a Centeon employee provided a representative of First Data Bank with the following information regarding Centeon's AWP for Gammar:

> She asked me to validate Centeon's AWP and wholesale list price for Gammar PIV 5 and 10 gram vials.
>
> ***
>
> I gave her the following info:
>
> "Currently it is not Centeon's business practice to sell Gammar PIV to wholesalers. But should a wholesaler place an order, our wholesale list price is $52/gram, or $260 for 5 gram vial, and $520 for 10 gram vial."
>
> "Centeon's suggested AWP is $400 for 5 gram vial, and $800 for 10 gram vial. This is pricing as reported to First Data Bank, but we do not sell product at these prices."

(ABAWP 005315) (Highly Confidential).

280. U.S. Rep. Thomas J. Bliley, in a May 4, 2000 letter to the CEO of Aventis (Behring), also stated concerns regarding Aventis' pricing of Gammar:

> The Office of Inspector General (OIG) at the Department of Health and Human Services determined that the Medicare-allowed amount for immune globulin, a pharmaceutical product sold by your company under the name Gammar, in Fiscal Year 1996 was $42.21. The OIG further estimated that the actual wholesale price of this drug was $16.12 and the highest available wholesale price that the OIG was able to identify was $32.11.

(P006962-P006966).

**8. Inflated AWPs From Aventis' Price Lists**

281. In response to government subpoenas, Aventis produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other

intermediaries. A review of those price lists reveals that Aventis has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical.

282. A March 4, 1997 price list issued by Arcola Laboratories (a division of Rhonel-Poulenc Rorer Pharmaceuticals sets the AWP for Calcimar (calcitonin-salmon) at $31.35, with a cost of $12.00 – for a spread of 161%. (AV-AAA-000705).

283. As set forth above, Aventis' scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

**9. Aventis Concealed its AWP Manipulation**

284. Aventis deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, in response to a May 26, 1995 fax request from *Red Book*, Aventis refused to provide Wholesale Acquisition Cost (WAC) for products it listed in the *Red Book* database – in spite of *Red Book's* assurances that WAC information would be distributed via electronic means only. (ABAWP 008420) (Highly Confidential). Aventis effectively hid the AWP spread from Plaintiffs and the Class.

**E. Baxter**

285. Baxter engages in an organization-wide and deliberate scheme to inflate AWPs. Baxter has stated fraudulent AWPs for all or almost all of its drugs those set forth below. The specific drugs of Baxter for which relief is sought in this case are set forth in Appendix A or in the proposed class certification order, and are summarized below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| BAXTER | Aggrastat | tirofiban hydrochloride | Glycoprotein Receptor Inhibitor (Blood Modifier)<br>Used in the treatment of acute coronary symptoms |
| | Ativan | lorazepam | Antianxiety Agent (Psychotherapeutic Agent); Anticonvulsant<br>Used to relieve anxiety and treat insomnia |
| | Bebulin VH | factor ix (systemic) | Antihemorrhagic Agent<br>Used to treat hemophilia B |
| | Brevibloc | esmolol hcl | Autonomic Nervous System Agent<br>Used in the treatment of tachyarrhythmias in critical situations |
| | Buminate | albumin (human) | Plasma Fraction (Blood Modifier)<br>Used in the treatment of hypovolemia and hypoalbuminemia |
| | Claforan | cephalosporin (systemic) | Antibacterial Agent (Anti-Infective Agent)<br>Used in the treatment of infections caused by bacteria |
| | Gammagard S/D | immune globulin solution | Antibacterial Agent (Anti-Infective Agent)<br>Used to prevent or treat some illnesses. |
| | Gentran | dextran | Blood Derivative; Blood Modifier<br>Used in the emergency treatment of shock |
| | Holoxan/Ifex | ifosfamide | Antineoplastic<br>Used in the treatment of various forms of cancer |
| | Iveegam EN | immune globulin iv | Antibacterial Agent (Anti-Infective Agent)<br>Used as replacement therapy in patients with primary immunodeficiency syndromes |
| | Osmitrol | mannitol | Osmotic Diuretic<br>Used to promote diureses during treatment of acute kidney failure. Also used to reduce intraocular and intracranial pressure |
| | Recombinate | factor viii | Antihemophilic Factor<br>Used to induce blood clotting |
| | Travasol | amino acid | Dietary Supplement<br>Used for nutritional support in cancer patients |
| | Vancocin HCl | vancomycin hydrochloride | Antibacterial Agent (Anti-Infective Agent)<br>Used in the treatment of infections caused by bacteria |
| | | cisplatin | Antineoplastic<br>Used to treat cancer of the bladder, ovaries, and testicles |
| | | dextrose | Caloric Agent; Electrolyte Replenisher<br>Used to increase intake of calories and fluids |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | | doxorubicin hcl | Antineoplastic<br>Used in the treatment of various forms of cancer |
| | | gentamicin | Antibacterial Agent (Anti-Infective Agent)<br>Used to treat serious bacterial infections |
| | | heparin | Anticoagulant (Cardiovascular Agent)<br>Used to decrease the clotting ability of the blood |
| | | sodium chloride | Flush; Abortifacient<br>Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion |

**1. Baxter Has Been the Target of Government Investigations**

286. Baxter has been investigated by the United States Department of Justice, Department of Health and Human Services Office of Inspector General, the Attorney General for the State of California, the Attorney General for the State of Texas, the Attorney General for the State of Illinois, and the Committee on Commerce of the House of Representatives.

287. These investigations confirm that Baxter has engaged in a deliberate scheme to inflate AWPs for many or most of its drugs. A Baxter document made public as a result of the congressional investigation entitled, "Confidential – Baxter Internal Use Only," acknowledged that: "Increasing AWPs was a large part of our negotiations with the large homecare companies." Baxter further admitted in internal documents that homecare companies that reimburse based on AWP make a significantly higher margin. Thus, Baxter's own documents demonstrate its active participation in the scheme to artificially inflate AWPs.

**2. Baxter's Definition and Understanding of AWP**

288. Despite its manipulation, Baxter understood what AWP should mean: "The average price that a pharmacy (or provider) pays for the product from their drug wholesaler or distributor." (BAX MDL 0011378) (Highly Confidential). Contrary to its own definition of

AWP, Baxter nonetheless set AWPs for its drugs far in excess of what providers paid for those drugs.

**3. Baxter Controls the Published AWP for its Products**

289. Baxter has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, a September 7, 1995 inter-office memorandum provides:

> I have been in contact with both *Red Book* and Medispan earlier this year about our AWPs. I told them that we will not be raising our AWPs for FVIII in 1995, and will only increase IGIV in the event of a label change. There are a few general rules about AWP adjustments.
>
> • A manufacturer may raise AWPs at any time in the year. There is a monthly publication called the *Red Book* Update that lists all changes to the April publication (the big red book).
>
> • If a manufacturer does decide to increase AWPs: - payors want a justification for the increase. This is why we typically don't increase the AWP unless we have a label change, product enhancement . . . .

(BAX MDL 0004754) (Highly Confidential).

**4. Baxter's AWP Manipulation Benefited Providers at the Expense of the Class**

290. In at least one internal document, Baxter recognized that deliberate manipulation of the spread was being wrongly used to gain competitive advantage by manufacturers:

> ***The deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers.***

(BAX MDL 0012778) (Highly Confidential) (emphasis added).

291. Despite this recognition, Baxter nonetheless continued to manipulate its AWPs in order to maintain the competitiveness of its own products based upon the spread. In a January 6,

1992 inter-office memorandum, Baxter informs its employees how to respond to inquiries concerning AWP increases for Baxter products:

> If you receive inquiries from customers or payors questioning our rationale on this recent increase in Published AWP for Baxter products please communicate the following message and no more.
>
> If any further information is needed please send the inquiry to me directly.
>
> A recent review of industry published direct prices and AWPs revealed that Baxter's published AWPs are significantly lower than competitive AWPs. We have therefore adjusted our AWPs to meet competitive levels.
>
> Most of Baxter General Healthcare Division's products are sold to distributors at negotiated contract prices that are different from AWPs. We do not have knowledge of or input to the actual prices charged to the provider by our distributors. The contracted prices to our distributors will not be directly affected by this change in AWPs.

(BAX MDL 0004210) (Highly Confidential).

292. In addition, Baxter's marketing and sales documents, which were prepared and disseminated to its employees and agents via the U.S. mail and interstate wire facilities, compared the costs of their respective drugs to those of their respective competitors and were intended to induce physicians to use Baxter drugs and shift market share in its favor. Other documents created and disseminated by Baxter compared the AWP and the actual "cost" of their respective drugs, so that medical providers could easily see the different "return-to-practice" amounts available for different levels of purchase.

**5. Specific Baxter AWPs Documented by the DOJ**

293. In a report published by the DHHS (AB-00-86), the DOJ documented at least 41 instances where the published AWPs for various dosages of drugs manufactured by Baxter were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the four drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular

dosage, based upon wholesalers' price lists, with the AWP reported by Baxter in the 2001 *Red Book*.

| Drug in Lowest Dosage Form | Baxter's 2001 *Red Book* AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|---|---|---|---|---|
| Dextrose | $928.51 | $2.25 | $926.26 | 41,167% |
| Dextrose Sodium Chloride | $357.69 | $2.93 | $354.76 | 12,108% |
| Sodium Chloride | $928.51 | $1.71 | $926.80 | 54,199% |
| Factor VIII | $1.28 | $.92 | $.36 | 39% |

(P006299-006316).

**6. Evidence Concerning Gammagard S/D (immune globulin solution)**

294. Baxter admittedly manipulated the AWP for Gammagard S/D. In 1996, Baxter distributed a memo providing "[t]he deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is a direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers." Immediately below this text is a handwritten note reading "[w]ill raise AWP for GG/SD by 15%." (BAX MDL 0012778) (Highly Confidential).

295. According to Baxter's own documents, the published AWPs for Gammagard S/D were higher than the actual prices provided to wholesalers. In a customer announcement dated September 24, 1996, Baxter increased the AWP for one particular dosage of Gammagard S/D from $640.71 to $737.00, and the WAC from $365.00 to $420.00. The difference between the new AWP and the new WAC ($317.00) constituted a 43% spread. (BAX MDL 005366) (Highly Confidential).

**7. Inflated AWPs From Baxter's Price Lists**

296. In response to government subpoenas, Baxter produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Baxter has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the

published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs (not already referenced above) with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of Baxter drugs from a document entitled "Baxter Healthcare Corporation Intravenous and Irrigation Solution Products Report" (BAX MDL 0003428-46) (Highly Confidential)).

**Table 1**

| Drug | AWP | DP | Difference | % Spread |
|---|---|---|---|---|
| Ringers | 10.84 | 6.34 | 4.50 | 71% |
| Lactated Ringers | 12.36 | 7.43 | 4.93 | 66% |
| Plasma-lyte 148 | 15.67 | 10.85 | 4.82 | 44% |
| 5% Travert and electrolyte no. 2 | 16.39 | 11.30 | 5.09 | 45% |
| 6% Gentran75 | 73.46 | 33.19 | 40.27 | 121% |
| Sterile Water | 9.97 | 6.15 | 3.82 | 62% |
| Sodium Lactate | 17.98 | 11.11 | 6.87 | 62% |
| Osmitrol | 70.28 | 35.12 | 35.16 | 100% |
| Gentamycin | 10.78 | 7.25 | 3.53 | 49% |
| Metronidazole injection | 15.34 | 7.85 | 7.49 | 95% |
| Rocephin | 40.18 | 32.67 | 7.51 | 23% |
| Nitroglycerin | 17.37 | 9.82 | 7.55 | 77% |
| Potassium Chloride Injection | 14.63 | 10.16 | 4.47 | 44% |
| Dopamine | 19.30 | 13.40 | 5.90 | 44% |
| Lidocaine | 22.74 | 13.48 | 9.26 | 67% |
| Heparin | 9.94 | 6.49 | 3.45 | 53% |
| Theophylline | 11.45 | 7.81 | 3.64 | 47% |
| Glycine for Irrigation | 32.87 | 19.70 | 13.17 | 67% |
| Tis-U-Sol | 22.73 | 11.36 | 11.37 | 100% |
| Acetic Acid | 20.70 | 10.91 | 9.79 | 90% |
| Irrigating Solution G | 16.67 | 11.04 | 5.63 | 51% |
| Balanced Salt Solution | 28.76 | 15.00 | 13.76 | 92% |
| Sodium Bicarbonate | 39.23 | 16.36 | 22.87 | 140% |

297. Table 2 is an analysis of certain dosages of Baxter drugs from a document entitled "IV Nutrition Products" (BAX MDL 0003421-26) (Highly Confidential).

**Table 2**

| Drug | AWP | DP | Difference | % Spread |
|---|---|---|---|---|
| Novamine Injection | 95.14 | 51.48 | 43.66 | 85% |
| Travasol | 83.44 | 40.21 | 43.23 | 108% |
| RenAmin Injection | 75.00 | 48.00 | 27.00 | 56% |

| | | | | |
|---|---|---|---|---|
| Aminess Essential Amino Acid | 107.35 | 66.00 | 41.35 | 63% |
| BranchAmin Injection | 93.60 | 60.00 | 33.60 | 56% |

**8. Baxter Provided Free Goods and Other Incentives**

13. Baxter also provided physicians with free goods with the understanding that physicians would bill for those goods, in violation of federal law. Billing for free goods was a way for physicians to obtain greater profit at the expense of the Class. Baxter's fraudulent use of free goods aimed at increasing market share is evidenced by an internal memorandum from a Baxter contract administrator to certain field sales managers encouraging the distribution by U.S. mail or otherwise of free product to achieve overall price reduction:

> BAXTER: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction on Recombinate pricing. Please note that they want to continue to be invoiced at the $.81 price. They have requested that we send them free product every quarter calculated by looking at the number of units purchased in that quarter and the $.13 reduction in price . . . free product given to achieve overall price reduction."

Letter from Stark, Committee on Ways and Means to Holman, Pres. Pharmaceutical Research and Manufacturers of America, Sept. 28, 2002 (P0075410-44).

298. As set forth above, Baxter's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

**F. Bayer**

299. Bayer engages in an organization-wide and deliberate scheme to inflate AWPs. Bayer has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Bayer for which relief is sought in this case are set forth in Appendix A, and are set forth below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| BAYER | Cipro | ciprofloxacin or ciprofloxacin hcl | Antibiotic Agent (Anti-Infective Agent)<br>Used in the treatment of various bacterial infections, including anthrax |
| | Cipro XR | ciprofloxacin hcl-ciprofloxacin betaine | Antibiotic Agent (Anti-Infective Agent)<br>Used in the treatment of various bacterial infections, including anthrax |
| | DTIC-Dome | dacarbazine | Antineoplastic<br>Used in the treatment of melanoma and Hodgkin's disease |
| | Gamimune N | immune globulin (human) iv | Immunizing Agent<br>Used as maintenance therapy in patients with compromised immune systems |
| | Koate-HP | antihemophilic factor (human) | Antihemophilic Factor (Blood Modifier)<br>Used to increase blood clotting and decrease bleeding episodes |
| | Kogenate | antihemophilic factor (recombinant) | Antihemophilic Factor (Blood Modifier)<br>Used to increase blood clotting and decrease bleeding episodes |
| | Mithracin | plicamycin | Antineoplastic; Antihypercalcemic Agent<br>Used in the treatment of various forms of cancer |

### 1. Bayer Has Been the Target of Government Investigations

300. In connection with its scheme to inflate AWPs, Bayer has been investigated by the Department of Justice, Department of Health and Human Services, Office of Inspector General, and the Commonwealth of Massachusetts. Bayer agreed to settle claims asserted by the United States government and 47 states arising from its fraudulent pricing and marketing practices. According to the DOJ's January 23, 2001 press release:

> The government's investigation of the allegations…revealed that [Bayer] beginning in the early 1990s, falsely inflated the reported drug prices – referred to by the industry as the Average Wholesale Price (AWP), the Direct Price and the Wholesale Acquisition Cost – used by state governments to set reimbursement rates for the Medicaid program. By setting an extremely high AWP and, subsequently, selling drugs at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit tremendously from reimbursement paid to them by the government.

> The Bayer AWPs at issue in the investigation involved Bayer's biologic products such as Kogenate, Koate-HP, and Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases. The investigation further revealed that the practice in which Bayer selectively engaged, commonly referred to as "marketing the spread," also had the effect of causing other drug companies to inflate their AWPs.

"Bayer Corporation Settlement on Medicaid Drug Prias" (P011236-011237).

301. As part of its settlement of government claims in 2000, Bayer is required, under the terms of a corporate integrity agreement, to provide state governments and the federal government with the average selling prices of its drugs – a price which accounts for all discounts, free samples, rebates and all other price concessions provided by Bayer to any relevant purchaser that result in a reduction of the ultimate cost to Bayer's customers.

302. In April 2003, Bayer also agreed to pay the government $251.6 million in civil penalties for violating the Federal Prescription Drug Marketing Act for alleged overcharges involving its antibiotic Cipro and its high blood pressure drug Adalat.

**2. Bayer Controls the Published AWP for Its Products**

303. Bayer has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one internal marketing memorandum, Bayer stated:

> I would like to formally request that you contact Redbook and request an AWP change for all sizes (670-20, 670-30, 670-50) of Kogenate from $1.18 per IU to $1.24 per IU to match Baxter's increase. I have attached a letter from Baxter to Redbook outlining their price change request. (Prior to making the change in AWP for Kogenate, please confirm with Redbook that Baxter has indeed initiated a price change.)

(BAY005278) (Highly Confidential).

**3. Bayer's AWP Manipulation Benefited Providers at the Expense of the Class**

304. As detailed in a September 28, 2000 letter from Representative Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, internal Bayer

documents reveal Bayer knowingly participated and directed the scheme to artificially inflate the AWPs for its products and to market the spread:

> BAYER: "Chris, if Baxter has increased their AWP then we must do the same. Many of the Homecare companies are paid based on a discount from AWP. If we are lowed [sic] than Baxter then the return will be lower to the HHC. It is a very simple process to increase our AWP, and can be done overnight."

(P007549.)

305. Tom Bliley, in a letter dated September 25, 2000 to the Health Care Financing Administration, analyzed drug sales in Florida and noted that sales of Bayer's WhinRho "skyrocketed" when competitors reduced their spreads but Bayer did not.

**4. Specific Bayer AWPs Documented by the DOJ**

306. In a report published by the DHHS, the DOJ documented at least 10 instances where the published AWPs for various dosages of two drugs manufactured by Bayer were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the two drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

| Drug | Bayer's 2001 *Red Book* AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|---|---|---|---|---|
| Immune Globulin | $450.00 | $362.50 | $87.50 | 24% |
| Factor VIII | $0.92 | $0.42 | $0.50 | 119% |

(AB-00-86 (P006299-006316)).

307. In a DHHS OIG report (*see* OEI-03-00-00310 (P006398-006424)), the government also discovered that the AWP for all immune globulin pharmaceuticals (of a dosage of 5g), including Bayer's Gamimune® (Bayer was one of five manufacturers of the dosage listed in the 1997 *Red Book*), were over inflated by an average spread of 32.21%.

308. According to the government's settlement with Bayer arising out of Bayer's fraudulent pricing and marketing practices, the Bayer AWPs at issue in the investigation (and ultimately settled) include the AWPs for Kogenate.

**5. Inflated AWPs From Bayer's Price Lists**

309. According to Bayer's own documents, the published AWPs for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, Bayer produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Bayer has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

**6. Bayer Provided Free Goods and Other Incentives**

310. In addition to marketing the spread, Bayer has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Bayer provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

311. Evidence of these practices is found in an October 1, 1996 Bayer internal memorandum addressing volume sales opportunities for the pharmaceutical Kogenate®:

> BAYER: "I have been told that our present Kogenate price, $.66 is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of $.60 to $.62 to secure this volume. From Quantum's stand [sic] point, a price off invoice, is the most desirable. We could calculate our offer in the form of a marketing grant, a special educational grant, payment for specific data gathering regarding Hemophilia treatment, or anything else that will produce the same dollar benefit to Quantum Health Resources."

312. As set forth above, Bayer's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

313. Bayer routinely offered its customers off-invoice discounts as one feature of its standard contracts. (BAYM002428).

**7. Bayer Concealed Its AWP Manipulation**

314. Bayer deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. Bayer routinely required that its customers keep secret the prices they were being charged for Bayer drugs. (BAYM000913, BAYM002436).

## G. The BMS Group (Bristol-Myers, OTN and Apothecon)

315. The BMS Group has engaged in an ongoing deliberate scheme to inflate AWPs. The specific drugs for which relief is sought in this case are identified in Appendix A and are as follows:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| BMS GROUP (Bristol-Myers, OTN and Apothecon) | Avapro | irbesartan | Antihypertensive Agent<br>Used to treat hypertension |
| | Blenoxane | bleomycin sulfate | Antineoplastic<br>Used in the treatment of various forms of cancer |
| | Buspar | buspirone hcl | Antianxiety Agent (Psychotherapeutic Agent)<br>Used to treat certain anxiety disorders or to relieve the symptoms of anxiety |
| | Carboplatin | paraplatin | Antineoplastic<br>Used to treat cancer of the ovaries |
| | Cefzil | cefprozil | Antibacterial Agent (Anti-Infective Agent)<br>Used in the treatment of infections caused by bacteria |
| | Coumadin | warfarin sodium | Anticoagulant (Blood Modifier)<br>Used to promote clotting |
| | Cytoxan | cyclophosphamide | Antineoplastic<br>Used in the treatment of various forms of cancer |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | Etopophos | etoposide phosphate | Antineoplastic<br>Used to treat cancer of the testicles and certain types of lung cancer |
| | Glucophage | meformin hcl | Antihyperglycemic Agent<br>Used to treat a type 2 diabetes mellitus. |
| | Monopril | fosinopril sodium | Antihypertensive Agent; Vasodilator (Cardiovascular Agent)<br>Used to treat hypertension |
| | Monopril HCT | fosinopril sodium & hydrochloro-thiazide | ACE Inhibitor (Cardiovascular Agent)<br>Used in the treatment of hypertension and congestive heart failure |
| | Plavix | clopidogrel bisulfate | Antithrombotic Agent<br>Used to lessen the chance of heart attack or stroke |
| | Rubex | doxorubicin hcl | Antineoplastic<br>Used in the treatment of various forms of cancer |
| | Serzone | nefazodone hcl | Antidepressant (Psychotherapeutic Agent)<br>Used to treat mental depression |
| | Taxol | paclitaxel | Antineoplastic<br>Used in the treatment of various forms of cancer |
| | Tequin | gatifloxacin | Antibacterial Agent (Anti-Infective Agent)<br>Used to treat bacterial infections |
| | Vepesid | etoposide | Antineoplastic<br>Used to treat cancer of the testicles and certain types of lung cancer |
| | Videx EC | didanosine | Antiviral Agent (Anti-Infective Agent)<br>Used in the treatment of HIV infection |
| | | amikacin sulfate | Antibiotic Agent (Anti-Infective Agent)<br>Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections |
| | | amphotercin b | Antifungal Agent (Anti-Infective Agent)<br>Used to help the body overcome serious fungus infections |

### 1. The BMS Group Has Been the Target of Government Investigations

316. In connection with its scheme to inflate AWPs, BMS has been investigated by the United States Department of Justice, Commonwealth of Massachusetts, Office of Inspector General of the U.S. Department of Health and Human Services, Attorney General for the State of Texas, State of California Department of Justice Office of the Attorney General, State of California Department of Justice, Bureau of Medi-Cal Fraud and Elder Abuse, and the U.S.

House of Representatives, Committee on Commerce. Defendant Apothecon has been investigated in connection with its scheme to inflate AWPs by at least the Office of Medicare Fraud and Elder Abuse, Office of Attorney General, State of Texas.

317. These investigations confirm that BMS engaged in an ongoing deliberate scheme to inflate AWPs. For example, by letter dated February 27, 2001 to BMS, Rep. Stark outlined numerous examples of illegal practices by BMS. Referring to a letter from Denis Kaszuba, a senior pricing analyst at BMS to Medispan, dated August 10, 1992 (BMSAWP/0011247), Rep. Stark noted:

> Bristol has control over the AWPs, DPs, and WACs published for its drugs and directs national publishers to change their prices. Bristol directed a national publisher of drug prices to increase all of Bristol's AWPs for oncology drugs by multiplying Bristol's supplied direct prices by a 25% factor rather than the previous 20.5% factor . . . The increase in the AWP created a spread that, in itself, provided a financial kickback to oncologists for prescribing Bristol's cancer drugs.

318. In the same letter, Rep. Stark noted:

> The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

**2. The BMS Group Controls the Published AWP for Its Products**

319. The BMS Group has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one BMS document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

> Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [*sic*] any other business unit of Bristol-Myers Squibb Company.

320. Other internal documents clearly indicate that BMS had direct control over the spread between its states wholesale price and the published AWP. A BMS office dispatch dated September 9, 1992 notes the need for a mark up of the AWP over the state wholesale price. "After reviewing the results of the wholesaler survey performed by Bristol Oncology . . we have determined that for those items with a labeler 0003, we will use a 1.25 mark-up and for those items with the labeler 00015, we will use a 1.20 mark-up. We noticed too, that FDB and Redbook use a 1.20 for everything." (BMSAWP/0011246).

**3. BMS's AWP Manipulation Benefited Providers at the Expense of the Class**

321. BMS was well aware that providers and other purchasers of its drugs were using the spread to determine whether to purchase its drugs. Indeed, BMS was aware of and tracked the prices and AWPs of its competitors in order to remain competitive. In an internal BMS memorandum, BMS identifies its competitors who sell etoposide (Gensia, Pharmacia, Abbott, Chiron, Ben Venue, Immunex and Astra) and their corresponding list price and AWPs. (BMS3CA/000128).

322. BMS created AWP competitor analyses that tracked the AWPs of its competitors' relevant drugs, and used that date internally to propose suggested AWPs for BMS drugs. One such competitor analysis set forth the competitor AWPs for Atenolol with chlorthalidone and provided an "Apothecon suggested AWP" for each dosage. (BMS3CA/000648)

323. BMS clearly believed that the maintenance of a spread on its drugs was important in gaining and maintaining market share. In an internal BMS document, concerning its drug Vepecid (etoposide), BMS noted:

> The Etopophos product file is significantly superior to that of etoposide injection . . . . Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished.

**4. Specific BMS AWPs Documented by the DOJ**

324. In a report published by the DHHS, the DOJ documented numerous instances where the published AWPs for various dosages of five (5) drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the BMS Group drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

| Drug | Manufacturer | BMS's 2001 *Red Book* AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|---|---|---|---|---|---|
| Amikacin Sulfate | Apothecon | $32.89 | $17.31 | $15.58 | 90% |
| Amphotercin B | Apothecon | $17.84 | $6.20 | $11.64 | 188% |
| Bleomycin Sulfate | BMS | $609.20 | $509.29 | $99.91 | 20% |
| Cyclophospamide | BMS | $102.89 | $45.83 | $57.06 | 125% |
| Etoposide (Vepesid) | BMS | $136.49 | $34.30 | $102.19 | 298% |

325. Other sources reveal additional evidence of fraudulent AWPs for drugs manufactured and marketed by the BMS Group:

**5. Other AWPs Related to VEPESID (etoposide)**

326. The February 27, 2001 letter from Rep. Stark to BMS noted that as to BMS ". . . the manipulated discrepancies between [BMS's] inflated AWPs and DPs versus their true costs are staggering. For example, in the 2000 edition of the *Red Book*, Bristol reported an AWP of $1296.64 for . . . Vepesid (Etoposide) for injection . . . while Bristol was actually offering to sell the exact same drug to [a large national group purchasing organization] for $70.00." The difference noted by Rep. Stark represents a % 1,752 spread related to Vepecid.

**6. Other AWPs Related to Blenoxane**

327. BMS internal documents reveal that in 1995, BMS set the *Red Book* AWP for Blenoxane at $276.29. At the same time, BMS was selling Blenoxane to oncologists practicing in St. Petersburg, Florida for only $224.22. In 1996, BMS increased its reported AWP for

Blenoxane to $291.49, while continuing to sell the drug to oncologist for $224.27. In 1997, BMS falsely reported that it had increased the AWP of Blenoxane to $304.60, when in reality, BMS had lowered the price to oncologists to $155.00. In 1998, BMS again reported a false AWP for Blenoxane of $304.60 while further reducing the actual price to oncologists to $140.00.

**7. The BMS Group Provided Free Goods and Other Incentives**

328. As part of its scheme the BMS Group also used free drugs and other goods to encourage participation by physicians. Thus, for example, the BMS Group provided free Etopophos® to two Miami oncologists in exchange for their agreement to purchase other BMS Group cancer drugs. Similarly, other documents show that the BMS Group provided free Cytogards in order to create a lower-than-invoice cost to physicians that purchased other cancer drugs through OTN. (A Cytogard is a device that prevents spillage of intravenous administered treatments such as BMS's cancer drug Etopophos®.)

329. As set forth above, the BMS Group's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

330. For example, in a report published by DHHS, the DOJ documented at least 12 instances where the published AWPs for drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers.

331. The chart below sets forth five examples where the BMS Group deliberately inflated AWPs that it reported for BMS Group drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

| **Drug** | **Manufacturer** | **BMS's 2001 *Red Book* AWP** | **DOJ Determined Actual AWP** | **Difference** | **Percentage Spread** |
|---|---|---|---|---|---|
| Amikacin Sulfate | Apothecon | $32.89 | $17.31 | $15.58 | 90% |
| Amphotercin B | Apothecon | $17.84 | $6.20 | $11.64 | 188% |

| | | | | | |
|---|---|---|---|---|---|
| Bleomycin Sulfate | BMS | $609.20 | $509.29 | $99.91 | 20% |
| Cyclophospamide | BMS | $102.89 | $45.83 | $57.06 | 125% |
| Etoposide (Vepesid) | BMS | $136.49 | $34.30 | $102.19 | 298% |

332. In 1997, an OIG Report identified three other Medicare Part B drugs with inflated AWPs – which the 1997 *Red Book* indicates were manufactured only by the BMS Group at that time: Paraplatin® (carboplatin), Rubet® (doxorubicin hydrochloride), and Taxol® (paclitaxel). Sales of these inflated drugs were substantial. For example, Paclitaxel generated $941 million in revenue for the BMS Group in 1997, and Carboplatin generated $702 million in revenue in 2001.

333. The government's investigation uncovered other drugs for which the BMS Group was stating a fraudulent AWP. Specifically:

a. In the 2000 edition of the *Red Book*, BMS reported an AWP of $1296.64 for Vepesid (Etoposide) for injection while BMS was actually offering to sell the exact same drug to a large customer for only $70.00.

b. From 1995 through 1998 the *Red Book* listed AWP for BMS' Blenoxane 15u increased from $276.29 to $304.60, while the actual cost to physicians declined from $224.22 to $140.00, resulting in a spread of $164.60 in 1998

334. An internal BMS Group document shows that the AWP set by the BMS Group for its drugs bears no relation to an ***actual*** wholesale price, and is greater than the highest price actually paid by providers. More specifically, in a discussion about lowering Vepesid's AWP in order to create sales for Etopophos, the BMS Group stated that the "AWP for Vepesid would be reduced from its current level to the highest bid price currently in the marketplace."

335. BMS Group documents also reveal that physicians were making medical decisions based on how much profit they could make from the AWP manipulated spread. In considering provider choice between BMS drugs Etopophos® and Vepesid® (Etoposide), the BMS Group noted that:

> The Etopophos product file is significantly superior to that of etoposide injection . . . . Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual

> acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished.

336. While the BMS Group and other Defendants have placed the blame for setting published AWPs on the publications in which the AWPs are contained, another BMS Group document demonstrates that publications reporting AWPs had no discretion to set AWPs, and instead published verbatim the prices reported by the BMS Group and other Defendants. In the document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

> Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [*sic*] any other business unit of Bristol-Myers Squibb Company.

**H. Dey**

337. Dey engages in an organization-wide and deliberate scheme to inflate AWPs. Dey has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Dey for which relief is sought in this case are set forth in Appendix A, and are identified below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| DEY | | acetylcysteine | Mucolytic (Respiratory Agent: Diagnostic Aid)<br>Used for certain lung conditions when increased amounts of mucus make breathing difficult |
| | | albuterol or albuterol sulfate | Bronchodilator (Respiratory Agent)<br>Used for relief of bronchospasm in asthma sufferers |
| | | cromolyn sodium | Antiallergic and Mast Cell Stabilizer<br>Used to help prevent or treat the symptoms of seasonal or chronic allergic rhinitis |
| | | ipratropium bromide | Bronchodilator (Respiratory Agent)<br>Used for relief of bronchospasm in asthma sufferers |
| | | metaproterenol sulfate | Bronchodilator (Respiratory Agent)<br>Used for relief of bronchospasm in asthma sufferers |

**1. Dey Has Been the Target of Government Investigations**

338. In connection with its scheme to inflate AWPs, Dey has been investigated by the United States Department of Justice, United States Department of Health and Human Services, Office of Inspector General, the United States District Attorney for the District of Massachusetts, the Attorney General of the State of California, the Attorney General for the State of Texas, the Attorney General of the State of Connecticut, and the District Attorney for the County of Suffolk, New York State.

339. These investigations confirm that Dey has engaged in a deliberate scheme to inflate the published AWPs for many of its drugs. For instance, Dey's spread for albuterol sulfate, a drug that constituted 37 % of Dey's income in 1998, drastically increased between 1992 and 1998. In 1992, Dey's *Red Book* AWP for albuterol sulfate (.083% concentration, 3 ml) was $32.30. McKesson's wholesale price for the drug was $25.45 (a spread of $ 6.85 or 27%). By 1998, Dey's *Red Book* AWP for the same concentration/dose of albuterol sulfate had barely slipped to $30.25, while McKesson's wholesale price had plummeted to $10.00 (a spread of $20.25 or 202%). See September 25, 2000 letter from U.S. Rep. Bliley to Nancy-Ann Min DeParle.

340. The federal government is not the only entity to uncover Dey's scheme to inflate AWPs. The Attorneys General of Texas and West Virginia recently discovered that due to over inflated AWPs, both state's Medicaid Programs have been defrauded by Dey for millions of dollars. Texas alleges that, between 1995 and 1999, it paid $13.7 million for Dey's albuterol sulfate and ipratropium bromide, when it should have paid only $8.7 million – an overcharge of $5 million. West Virginia alleges that Dey and others manipulated the AWP to significantly overcharge state agencies and residents for several drugs, including albuterol, from at least 1995 through 2000.

341. In its own suit against Dey and other pharmaceutical manufacturers for AWP manipulation, the Attorney General for the State of Connecticut documented significant spreads

between Dey's published AWPs and actual wholesale prices for many of its drugs. Incorporated below are examples cited by the Connecticut Attorney General:

| Drug | NDC # | Year | AWP | ACTUAL PRICE | SPREAD | % OVERCHARGE |
|---|---|---|---|---|---|---|
| ALBUTEROL | 49502-0303-17 | 1996 | $21.70 | $3.25 | $18.45 | 488% |
| IPATROPIUM BORMIDE | 49502-0685-03 | 2001 | $44.10 | $8.35 | $35.58 | 355% |
| IPATROPIUM BROMIDE | 49502-0685-03 | 2000 | $44.10 | $11.45 | $32.65 | 239% |
| IPATROPIUM BROMIDE | 49502-0685-03 | 1999 | $44.10 | $11.45 | $30.11 | 177% |

**2. Dey Controls the Published AWP for Its Products**

342. Dey has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. Dey's own documents indicate that it initially set both the AWP and WAC for its products and also regularly approved subsequent AWPs and WACs published by industry compendia. For example:

a. In a January 13, 1996 letter from Dey to First Data Bank, Day announced the availability of a new ipratropium bromide inhalation solution. The letter includes the following instructions to First Data Bank:

> "Effective immediately, please update your database to reflect the introduction of this new DEY product as follows:

| NDC/ Order Number | Description | Vial Size | Strength | Units per Ctn | Ctns per Case | AWP | WAC |
|---|---|---|---|---|---|---|---|
| 49502-685-03 | Ipatropium Bromide Inhalation Solution 2.0% | 2.5ml | 0.5mg/2.5ml | 25 | 12 | **$44.10** | **$25.50** |
| 49502-685-60 | Ipatropium Bromide Inhalation Solution 2.0% | 2.5ml | 0.5mg/2.5ml | 60 | 12 | **$105.60** | **$60.90** |

(DL-CA00120) (Confidential)

b. In a 1998 worksheet produced by *Red Book* to Dey in order to verify its listings of Dey products, an employee of Dey went through each of the Dey products listed in the *Red Book* and approved each of the AWPs and WACs for each of its products. Handwritten comments on the document include the notation "9/11/98 – checked AWP & WAC pricing (backup attached)" (DL-CA 00080) (Confidential).

**3. Dey's AWP Manipulation Benefited Providers at the Expense of the Class**

343. The purpose of Dey's AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries. This is clear from Dey's own documents. For example:

a. Dey was aware that its customers were "spread shopping" and competed by increasing the spread to its customers. In an internal worksheet filled out by Dey in preparation for a bid of potential sales to one of its customers, Dey listed the current contract price of various products as well as a recommended new contract price. In the notes next to these figures the worksheet states, "This account needs AWP-40% or better to see profit due to the employer groups they serve. Have not made the switch to our product line due to the spread . . ." (DL-TX-0014029)

b. Competition between generic products produced by Dey was fierce and the spread was a major factor in this competition. In another similar bid price worksheet for a different customer, the corresponding notes state "cromolyn pricing is at AWP-40% and 35% respectively – bear in mind that we are competing with the branded spread and the generic perception of [sic] everything should be AWP-60%" (DL-TX-0014439)

344. This competition came at the expense of Plaintiffs and the Class whose payments were based on AWP. For instance, Albuterol sulfate, a multisource drug and one of Dey's top selling products, was a focus of the federal government's investigation into AWP inflation. OIG found that "Medicare's reimbursement amount for albuterol was nearly six times higher than the

median catalog price" and that "Medicare and its beneficiaries would save between $226 million and $245 million a year if albuterol were reimbursed at prices available to suppliers." *See* "Excessive Medicare Reimbursement for Albuterol," OEI-03-01-00410, March 2002.

345. The OIG determined that the Medicare-allowed amount for albuterol sulfate in 1996 was $0.42. However the actual wholesale price was $0.15, and the highest available wholesale price was $0.21.

346. GAO also found that albuterol sulfate was one of a small number of products that accounted for a large portion of Medicare spending and volume. More specifically, albuterol sulfate ranked first in volume of units covered by Medicare, accounting for 65.8% of total units reimbursed. Furthermore, albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than 400 covered drugs. *See* GAO Report to Congressional Committees, MEDICARE: Payments for Covered Outpatient Drugs Exceed Providers' Cost, Tables 1 and 2, pp. 7-8.

**4. Specific Dey AWPs Documented by the DOJ**

347. In a report published by the DHHS, the DOJ documented at least 15 instances where the published AWPs for various dosages of 4 drugs manufactured by Dey were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each of the 4 drugs. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Dey in the 2001 *Red Book*.

| **Drug in Lowest Dosage Form** | **2001 *Red Book* AWP** | **DOJ Determined AWP** | **Difference** | **Percentage Spread** |
|---|---|---|---|---|
| Acetylcysteine | $59.88 | $25.80 | $34.08 | 132% |
| Albuterol Sulfate | $30.25 | $9.17 | $21.08 | 230% |
| Cromolyn Sodium | $42.00 | $23.01 | $18.99 | 82% |
| Metaproterenol Sulfate | $30.75 | $11.29 | $19.46 | 172% |

### 5. Inflated Dey AWPs From Dey's Price Lists

348. According to Dey's own documents, the published AWPs for many of its own products were higher than the actual prices charged wholesalers and other intermediaries. Table 1 below is excerpted from a pricing proposal by Dey to McKesson Drug Company, one of the county's largest wholesalers, dated December 20, 1995.

**Table 1**

| Generic Name | Strength | Size | AWP | WAC | Suggested Sell Price | % Discount from WAC | % Spread |
|---|---|---|---|---|---|---|---|
| Acetylcysteine Solution | 10% | 4 mL | $67.80 | $25.80 | $18.00 | -40.0% | 277% |
| Acetylcysteine Solution | 10% | 10 mL | $40.26 | $15.27 | $13.50 | -30.0% | 198% |
| Acetylcysteine Solution | 10% | 30 mL | $110.48 | $41.97 | $33.50 | -35.0% | 230% |
| Acetylcysteine Solution | 20% | 4 mL | $81.36 | $31.08 | $21.50 | -40.0% | 278% |
| Acetylcysteine Solution | 20% | 10 mL | $48.66 | $18.57 | $16.20 | -30.0% | 200% |
| Acetylcysteine Solution | 20% | 30 mL | $133.43 | $50.64 | $39.90 | -35.0% | 234% |
| Acetylcysteine Solution | 20% | 100 mL | $92.21 | $75.90 | $59.90 | -40.0% | 54% |
| Albuterol Sulfate Inhalation Soln. | 0.083% | 3 mL | $30.25 | $14.50 | $12.00 | -29.3% | 152% |
| Albuterol Sulfate Inhalation Soln. | 0.083% | 3 mL | $36.30 | $17.40 | $14.40 | -29.3% | 152% |
| Albuterol Sulfate Inhalation Soln. | 0.083% | 3 mL | $72.60 | $34.50 | $28.80 | -28.7% | 152% |
| Cromolyn Sodium Inhalation, USP | 20 mg/2ml | 2 mL | $42.00 | $34.20 | $29.00 | -25.0% | 45% |
| Cromolyn Sodium Inhalation, USP | 20 mg/2ml | 2 mL | $84.00 | $66.00 | $58.00 | -22.3% | 45% |
| Metaproterenol Sulfate Inhalation Soln. | 0.4% | 2.5 mL | $30.75 | $11.00 | $10.00 | -21.5% | 207% |
| Metaproterenol Sulfate Inhalation Soln. | 0.6% | 2.5 mL | $30.75 | $11.00 | $10.00 | -21.5% | 207% |
| Sodium Chloride Solution | 0.9% | 3 mL | $24.20 | $13.00 | $10.94 | -32.7% | 121% |
| Sodium Chloride Solution | 0.9% | 5mL | $24.20 | $13.00 | $10.94 | -32.7% | 121% |

(DL-TX 0011179)

### 6. Dey Provided Free Goods and Other Incentives

349. In addition to marketing the spread, Dey has utilized other impermissible inducements to stimulate sales of its drugs without accounting for them in its WAC or AWP. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements,

Dey provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

350. For example, in an announcement of a special incentive program to its customers to induce the purchase of its Ipratropium Bromide Inhalation solution, Dey sent its customers an offer sheet entitled "Profitability Enhancement For You" in which it stated "For every dollar of Dey Cromolyn Sodium unit-dose purchased, Dey will provide free goods of either: Coromolyn Sodium Inhalation Solution 0.02%, 2.5ml, at 1.0 times the rebate amount -OR- Ipatropium Bromide Inhalation Solution 0.02%, 2.5ml, when it launches, at a value of 1.5 times the rebate amount for Cromolyn." (DL-TX-0004775).

### 7. Dey Has Concealed Its AWP Manipulation

351. In an effort to conceal the existence of a spread from end payors, Dey concealed the true wholesale prices of its drugs. For instance, in a handwritten memorandum to Dey's pricing committee a potential pricing structure with a customer was discussed:

> "I met with IPC to discuss our contract offer (illegible). . . Tom Konnelly (IPC) said he wanted to keep net pricing hidden from 3rd parties by increasing in the purchase price on our offer by 25%. IPC then requires a 25% rebate back to IPC. . . I have remarked the pricing. If this offer is accepted, the higher price will go into McKesson as a chargeback contract. Dey will then rebate IPC 25% on contract purchases on a quarterly basis. . ."

(DL-TX-0024844)

352. As set forth above, Dey's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

## I. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)

353. Fujisawa engages in an organization-wide and deliberate scheme to inflate AWPs. Fujisawa has stated fraudulent AWPs for all or almost all of its drugs, including those set forth

below. The specific drugs of Fujisawa for which relief is sought in this case are set forth in Appendix A and are identified as follows:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| FUJISAWA GROUP (Fujisawa Healthcare, Fujisawa Pharmaceutical and Fujisawa USA) | Aristocort | triamcinolone, triamcinolone diacetate or triamcinolone acetonide | Anti-Inflammatory, Steroidal; Used in the treatment of asthma |
| | Aristospan | triamcinolone hexacetonide | Anti-Inflammatory Agent, Steroidal Used to provide relief for inflamed areas of the body |
| | Cefizox | ceftizoxime sodium or ceftizoxime in d5w | Antibiotic Agent (Anti-Infective Agent) General antibiotic |
| | Cyclocort | amcinonide | Anti-Inflammatory Agent Used to treat inflammatory symptoms of skin disorders |
| | Lyphocin | vancomycin hydrochloride | Antibacterial Agent Used to treat infections in many different parts of the body |
| | Nebupent | pentamidine isothionate | Antiprotozoal Agent Used to try to prevent Pneumocystis carinii pneumonia |
| | Pentam 300 | pentamidine isethionate | Anti-Infective Agent Used in the treatment of pneumonia |
| | Prograf | tacrolimus | Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants |
| | | acyclovir sodium | Antiviral Agent Used to treat herpes simplex infections, varicella-zoster (chickenpox) in people with weakened immune systems, and severe genital herpes infections |
| | | dexamethasone sodium phosphate | Anti-Inflammatory Agent; Antiemetic (Gastrointestinal Agent) Used in various applications to treat inflamed areas of the body |
| | | doxorubicin hydrochloride | Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma |
| | | fluorouracil | Antineoplastic Used to treat cancer, including colon, rectum, breast, stomach, and pancreas |
| | | gentamicin sulfate | Antibacterial Agent Used to treat serious bacterial infections |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | | vinblastine sulfate | Antineoplastic<br>Used in the treatment of various forms of cancer, including lymphoma and breast cancer |

**1. Fujisawa Has Been the Target of Government Investigations**

354. In connection with its scheme to inflate AWPs, Fujisawa has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

**2. Fujisawa Controls the Published AWP for Its Products**

355. Fujisawa controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, on March 10, 1997, Fujisawa provided MediSpan with an updated listing of pack prices – including AWPs – for all of its products. (FJ-MDL 015152-015159).

**3. Fujisawa's AWP Manipulation Benefited Providers at the Expense of the Class**

356. The purpose of Fujisawa's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. Fujisawa understood that providers and intermediaries sought significant AWP spreads. In a March 1995 Monthly Report, dated March 30, 1995, Fujisawa noted:

> We have lost our Vanco business at Chartwell. They have recently been handed an edict to order those products with the largest spread between acquisition cost and AWP. Abbott has unbelievably high Vanco AWP. In an effort to counter this loss I suggested we look at picking up the Cefazolin business where our AWP for one gram Cefazolin is over $8. Unfortunately our 10 gram price does not follow the same formula and is in the $45 range while Schein is approximately $58. We do however have a shot at Cefizox for Medicaid/Medicare patients which make up 50% of Chartwell's patients. Medicaid does not reimburse Chartwell for the Rocephin they currently use and while they will not reimburse for Cefizox either they could acquire Cefizox at a

> fraction of the cost. They use $400,000 in Rocephin annually, $200,000 for Medicaid/Medicare patients. That works out to better than $100K in savings for Chartwell.

(FJ-MDL 005687-88) (Confidential).

357. Fujisawa, in a conscious effort to increase the spread for providers and intermediaries, changed its AWPs and marketing practices accordingly. In a May 1995 Monthly Report, dated May 30, 1995, Fujisawa addressed its recent decision to increase its AWP for Vancomycin Hydrochloride and aggressively market the resulting spread increase:

> Many thanks to Rick and Bruce for adjusting the AWP on the five gram Vanco. This should lead to more business. As I have previously reported, some companies are still using AWP for reimbursement purposes. Chartwell has been told to search for the largest spread and order accordingly. I would have liked to see us match Abbott's AWP for our complete Vanco, and Cefazolin line. I will settle for the five gram at $1 below Abbott but that means that we still have to compete at the other end of the equation. For example, if Abbott's AWP is $163 and their contract is $30 and if our AWP is $162 we will have to be at least $29 to have the same spread. Follow?

(FY-MDL 005668-69) (Confidential).

358. In an October 5, 1993 interoffice memorandum discussing Fujisawa's communications with industry pricing compendia, Fujisawa acknowledged that the AWPs for nearly all of its products is inflated at least 33% over direct list prices:

> One of the issues regarding our companies AWP listing is that the databases only use our listing as a "Suggested Manufacturers AWP". The standard wholesaler mark-up used by those databases is currently at 25% above direct list price which is our hospital list. Almost all of our products are at 33% or higher above list price.

(FJ-MDL 008346) (Confidential).

359. Further, just as Fujisawa motivates providers to administer drugs based on the AWP, Fujisawa rewards PBMs based on the degree of influence they exert to drive utilization of Fujisawa products. (FJ-MDL 010272-78) (Confidential).

**4. Specific Fujisawa AWPs Documented by the DOJ**

360. In a report published by the DHHS (AB-00-86), the DOJ documented at least 35 instances where the published AWPs for various dosages of 6 drugs manufactured by Fujisawa were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 6 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Fujisawa in the 2001 *Red Book*.

| Drug | The Fujisawa Group's 2001 *Red Book* AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|---|---|---|---|---|
| Acyclovir Sodium | $565.10[3] | $371.50 | $193.60 | 52% |
| Dexamethasone Sodium Phosphate | $1.04[4] | $.66 | $.38 | 58% |
| Fluorouracil | $2.87 | $1.20 | $1.67 | 139% |
| Gentamacin Sulfate | $12.64[5] | $5.40 | $7.24 | 134% |
| Pentamidine Isethionate | $98.75 | $36.00 | $62.75 | 174% |
| Vancomycin Hydrochloride | $10.97[6] | $7.00 | $3.97 | 57% |

(P006299-006316).

**5. Inflated AWPs From Fujisawa Price Lists**

361. In response to government subpoenas, Fujisawa produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Fujisawa has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spreads offered to each specific customer here is not practical.

[3] Calculation based on the AWP listed in the 1998 *Red Book*.

[4] Calculation based on the AWP listed in the 1998 *Red Book*.

[5] Calculation based on the AWP listed in the 1998 *Red Book*.

[6] Calculation based on the AWP listed in the 1998 *Red Book*.

362. Set forth below in Table 1, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa customer price list dated August 24, 1995, and their associated AWP spread. (FJ-MDL 013079-81) (Confidential).

**Table 1**

| Drug | Contract Price | AWP | $ Diff AWP | % Spread |
|---|---|---|---|---|
| Triamcinolone | $14.33 | $17.95 | $3.62 | 25% |
| Calcium Gluconate | $11.50 | $34.00 | $22.50 | 196% |
| Cefazolin Sodium | $139.00 | $367.13 | $228.13 | 164% |
| Ceftizoxime Sodium | $7.50 | $11.86 | $4.36 | 58% |
| Amcinonide | $41.50 | $52.13 | $10.63 | 26% |
| Doxycycline Hyclate | $15.00 | $73.75 | $58.75 | 392% |
| Fluphenazine Hydrochloride | $24.10 | $30.25 | $6.15 | 25% |
| Folic Acid | $7.25 | $11.85 | $4.26 | 63% |
| Levothyroxine Sodium | $3.90 | $38.43 | $34.53 | 885% |
| Lidocaine Hydrochloride | $17.00 | $24.50 | $7.50 | 44% |
| Magnesium Sulfate | $22.00 | $138.25 | $116.25 | 528% |
| Mannitol | $28.00 | $56.50 | $28.50 | 101% |
| Neostigmine Methylsulfate | $8.20 | $89.30 | $81.10 | 989% |
| Oxytocin | $13.50 | $24.50 | $11.00 | 81% |
| Potassium Acetate | $92.00 | $312.40 | $220.40 | 240% |
| Potassium Chloride | $12.25 | $30.50 | $18.25 | 149% |
| Potassium Phosphate | $30.25 | $133.75 | $103.50 | 342% |
| Pyridoxine Hydrochloride | $35.00 | $47.00 | $12.00 | 34% |
| Scopolamine Hydrobromide | $22.00 | $30.00 | $8.00 | 36% |
| Selenium | $18.25 | $195.25 | $177.00 | 970% |

363. Set forth below in Table 2, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa price list dated November 5, 1996, and their associated AWP spread. (FJ-MDL 008240-53) (Confidential).

**Table 2**

| Drug | Wholesaler Price | AWP | $ Diff AWP | % Spread |
|---|---|---|---|---|
| Adenocard IV | $21.95 | $26.34 | $4.39 | 20% |

| Drug | Wholesaler Price | AWP | $ Diff AWP | % Spread |
|---|---|---|---|---|
| Adenoscan | $179.00 | $223.75 | $44.75 | 25% |
| Aristocort A | $7.05 | $8.46 | $1.41 | 20% |
| Atropine Sulfate Injection | $.64 | $1.12 | $.48 | 75% |
| Doxorubicin | $12.44 | $45.50 | $33.06 | 266% |
| Furosemide | $.74 | $.98 | $.24 | 32% |
| Hydroxyzine Hydrochloride | $.42 | $.65 | $.23 | 55% |
| Protamine Sulfate | $3.33 | $5.32 | $1.99 | 60% |
| Selepen | $18.24 | $29.93 | $11.68 | 64% |
| Sodium Acetate | $8.81 | $14.63 | $5.82 | 66% |
| Sodium Bicarbonate | $2.04 | $3.33 | $1.29 | 63% |
| Sodium Chloride | $.68 | $1.40 | $.72 | 106% |
| Sodium Phosphate | $5.81 | $9.08 | $3.27 | 56% |
| Tracelyte | $8.26 | $11.57 | $3.31 | 40% |
| Vinblastine Sulfate | $26.50 | $43.23 | $16.73 | 63% |
| Water for Injection | $1.10 | $2.34 | $1.24 | 113% |

364. As set forth above, Fujisawa's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

## J. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

365. The GSK Group has engaged in an organization-wide and deliberate scheme to inflate AWPs. The GSK Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs manufactured and/or distributed by the GSK Group for which relief is sought in this case are set forth in Appendix A and are identified below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| GSK GROUP (SmithKline | Advair Diskus | salmeterol-fluticasone | Bronchodilator (Respiratory Agent)<br>Used for treatment of asthma |
| Beecham, GlaxoSmithKline and Glaxo Wellcome) | Agenerase | amprenavir | Antiviral Agent<br>Used in treatment of HIV infection |
| | Alkeran | melphalan | Antineoplastic<br>Used to treat ovarian cancer and a certain type of cancer in the bone marrow |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | Amerge | naratriptan succinate | Antimigraine Agent<br>Used for treatment of migraine attacks |
| | Beconase AQ | beclomethasone dipropionate monohydrate | Anti-Inflammatory Agent<br>Used to treat discomfort of hay fever, other allergies, and other nasal problems |
| | Ceftin | cefuroxime axetil | Antibacterial Agent<br>Used to treat infections caused by bacteria |
| | Combivir | lamivudine-zidovudine | Antiviral Agent<br>Used in treatment of HIV infection |
| | Daraprim | pyrimethamine | Antiprotozoal<br>Used for treatment of malaria and other protazoal infections |
| | Epivir | lamivudine | Antiviral Agent<br>Used in treatment of HIV infection |
| | Flonase | fluticasone propionate (nasal) | Anti-Inflammatory Agent<br>Used for treatment of allergic and nonallergic rhinitis |
| | Flovent | fluticasone propionate (inh) | Antiasthmatic (Anti-Inflammatory Agent)<br>Used for treatment of asthma |
| | Imitrex | sumatriptan or sumatriptan succinate | Antimigraine Agent<br>Used for treatment of migraine attacks or cluster headaches |
| | Kytril | granisetron hcl | Antiemetic (Gastrointestinal Agent)<br>Used to prevent the nausea and vomiting that may occur after chemotherapy |
| | Lamictal | lamotrigine | Anticonvulsant<br>Used to help control some types of seizures in the treatment of epilepsy |
| | Lanoxin | digoxin | Antiarrhythmic Agent (Cardiovascular Agent)<br>Used to improve the strength and efficiency of the heart, or to control the rate and rhythm of the heartbeat. |
| | Leukeran | chlorambucil | Alkylating Agent (Antineoplastic)<br>Used to treat cancer of the blood and lymph system |
| | Mepron | atovaquone | Antiprotozoal<br>Used to treat and to prevent pneumonia |
| | Myleran | busulfan | Antineoplastic<br>Used to treat some kinds of cancer of the blood. |
| | Navelbine | vinorelbine tartrate | Antineoplastic<br>Used for treatment of lung cancer |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | Paxil | paroxetine hcl | Antianxiety agent; Antidepressant (Psychotherapeutic Agent)<br>Used in the treatment of various psychotherapeutic disorders |
| | Purinethol | mercaptopurine | Antimetabolite (Antineoplastic)<br>Used to treat some kinds of cancer. |
| | Relenza | zanamivir | Antiviral Agent<br>Used in the treatment of the infection caused by the flu virus (influenza A and influenza B). |
| | Retrovir | zidovudine | Antiviral Agent<br>Used for treatment of HIV infection |
| | Serevent | salmeterol xinofoate | Bronchodilator (Respiratory Agent)<br>Used to treat or prevent symptoms of asthma, chronic bronchitis, emphysema, and other lung diseases |
| | Trizivir | abacavir sulfate-lamivudine-zidovudine | Antiviral Agent<br>Used for treatment of HIV-1 infection |
| | Valtrex | valacyclovir hcl | Antiviral Agent<br>Used for treatment of shingles and genital herpes |
| | Ventolin HFA | albuterol sulfate | Bronchodilator (Respiratory Agent)<br>Used for treatment or prevention of bronchospasm |
| | Wellbutrin | bupropion hcl | Antidepressant (Psychotherapeutic Agent)<br>Used for treatment of depression |
| | Zantac | rantidine hydrochloride | Gastrointestinal Agent<br>Used in the treatment of active duodenal ulcer |
| | Ziagen | abacavir sulfate | Anti Infective Agent<br>Used in the treatment of HIV infection |
| | Zofran | ondansetron hcl | Antiemetic (Gastrointestinal Agent)<br>Used to treat or prevent the nausea and vomiting that may occur after chemotherapy |
| | Zofran ODT | ondansetron | Antiemetic (Gastrointestinal Agent)<br>Used to treat or prevent the nausea and vomiting that may occur after chemotherapy |
| | Zovirax | acyclovir | Antiviral Agent<br>Used for treatment of shingles, genital herpes and herpes simplex |
| | Zyban | buproprion hcl | Antidepressant (Psychotherapeutic Agent)<br>Used to relieve mental depression. Also used to aid in cessation of smoking |
| | | thioguanine | Antineoplastic<br>Used to treat some kinds of cancer |

**1. The GSK Group Has Been the Target of Government Investigations**

366. In connection with its scheme to inflate AWPs, the GSK Group has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the Attorney General for the State of Nevada, Medicaid Fraud Control Unit.

367. These investigations confirm that the GSK Group has engaged in a deliberate scheme to inflate the published AWPs for its drugs.

**2. The GSK Group's Definition and Understanding of AWP**

368. In a GSK document entitled "Zofran Tablets & Zofran Injection: Sales Training Guide Reimbursement Module" (GSK-MDL-ZN02-035925) (Highly Confidential), GSK defines AWP as follows:

> Average Wholesale Price (AWP): The composite wholesale prices charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book and used by third-party payers as a basis for reimbursement.

(GSK-MDL-ZN02-035985) (Highly Confidential). Thus, by its own definition, GSK recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWPs directly affect the payments made by the Class.

**3. The GSK Group Controls the Published AWP for Its Products**

369. The GSK Group has controlled and set the AWPs for its pharmaceutical products during the Class Period. As set forth below, any claim that The GSK Group only reports a WAC to industry compendia and therefore is not responsible for the published AWPs is belied by its own documents. For example:

a. In 1991 a Glaxo document entitled "Zofran Third Party Payment Plan," among the many recommendations concerning the pricing of its then new drug Zofran was the

recommendation that "In establishing direct-to-wholesaler and *Red Book* wholesale prices for Zofran, Glaxo should take into consideration physicians' expected profit margins." (GSK-MDL-ZN02-03428) (Highly Confidential).

b. Expanding further on the recommendation above, elsewhere in the same document it is stated: "Because insurers often reimburse physician-infused drugs up to the average wholesale price (AWP), the doctor's profits are determined by the differential between the AWP and the price they pay to the wholesaler or pharmacy supplier. The company should ensure that doctors will make acceptable return on Zofran® by managing markups through the distribution chain." (GSK-MDL-ZN02-034366) (Highly Confidential).

370. As do all of the Defendants, GSK has direct control over the "markups" in the distribution chain for its products. That control results from an ability to set the published AWP.

**4. The GSK Group's AWP Manipulation Benefited Providers at the Expense of Plaintiffs and the Class**

371. GSK acknowledged that the AWP, as published in industry compendia, was used as the basis for most payments by third party payors. GSK's own documents state, "Most, but not all, plans determine a payment for new drugs, based on the drug's cost as listed in the *Red Book* and pay all providers that amount less any patient co-payments." (GSK-MDL-ZN02-035965) (Highly Confidential). Elsewhere in the same document GSK acknowledges: "Payment amounts for most payers is usually based on the AWP as listed in *Red Book*, however, co-payments, especially for Zofran Tablets will be required." (GSK-MDL-ZN02-035973) (Highly Confidential).

372. The purpose of The GSK Group's AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. That scheme has resulted in a system where drugs are administered based upon a profit incentive to physicians and other intermediaries and which results in an incentive to prescribe more expensive, rather than cheaper drugs. In talking points prepared in advance of

negotiations with clinics, Glaxo instructed its sales people to remind customers that "Cheaper is not necessarily a prudent medical or business decision" and that "Cheaper ≠ Good medicine or Good Business!" (GSK-MDL-ZN02-077818-19) (Highly Confidential).

373. The GSK Group tried to maximize spread because it understood that its customers routinely engaged in "spread shopping" – comparing its AWPs with those of its competitors in order to determine the greatest spread (and therefore sell or administer the drug with the greatest spread).

374. Perhaps the most flagrant example of the GSK Group's fraudulent manipulation of AWPs is found in the documents relating to Glaxo's Zofran® and SKB's Kytril®. These two drugs both minimize the nausea associated with chemotherapy, and, prior to the merger of Glaxo and SKB, competed head-to-head in the same market. As detailed below, much of that competition concerned which product could generate ***the greater spread***, or profit, for physicians; not over which product was better for patients.

**5. Glaxo's Zofran®**

375. A Glaxo marketing document, sent to its sales and marketing personnel via U.S. Mail and interstate wire facilities, advises that they should emphasize to medical providers both the benefits of Zofran® and the financial benefits of the spread. Specifically:

> By using a 32 mg bag, the physician provides the most effective dose to the patient and increases his or her profit by $_____ in reimbursement as well as paying no upcharges for the bag or admixing

376. A follow-up internal Glaxo memo, dated October 27, 1994, entitled "Zofran Pricing Recommendation," states: "Physician reimbursement for the administration of intravenous oncology drugs is based on the spread between acquisition cost and the AWP." The memo later notes that "Kytril carries a 20% spread between List Price and AWP compared to Zofran which carries a 16 2/3% spread providing SKB with a significant advantage in the clinic setting with respect to reimbursement." (P007015-P007490, at P007487-P007490).

377. In response to the larger spread being offered on Kytril, this same internal document discusses several options to increase Zofran's spread "to balance the reimbursement spread which currently exists between Zofran and the market in which it competes. . . ." The pricing options considered for increasing the "spread" for Zofran® included:

Recommendation #1

| | |
|---|---|
| . 4.5% price increase | $178.97 to $187.02 |
| . Increase AWP | 16 2/3% to 20%<br>$214.76 to $233.78 (8.5%) |
| . 3%Wholesaler Rebate (11/14/94 - 1/31/95) | $187.02 to $172.92 (chargeback)<br>$179.92 to $167.31 (rebate) |

378. In an effort to hide the fact that Glaxo was increasing the spread for Zofran®, Glaxo elected to not only increase its AWP and provide rebates, but to also include a small actual price increase. In describing the reason for an increase in the actual selling price, an internal Glaxo document states:

> The recommended multi-tiered modification to current promotion, should also provide an immediate resultant impact to weekly unit sales without being easily intelligible by SKB as to the means by which this was achieved. Thus, providing additional time before a competitive response would be delivered.

379. Glaxo internal documents, however, recognized that as a result of its increasing the spread for Zofran®, SKB would have two options:

| | |
|---|---|
| Option 1: | Decrease the purchase price of Kytril. |
| Option 2: | Take a price increase to raise the AWP while maintaining purchase price to generate a higher spread than $52.00. |

(P007015-P007490, at P007489-P007490).

380. In order to increase the spread for Zofran®, Glaxo increased the AWP for a 20 ml injection of Zofran® to $233.02 in January of 1995. This was discussed in an October 27, 1994

memo entitled "Zofran Pricing Recommendation" and further discussed at a Glaxo pricing committee meeting on November 4, 1994. (P007015-P007490, at P007487-P007490).

381. In February 1995, the *Florida Infusion Chemo Net* reported that Glaxo was increasing the published AWP for Zofran®, but was specifically offering incentives to lower the actual price offered to medical providers, thereby allowing medical providers to seek reimbursement at inflated prices. Specifically:

> Effective January 3, 1995. Glaxo has increased the acquisition costs of Zofran injection. The new AWP is set at $233.02. However, the company has provided incentives to the market place which will ensure that Zofran price to physicians and clinics will be lower than the contractual price available prior to the increase.

Letter from Bliley, Chairman Commerce Committee to Nancy Min DeParle, Sept. 25, 2000 (P007015-P007490, at P007046).

382. Glaxo was fully aware that the larger spread for its product would be a big selling point. A flier in GSK's possession but produced by wholesaler NSS advertises to physicians that:

> Your Zofran™ Deal Just Got Better!!!
>
> (Effective 4:00pm January 9, 1995)
>
> *New AWP $233.02
>
> New Price from NSS
>
> ** $161.00 * *

(GSK-MDL-ZN02-034942) (Highly Confidential).

383. In March 1996, Glaxo again increased the AWP for Zofran® by 4.8%. In response, SKB immediately increased the AWP for Kytril by 4.8%. An internal SKB memo, dated March 21, 1996, entitled "Kytril Price Increase," states:

> I recommend a 4.8% price increase effective March 25, 1996 for all Kytril presentations. This is in response to a Glaxo Wellcome price increase of 4.8% for Zofran effective March 8, 1996.

(P007015-P007490, at P007078).

384. In a Glaxo internal memo dated October 25, 1994, entitled "Issue considerations on Zofran pricing strategies," Nancy Pekarek (a communications manager for Glaxo who later became Vice-President of U.S. Corporate Media Relations) recognized the implications of increasing the AWP to create a better spread:

> If Glaxo chooses to increase the NWP and AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices, we must prepare for the potential of a negative reaction from a number of quarters. Some likely responses:
>
> (1) Press: Glaxo's health care reform messages stressed the importance of allowing the marketplace to moderate prices. On the surface, it seems that in response to the entrance of a competitor in the market, Glaxo has actually raised its price on Zofran-perhaps twice in one year. How do we explain that price increase on a drug that is already been cited in the press as one of, if not the most expensive drug on the hospital formulary?
>
> ***If we choose to explain the price increase by explaining the pricing strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share.***
>
> (2) Congress: Congress has paid a good deal of attention to pharmaceutical industry pricing practices and is likely to continue doing so in the next session. How do we explain to Congress an 8% increase in the NWP between January and November of 1994, if this policy is implemented this year? How do we explain a single 9% increase in the AWP? ***What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of the government?*** How will this new pricing structure compare with costs in other countries?
>
> (3) ***Private insurers, out-of-pocket payers: These groups, and perhaps others, are likely to incur greater costs as a result of this pricing strategy. How will they be affected? What response do we have for them?***

(GSK-MDL-Z01-05675) (Highly Confidential) (emphasis added).

385. Glaxo also knew that Zofran® products were being marketed based on the spread between the actual cost and the published AWP. For example, when Glaxo introduced the Zofran® premixed IV bag, it used marketing materials which stated:

Convenient
Costs Less Than Vial
Higher AWP
Better Reimbursement

(P007015-007490, at P007243).

386. Other internal Glaxo documents directly compared the "Profit Per Dose" and "Profit as %" and "Profit Per Vial" of Zofran® to Kytril®. These comparisons also identified that in order to increase the spread for Zofran®, Glaxo included "early pay disc" and "rebates" and "incentive."

387. In marketing the new Zofran® premixed IV bag, Glaxo produced and used a document entitled "Profit Maximization – It's In the Bag." This document compared Kytril® to Zofran® based upon its total return of investment (ROI). Specifically, Glaxo's marketing materials including the following chart:

| | Cost | AWP | Potential Reimbursement/ Patient | Reimbursement/ Year | ROI |
|---|---|---|---|---|---|
| Zofran 32mg bag | $110.41 | $195.00 | 84.59 | $13,957,350 | 76.6% |
| Kytril 1 mg vial | $102.73 | $175.00 | 72.27 | $11,924,000 | 70.3% |

(P007114) (Highly Confidential).

388. Another Glaxo document entitled "Profit Maximization – Continued" reflects how much "Total Revenue Potential" there was for using Zofran® because of the large spread between the cost and reimbursement for various Zofran® products. (P007115) (Highly Confidential).

389. An internal SKB document further acknowledges Glaxo's attempts to use and market the spread and its effects on the Class:

> As of late, Glaxo promotional efforts have focused almost entirely on the financial benefits of "up-dosing" rather than efficacy of Zofran. ***Though physicians have certainly benefited financially from such tactics, it is costing 3rd party payers and patients more for medication***.

(P007115-P007490, at P007138-P007139) (Highly Confidential) (emphasis added).

390. In a September 27, 2000 article in *USA Today*, Glaxo spokesman Rick Sluder (who received a copy of the October 24, 1994 memo described herein) discussed the issue of the spread and blamed a system that set up a reimbursement method that relies on average wholesale prices which are not actually "representative of actual prices." Mr. Sluder, admitting that Glaxo changed its wholesale prices to keep up with competitors who changed wholesale prices, stated "We didn't want to put ourselves at a price disadvantage." Mr. Sluder also admitted that the marketing of Glaxo drugs is based, in part, on the spread. In fact, he noted that Glaxo's sales staff is briefed on the price advantages to doctors who bill and get reimbursed based upon the AWP. (E-mail from Clapton to Vaughan dated Sept. 27, 2000 citing "How Drug Makers Influence Medicare Reimbursements to Doctors; WALL STREET JOURNAL (P007501-P007506).

**6. SKB's Kytril**

391. According to its internal documents (and prior to selling Kytril®'s global rights to the Roche Group in December 2000), SKB also knew that by creating the spread for Kytril®, it could directly affect the amount of revenue medical providers receive and thereby affect overall demand for Kytril®. Specifically, an August 6, 1996 internal SKB memo stated:

> In the clinic setting however, since Medicare reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP.
>
> * * *
>
> From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regimens.

(P007015-P007490, at P007249-P007250).

392. Internal SKB documents reveal how it marketed the spread. One internal document entitled "Price Comparison of Kytril and Zofran for Reimbursement" discussed how much additional revenue and "spread per patient" a medical provider would make by using Kytril® due to its larger spread. It stated:

> Kytril reimbursement for 5 patients treated $540.00 - Kytril 6 treated patients $423.12
>
> Difference = $117.00 every 6 patients.
>
> Use 5ht3 5 times a day = $2,340.00 month. $28,080.00 year more!

(P007015-P007490, at P007117).

393. Other internal SKB documents entitled "Cost v. Profit" and "Kytril Profit Model" compare Kytril® and Zofran® to demonstrate how much additional profit/revenue the medical provider will receive by using Kytril®.

**7. General Counsel Correspondence Between Glaxo and SKB**

394. Most revealing is an exchange of correspondence between counsel for Glaxo and SKB over Zofran® and Kytril® in which each accuse the other of fraud.

395. On February 6, 1995, Timothy D. Proctor, Senior Vice President, General Counsel and Secretary for Glaxo, sent a letter to J. Charles Wakerly, Senior Vice President, Director and General Counsel of SKB informing him of "several issues pertaining to the advertising and marketing of Kytril":

> Glaxo's sales representatives have encountered a substantial amount of what appear to be "homemade" Kytril vs. Zofran cost comparisons. It is our understanding that many of these pieces have been generated through a company-provided lap top computer program.
>
> . . . .
>
> In addition, a significant number of these pieces (see Exhibits F-J) contain direct statements or make references as to how institutions can increase their "profits" from Medicare through the use of Kytril. Some even go so far as to recommend that the medical professional use one vial of Kytril for two patients (see Exhibit F)

> but charge Medicaid for three vials. This raises significant fraud and abuse issues which I am sure you will want to investigate."

(P007015-P007490, at P007123-P007126).

396. On February 22, 1995, Ursualy B. Bartels, Vice President and Associate General Counsel for SKB, wrote in response that SKB was investigating Glaxo's claims and asked whether Glaxo had specific information regarding the improper marketing of Kytril. Mr. Bartels also accused Glaxo of using false and misleading marketing materials regarding Zofran that rely on the medical providers' ability to garner more profit. Specifically, he stated:

> Regarding similar concerns, we would like to draw your attention to reports we are receiving from our field force regarding reimbursement issues. In an apparent effort to increase reimbursement to physicians and clinics, effective 1/10/95, Glaxo increased AWP for Zofran by 8.5%, while simultaneously fully discounting this increase to physicians. The latter was accomplished by a 14% rebate available to wholesalers on all non-hospital Zofran sales on the multi-dose vial. ***The net effect of these adjustments is to increase the amount of reimbursement available to physicians from Medicare and other third party payors whose reimbursement is based on AWP.*** Since the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in AWP was designed to increase revenue per unit to Glaxo. ***Absent any other tenable explanation, this adjustment appears to reflect an intent to induce physicians to purchase Zofran based on the opportunity to receive increased reimbursement from Medicare and other third party payors. In fact, we have had numerous verbal reports from the field concerning Glaxo representatives who are now selling Zofran based on the opportunity for physicians to receive a higher reimbursement from Medicare and other third-party payors while the cost to the physician of Zofran has not changed.***

(P007015-007490, at P007478-P007481) (emphasis added).

397. On April 25, 1995, Adrianna L. Carter, Glaxo Assistant General Counsel, responded to SKB's February 22, 1995 letter. Ms. Carter provided, pursuant to SKB's request, numerous additional examples of false and misleading marketing materials concerning "cost comparisons distributed to health care professionals by SmithKline representatives." Ms. Carter also denied SKB's allegations regarding "fraud and abuse" over the price increase of Zofran.

However, Ms. Carter did admit that the AWP price increase for Zofran® does not affect the actual cost to medical providers and that Glaxo's sales representatives were using the "spread" to gain market share. Specifically, Ms. Carter stated:

> It is true that, despite a price increase, some physicians and other healthcare professionals will not see the higher price as the result of rebates or other incentives.
>
> * * *
>
> It is also true that our sales representatives have been explaining the relationship between the price and Medicare reimbursement for Zofran to physicians.
>
> * * *
>
> Finally, Ms. Carter stated that despite SKB's assertions that any alleged improper marketing of Kytril would end, "Unfortunately, despite your efforts, these activities are still ongoing."

(P007015-007490, at P007127-P007131).

398. The fact that Glaxo and SKB each accused the other of similar conduct, but neither took any action to bring it to the attention of the public or the appropriate authorities, is evidence that each of them were engaged in an ongoing scheme to defraud the Plaintiffs and Class.

**8. Other Improper Incentives**

399. In addition to marketing the spread on its products, the GSK Group has also used other methods to induce physicians and other intermediaries to use its drugs such as rebates and free samples in order to increase the spread between acquisition costs and reimbursement.

400. In an e-mail by GSK account representative Paul J. Ostruszka explaining how he was able to increase the market share of Zofran over Anzimet, among the suggested techniques he recommends to his fellow GSK account reps is "Ask your customers how much JUST 1 FREE Zofran Tablet Sample is WORTH" (emphasis in original). This e-mail was later forwarded to the entire Zofran team. (GSK-MDL-ZN02-077634).

401. An advertisement in the *Florida Infusion Chemo net* reveals that SKB created the spread not only by artificially inflating the AWP for Kytril®, but also by providing discounts and rebates. Specifically, the advertisement states:

> We have been notified that, effective April 1, 1995, SmithKline's long running promotional rebate for Kytril purchases will come to a very successful conclusion.

(P007015-007490, at P007187).

402. SKB also knew that medical providers were billing Plaintiffs and the Class for a 1 mg single dose vial per patient, but actually were using less than the full single dose per patient. Depending on the weight of a patient, medical providers were able to use less of the drug, *i.e.*, the lighter the patient, the less Kytril® was needed. SKB subsequently introduced a Kytril® 4 mg Multi-Dose vial that allowed medical providers to bill 6 treatments for the cost of 4. For example, an SKB marketing document entitled "Kytril Vial Usage" states, "You can use only three vials of Kytril for four patients." (P007015-007490, at P007068 and P007455).

403. SKB also used other financial incentives to decrease medical providers' costs and thereby increase profits. For example, SKB promised to contribute to research and education programs through the OnCare Foundation if OnCare agreed to use Kytril instead of a competing drug. (P007015-007490, at P007061).

**9. Specific GSK Group AWPs Documented by the DOJ**

404. In a report published by the DHHS (the "DHHS Report"), the DOJ documented that the published AWPs for various dosages of Zofran and Kytril manufactured by The GSK Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the AWPs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The GSK Group in the 2001 *Red Book*.

| Drug | GSK 2001 *Red Book* AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|---|---|---|---|---|
| Ondanestron (Zofran) | $128.24 | $22.61 | $101.63 | 450% |
| Granisetron (Kytril) | $195.20 | $139.04 | 56.16 | 40% |

(P006299-P006316).

405. As set forth above, the GSK Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

## K. Immunex

406. Immunex engages in an organization-wide and deliberate scheme to inflate AWPs. Immunex has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Immunex for which relief is sought in this case are set forth in Appendix A and are identified below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| IMMUNEX | Leukine | sagramostin | Antineutropenic Agent<br>Used to help produce bone marrow and white blood cells |
| | Novantrone | mitoxane hydrochloride | Antineoplastic<br>Used in the treatment of multiple sclerosis and various forms of cancer |
| | Thioplex | lyophilized thiotepa | Antineoplastic<br>Used in the treatment of ovarian and breast cancer, lymphoma and bladder tumors |
| | | leucovorin calcium | Antianemic Agent (Blood Modifier)<br>Used in the treatment of anemia |
| | | methotrexate sodium | Antineoplastic<br>Used in the treatment of various forms of cancer |

### 1. Immunex Has Been the Target of Government Investigations

407. In connection with its scheme to inflate AWPs, Immunex has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of

Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

**2. Immunex Definition and Understanding of AWP**

408. Immunex's internal documents reveal that it understood how industry compendia defined and utilized AWPs:

> Red Book Definition of AWP
>
> The average wholesale price as we consider it here at Red Book is the price a retail hospital or pharmacy pays if purchases product from wholesaler before the discount if any.
>
> Blue Book Definition of AWP
>
> AWP represents an average price which a wholesaler would charge a pharmacy for a particular product.

(IAWP002238) (Highly Confidential).

**3. Immunex Controls the Published AWP for its Products**

409. Immunex controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In 2000, in the midst of numerous government investigations concerning AWP manipulation, Immunex denied responsibility for controlling the published AWP for its products. For example, in an October 26, 2000 letter to *Red Book*, Immunex states in pertinent part:

> As requested, enclosed please find an updated summary of list pricing and package information for Immunex products. Please note that Immunex Corporation is not responsible for setting the Average Wholesale Price (AWP). Therefore, we do not set or approve AWP information for any Immunex products.

(IAWP023473) (Highly Confidential). Previously, in a 1996 interview, an Immunex spokesperson had informed Barron's that "drug manufacturers have no control over the AWPs published." (IAWP003071) (Hooked on Drugs," Barron's, Jun. 10, 1996).

410. Immunex's internal documents, however, establish that it controlled the AWP for all of its products throughout the Class Period. For example:

a. A January 12, 1996 letter from *Red Book* to Immunex, in pertinent part, states:

> This letter is a confirmation letter that we have received and entered your latest AWP price changes in our system.

(IAWP008102) (Highly Confidential).

b. A January 12, 1995 letter from Immunex to *Red Book* states:

> Below you will find a list of new suggested Average Wholesale Prices (AWPs) for selected Immunex products, along with a new NDC … all effective January 10, 1995 … Please update your databases accordingly. A new copy of Immunex's Average Wholesale Price Product Pricing Guide will be sent to you next week.

(IAWP016500) (Highly Confidential).

**4. Immunex's AWP Manipulation Benefited Providers at the Expense of the Class**

411. The purpose of Immunex's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. Immunex understood that providers and intermediaries were reimbursed at AWP – and benefited from a larger spread.

a. In an internal document entitled "Health Care Policy Fast Facts," created in 1995, Immunex urged its sales personnel to remember "[p]hysician's offices use their own charge schedule for billing purposes, and get reimbursed at AWP, based on the published prices in the pricing databases." (IAWP012961) (Highly Confidential).

b. Recently, in a January 3, 2000 interoffice memo, Immunex discussed the significant revenues to be made by providers which used its Leucovorin and Methotrexate products. Specifically, Immunex stated that, "Leucovorin and Methotrexate represent significant revenue sources for the physician office or clinic. Due to the 'spread' (difference between

acquisition cost and AWP), physicians have reaped substantial profits." (IAWP051149-52) (Highly Confidential).

412. Immunex, in a conscious effort to increase the spread for providers and intermediaries, changed its AWPs and marketing practices accordingly. In a February 21, 1997 internal memo discussing reimbursement on its products, in pertinent part, Immunex stated:

> The following are the reimbursement schema for Leukine, Novantrone, Thioplex and Leucovorin:
>
> Here's the way it works [for Leukine] – the Red Book Price (AWP) for our 250 mcg is $117.79 and $221.71. **However**, payors take the $117.79 and divide it by 5, now that we bill per 50 mcg increments. This is equal to $23.56 per 50 mcg, hence reimbursement on a 500 mcg vial is $235.60. We need to take into account that in some AOR markets they get AWP or AWP plus a percentage, in others, depending on the makeup of the patient population, they may only get the 80% Medicare allowable ($188.48). So here's what the spread looks like:

| | |
|---|---|
| $235.60 (AWP) | $188.48 (80% Medicare allowable) |
| -$112.06 (AOR contract price) | -$112.06 |
| +$123.54 per 500 mcg vial (110% spread) | $76.42 (68% spread) |

(IAWP008528) (Highly Confidential) (emphasis in original).

413. Immunex performed an analysis of competitive AWP pricing (IAWP003407-13) (Highly Confidential) and established a "Reimbursement Hotline" for a number of its products (IAWP016686-88) (Highly Confidential).

414. Immunex, through its employees and agents, also provided free samples of its drugs to customers. (IAWP005418) (Highly Confidential) The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class.

**5. Specific Immunex AWPs Documented by the DOJ**

415. In a report published by the DHHS (the "DHHS Report"), the DOJ documented at least 7 instances where the published AWPs for various dosages of 2 drugs manufactured by

Immunex were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 2 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Immunex in the 2001 *Red Book*.

| Drug | 2001 *Red Book* AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|---|---|---|---|---|
| Leucovorin Calcium | $137.94 | $14.58 | $123.36 | 846% |
| Methotrexate Sodium | $20.48 | $7.10 | $13.38 | 188% |

(P006299-P006316).

416. In a report published by DHHS in 1997, the Department undertook an analysis of the twenty drug codes that represented the largest dollar outlays to the Medicare Program and compared Medicare's payments with the prices available to the physician and supplier communities. For mitoxantrone hydrochloride, sold by Immunex under the brand name Novantrone, the DHHS found that Medicare paid $172.81, while the actual average wholesale price was $142.40, resulting in a spread of 21.36%. "Excessive Medicare Payments for Prescription Drugs" (Dec. 1997).

**6. Inflated AWPs From Immunex Price Lists**

417. In response to government subpoenas, Immunex produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Immunex has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

418. As set forth above, Immunex's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

### 7. Immunex Concealed Its AWP Manipulation

419. Immunex deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, under the guise of "simplifying" its product listings, on June 3, 1994, Immunex instructed the *Red Book* to "delete all references to Direct Price for all Immunex products, effective immediately" and confirmed that "only AWP (Average Wholesale Price) w[ould] be listed for [its] products[.]" (IAWP016524) (Highly Confidential). Immunex effectively hid the AWP spread from Plaintiffs and the Class.

## L. The Johnson & Johnson Group (J&J, Centocor and Ortho)

420. The Johnson & Johnson Group engages in an organization-wide and deliberate scheme to inflate AWPs. The Johnson & Johnson Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of the Johnson & Johnson Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| JOHNSON & JOHNSON GROUP (J&J, Janssen, McNeil, Ortho and | Aciphex | rabeprazole sodium | Gastric Acid Pump Inhibitor (Gastrointestinal Agent)<br>Used in the treatment of gastroesophageal reflux disease and duodenal ulcers |
| Centocor) | Bicitra | sodium citrate & citric acid | Alkalizer<br>Used in the prevention of kidney stones |
| | Duragesic | fentanyl | Analgesic<br>Used in the treatment of chronic pain |
| | Elmiron | pentosan polysulfate sodium | Anti-Inflammatory Agent<br>Used for relief of pain associated with interstitial cystitis |
| | Erycette | erythromycin | Antiacne Agent; Antibacterial Agent<br>Used to help control acne |
| | Flexeril | cyclobenzaprine | Skeletal Muscle Relaxant (Analgesic)<br>Used in the treatment of muscle spasm associated with musculoskeletal conditions |
| | Floxin | ofloxacin | Antibacterial Agent<br>Used in the treatment of pneumonia, bronchitis, gonorrhea and certain other infections |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | Grifulvin | griseofulvin microsize | Antifungal Agent<br>Used to treat fungus infections of the skin, hair, fingernails, and toenails |
| | Haldol | haloperidol lactate | Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent)<br>Used to treat nervous, mental, and emotional conditions |
| | Haldol Decanoate | haloperidol decanoate | Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent)<br>Used to treat nervous, mental, and emotional conditions |
| | Levaquin | levofloxacin | Antibacterial Agent<br>Used to treat bacterial infections in many different parts of the body |
| | Monistat | miconazole nitrate | Antifungal Agent<br>Used in the treatment of yeast infections |
| | Mycelex | clotrimazole | Antifungal Agent<br>Used in the treatment of candidiasis and tinea versicolor |
| | Pancrease | amylase-lipase-protease | Digestant; Enzyme, Pancreatic (Gastrointestinal Agent)<br>Used in the treatment of gastrointestinal orders |
| | Parafon Fort | chlorzoxazone | Skeletal Muscle Relaxant (Analgesic)<br>Used to relax certain muscles and relieve the pain and discomfort caused by strains, sprains, or other injuries to muscles |
| | Polycitra | potassium & sodium citrates w/ citric acid | Alkalizer<br>Used in the prevention of kidney stones |
| | Procrit | epoetin alfa | Antianemic<br>Used in the treatment of anemia in HIV-infected, cancer or chronic renal failure patients |
| | Regranex | becaplermin | Biological Response Modifier<br>Used in the treatment of diabetic neuropathic ulcers |
| | Remicade | infliximab | Anti-Inflammatory Agent; Antirheumatic Agent<br>Used to treat Crohn's disease and rheumatoid arthritis |
| | Reminyl | galantamine hydrobromide | Cholinesterase Inhibitor (Central Nervous System Agent)<br>Used in the treatment of dementia of the Alzheimer’s type |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | Renova | tretinoin | Antiacne Agent<br>Used for mitigation of fine wrinkles and other attributes of facial skin |
| | Retin-A | tretinoin | Antiacne Agent<br>Used to treat acne |
| | Retin-A Micro | tretinoin microsphere | Antiacne Agent<br>Used to treat acne |
| | Risperdal | risperidone | Antipsychotic Agent (Psychotherapeutic Agent)<br>Used to treat the symptoms of psychotic disorders |
| | Spectazole | econazole nitrate | Antifungal Agent<br>Used to treat infections caused by a fungus |
| | Sporanox | itraconazole | Antifungal Agent<br>Used in the treatment of various fungal infections |
| | Terazol | terconazole vaginal | Antifungal Agent<br>Used to treat yeast (fungus) infections of the vagina |
| | Testoderm | testosterone | Androgen; Antianemic Agent; Antineoplastic<br>Used for replacement therapy in males with a deficiency or absence of testosterone |
| | Tolectin | tolmetin sodium | Antirheumatic Agent<br>Used to relieve some symptoms caused by arthritis |
| | Topamax | topiramate | Anticonvulsant<br>Used to help control some types of seizures in the treatment of epilepsy |
| | Tylox | acetaminophen w/ codeine | Analgesic<br>Used to relieve pain. |
| | Tylenol with codeine | | |
| | Ultracet | tramadol-acetaminophen | Analgesic<br>Used to relieve pain |
| | Ultram | tramadol hcl | Analgesic<br>Used for management of pain |
| | Urispas | flavoxate hydrochloride | Autonomic Nervous System Agent<br>Used in the treatment of symptoms of various urologic disorders. |
| | Vascor | bepridil hcl | Antianginal Agent<br>Used to relieve and control angina pectoris and hypertension |

### 1. The Johnson & Johnson Group Has Been the Target of Government Investigations

421. In connection with its scheme to inflate AWPs, the Johnson & Johnson Group has been investigated by the General Accounting Office and the Office of the Attorney general for the Commonwealth of Massachusetts.

422. J&J's internal documents reveal that it was familiar with and understood how industry compendia defined and utilized AWPs. For example, in a rebate agreement between J&J and Merck-Medco Managed Care, Inc. dated December 19, 1996, the parties defined AWP as meaning "the average wholesale price as published in the most current version of either First Data Bank or the Red Book." (J&J000599) (Highly Confidential).

423. The Johnson & Johnson Group has engaged in an ongoing deliberate scheme to inflate AWPs and to market the spread to increase the sales of its products. In a report published by the GAO, federal investigations have documented fraudulently inflated AWPs reported for epotein alpha (sold by J&J as Procrit). J&J is identified in various annual *Red Book* publications as one of two sources for epoetin alfa. The other source for epoetin alfa is Defendant Amgen.[7]

424. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services. These massive federal expenditures for epoetin alfa, caused by the J&J Group and Amgen's AWP scheme as well as the inflated cost to Plaintiffs and members of the Class, are even more outrageous given the fact that the research and development of epoetin alpha was originally underwritten by grants from the federal government.[8]

[7] Amgen markets epoetin alfa for use in the treatment of dialysis patients while the right to market epoetin alfa for all other uses is licensed to Defendant J&J.

[8] Epogen® and Procrit® are based on different uses of a patented process technology developed at Columbia University with support from grants from the NIH. Columbia licensed their technology to Amgen for Epogen® and to Johnson & Johnson for Procrit®. *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected,* Department Of Health And Human Services National Institutes Of Health, July 2001.

425. By way of further example, the J&J Group has deliberately overstated and continues to overstate the AWP for Remicade®. The published AWP for Remicade® continued to increase each year during the class period. For example, the AWP was listed as $611.33 for a 100 mg vial of Remicade® as of November 1999, and rose to $665.65 when listed in the 2001 edition of the *Red Book*. At the same time, J&J deliberately marketed and promoted the sale of Remicade® to physicians based on the availability of inflated payments made by Medicare, assuring them that they would make a significant profit from the purchase of Remicade® as a result of the spread between the actual price to physicians and reimbursement based on the published AWP.

426. The J&J Group created promotional materials and worksheets to allow them to market the spread between the published AWP and the actual selling price to doctors. For example, a publication accessible through Defendants' web sites entitled "Office-Based Infusion Guide" demonstrates Defendants' aggressive marketing of this spread, specifically noting that, "[d]epending on reimbursement, office-based infusion may provide a financial impact to a physician's practice." Moreover, the "Financial Analysis" section of the guide includes a "REMICADE® (infliximab) Financial Impact Worksheet," which enables doctors see in actual dollars how much additional revenue the use of Remicade® would bring to their practice.

427. As set forth above, the J&J Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

428. Set forth below in Table 1 are the contract prices (not already referenced above) included in a J&J contract price list (effective from April 1, 1997 through March 31, 1998) contained in a supply agreement with Managed Healthcare Associates, Inc. dated March 17, 1997 and the AWP published in the 1997 *Red Book*, and their associated AWP spread. (J&J000121-23) (Highly Confidential).

**Table 1**

| Drug | Contract Price | AWP | $ Diff AWP | % Spread |
|---|---|---|---|---|
| Procrit (epoetin alfa) | $950.00 (4000 u/ml 25x1 ml vials) | $1200 | $250 | 20.8% |
| Ultram (tramadol hcl | $53.97 (1x100 50 mg) | $62.34 | $8.37 | 13.4% |
| Duragesic fentanyl transdermal) | $44.94 (25M 25mcg/hr 1x5) | $53.94 | $9 | 16.7% |
| Floxin (ofloxacin) | $276.89 (1x100 btls 200 mg/case) | $332.28 | $55.39 | 16.7% |
| Propulsid (cisapride) | $56.62 (10mgx100) | $67.96 | $11.34 | 16.7% |
| Risperdal (risperidone) | $335.59 (3 mg 1x100) | $402.72 | $67.13 | 16.7% |
| Topamax tiramate) | $123.00 (100 mg 1x60) | $147.60 | $24.6 | 16.7% |

### 2. J&J Concealed Its AWP Manipulation

429. J&J deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. J&J routinely required that its customers keep secret the prices they were being charged for J&J drugs. (J&J001022; J&J000110; J&J001430; J&J001483).

## M. Pfizer

430. Pfizer engages in an organization-wide and deliberate scheme to inflate AWPs and has stated fraudulent AWPs for many of its drugs. The specific drugs of Pfizer for which relief is sought in this case are set forth in Appendix A or in the proposed class certification order, and are summarized below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| PFIZER | Accupril | quinapril hcl | ACE Inhibitor (Cardiovascular Agent)<br>Used in the treatment of hypertension |
| | Cardura | doxazosin mesylate | Autonomic Nervous System Agent<br>Used to treat hypertension and benign prostatic hypertrophy |
| | Estrostep FE | norethindrone-ethinyl estradiol-fe | Oral Contraceptive<br>Also used in the treatment of acne |
| | Femhrt 1/5 | ethinyl estradiol-norethindrone acetate | Estrogen Combination (Hormone)<br>Used in the treatment of menopause and prevention of postmenopausal osteoporosis |
| | Lipitor | atorvastatin calcium | Antilipemic Agent (Cardiovascular Agent)<br>Used to lower cholesterol |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | Nardil | phenelzine sulfate | Antidepressant (Psychotherapeutic Agent)<br>Used in the treatment of depression |
| | Neurontin | gabapentin | Anticonvulsant<br>Used in the treatment of epilepsy |
| | Zithromax | azithromycin | Macrolide Antibiotic Agent (Anti-Infective Agent)<br>General antibiotic |
| | Zoloft | sertraline hcl | Serotonin Reuptake Inhibitor (Psychotherapeutic Agent: Antidepressant)<br>Used in the treatment of depression |
| | Zyrtec | cetirizine hcl | Antihistamine<br>Used in the treatment of allergic rhinitis |

431. Pfizer manufactures and distributes some of the nation's most popular and highest selling brand name drugs.

432. Historically, Pfizer almost never changes the "spread" between the posted AWP and posted WAC for a Pfizer brand name product. Once initially launched, a Pfizer brand name product continues to bear the same difference between the posted AWP and the posted WAC (*e.g.*, 16 2/3%, or 20%, or sometimes 25%).

433. In January 2002, Pfizer announced a prescription drug discount card that would be available to elderly and poor consumers along eligibility criteria similar to that of other discount cards.

434. At the same time, January 2002, Pfizer secretly increased the AWP/WAC spread to 25% for *all* of its brand name drugs. If a drug theretofore had a posted AWP/WAC spread of 20%, it was increased to 25% (something which Pfizer, and indeed all other drug companies, almost never do). If a Pfizer brand name drug already had had a 25% AWP/WAC spread, it remained so.

435. By doing so, Pfizer knew that the purpose and effect of these new listings would be to increase reimbursement payments by end payors by amounts that would be greater than actual transaction costs for other participants in the distribution chain (*i.e.*, wholesalers,

distributors, pharmacies and PBMs). Also in doing so, Pfizer knew that the posted AWPs for many of their brand name drugs would become more misrepresentative of actual average wholesale prices given that the increased AWP/WAC spread bore no relation to actual transaction cost changes occurring in the marketplace.

436. Pfizer has been investigated by the Office of the Inspector General of the Department of Human Health Services and has entered into a $49 million settlement arising from illegal practices with respect to Lipitor. OIG-HSS found that Pfizer has been providing unrestricted educational grants and rebates that were in fact discounts off the purchase price of Lipitor. Pfizer concealed these discounts from states who were entitled to receive the "best price" for Lipitor.

437. The provision of educational grants and rebates on Lipitor also had the effect of inflating the reported AWP.

438. On information and belief, based in part due to the substantial nature of the spreads between AWP and WAC identified in Appendix A, Pfizer has inflated its AWP on other drugs at issue.

**N. The Pharmacia Group (Pharmacia and P&U)**

439. The Pharmacia Group engages in an organization-wide and deliberate scheme to inflate AWPs. The Pharmacia Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of The Pharmacia Group for which relief is sought in this case are set forth in Appendix A or in the proposed class certification order, and are summarized below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| PHARMACIA GROUP (Pharmacia and P&U) | Adriamycin | doxorubicin hydrochloride | Antineoplastic<br>Used in the treatment of various forms of cancer |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | Adrucil | fluorouracil | Antimetabolite; Antineoplastic<br>Used in the treatment of various forms of cancer |
| | Amphocin | amphotericin b | Antifungal (Anti-Infective Agent)<br>Used in the treatment of serious fungal infections |
| | Celebrex | celecoxib | Analgesic; Antirheumatic Agent<br>Used to relieve some symptoms caused by arthritis |
| | Cleocin-T | clindamycin phosphate (topical) | Antibacterial Agent (Anti-Infective Agent)<br>Used to treat bacterial infections |
| | Cytosar-U | cytarabine | Antineoplastic<br>Used in the treatment of cancer of the blood |
| | Depo-Testosterone | testosterone cypionate | Androgen (Hormone)<br>Used to replace hormones or stimulate growth |
| | Neosar | cyclophospamide | Alkylating Agent (Antineoplastic)<br>Used in the treatment of various forms of cancer as well as some kidney disease |
| | Solu-Cortef | hydrocortisone sodium succinate | Anti-Inflammatory Agent; Skin and Mucous Membrane Agent<br>Used to provide relief for inflamed areas of the body. Also used as replacement therapy in adrenocortical insufficiency |
| | Solu-Medrol | methylprednisolone sodium succinate | Anti-Inflammatory Agent<br>Used to provide relief for inflamed areas of the body. Also used as replacement therapy in adrenocortical insufficiency |
| | Toposar | etoposide | Antineoplastic<br>Used in the treatment of testicular and lung cancer |
| | Vincasar | vincristine sulfate | Antineoplastic<br>Used in the treatment of various forms of leukemia and cancer |
| | | bleomycin sulfate | Antineoplastic; Antibiotic Agent (Anti-Infective Agent)<br>Used in the treatment of various forms of cancer |

**1. The Pharmacia Group Has Been the Target of Government Investigations**

440. In connection with its scheme to inflate AWPs, The Pharmacia Group has been investigated by the Department of Justice, the Texas Attorney General, the California Attorney General, the Massachusetts Attorney General, the Attorney General of the State of Connecticut,

the Attorney General of the State of New York, and the Department of Health and Human Services Office of Inspector General.

**2. Pharmacia's Definition and Understanding of AWP**

441. Pharmacia understands that third party reimbursement is based on its published AWPs. According to a "Strategic Presentation on Average Wholesale Price (AWP)" prepared by P&U, the "Definition of AWP" is:

> An artificial pricing index that is used as a common basis for third-party reimbursement to pharmacists and physicians.
>
> -The difference between the published AWP (less a percentage) and the direct price is the profit margin that drives these classes of trade.

(PH 025785) (Highly Confidential). During this same presentation, Pharmacia provided an "AWP History":

- Historically, Wholesalers viewed AWP as an actual average selling price to their customers.
- Competition of 1980's led to AWP representing a "Suggested List Price"
- P&U AWP = 125% of Direct Price (DP)
- Exceptions being VANTIN, CVC, GENOTROPIN, and RESCRIPTOR = 120% of DP

(PH025791) (Highly Confidential). Further, the presentation recognized that "'95 Medicare (Part B) outpatient drug bill (I.V./inhalants/oncolitics/nutritionals) of $1.8 billion based primarily on AWP." (PH025793) (Highly Confidential).

**3. The Pharmacia Group Controls the Published AWP for Its Products**

442. The Pharmacia Group has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In its presentation entitled "Strategic Presentation on Average Wholesale Price (AWP)," P&U included a flow chart that shows P&U communicates its AWPs to First Data Bank, Medi-Span

and *Red Book*. This same flow chart then shows that third party payors rely on these industry compendia for prices. (PH025792) (Highly Confidential).

**4. The Pharmacia Group's AWP Manipulation Benefited Providers at the Expense of the Class**

443. The Pharmacia Group has engaged in an ongoing deliberate scheme to inflate AWPs. According to one member of the Congressional Ways and Means Committee:

> The evidence . . . indicates that [Pharmacia & Upjohn] have knowingly and deliberately inflated their representations of the average wholesale price ("AWP"), wholesale acquisition cost ("WAC") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers.
>
> * * *
>
> [T]hese practices must stop and … these companies must return the money to the public that is owed because of their abusive practices.

*See* Extension of Remarks of U.S. Representative Pete Stark in the House of Representatives, October 3, 2000 (P007545-P007547).

444. In a letter dated October 3, 2000 to Pharmacia (with accompanying exhibits), Representative Stark addressed the Pharmacia Group's illegal practices:

> The manipulated disparities between your company's reported AWPs and DPs are staggering. For example, in 1997, Pharmacia & Upjohn reported an AWP of $946.94 for 200 mg. of Adriamycin PFS while offering to sell it to American Oncology Resources (AOR) for $168.00 and to Comprehensive Cancer Center for $152.00 (Composite Exhibit "1"). Your company then aggressively marketed its cancer drugs to health care providers by touting financial inducements and other types of incentives. Pharmacia & Upjohn created and marketed the financial inducements for the express purpose of influencing the professional judgment of doctors and other health care providers in order to increase the company's market share.
>
> * * *
>
> Pharmacia & Upjohn's own internal documents . . . reveal that the company abused its position as a drug innovator in an initial *Phase III* FDA clinical trial for a cancer drug used to treat

lymphoma (Composite Exhibit "2") (emphasis in original).

". . . Clinical Research Trials

> Initial Phase III Protocol trial for "Oral Idamycin" in lymphomas. This trial will offer AOR $1.1M [million] in additional revenues. Two hundred twenty-five (225) patients at $5,000 per patient . . . (emphasis added by Rep. Stark)
>
> The above . . . items are contingent on the signing of the AOR Disease Management Partner Program. AOR's exclusive compliance to the purchase of the products listed in the contract product attachment is also necessary for the above items to be in effect."

The linking of doctor participation in FDA clinical drug trials to their purchase and administration of profit-generating oncology drugs is entirely inconsistent with the objective scientific testing that is essential to the integrity of the trial.

* * *

It is clear that Pharmacia & Upjohn targeted health care providers, who might be potential purchasers, by creating and then touting the windfall profits arising from the price manipulation. For example, Pharmacia & Upjohn routinely reported inflated average wholesale prices for its cancer drug Bleomycin, 15u, as well as direct prices. The actual prices paid by industry insiders was in many years less than half of what Pharmacia & Upjohn represented. Pharmacia & Upjohn reported that the average wholesale price for Bleomycin, 15u, rose from $292.43 to $309.98, while the price charged to industry insiders fell by $43.15 (Composite Exhibit "4").

* * *

Pharmacia & Upjohn reported price increases in October 1997 with full knowledge that the true prices of the drugs were falling. For example, Composite Exhibit "7" reveals that Pharmacia & Upjohn voluntarily lowered its price of Adriamycin PFS 200 mg to $152.00 while reporting an AWP of $946.94:

> "Dear Willie,
>
> > A (VPR) Voluntary Price Reduction will become effective May 9, 1997. The wholesalers have been notified, however it may take two weeks to complete the transition . . ."

Additionally, internal Pharmacia & Upjohn documents secured through the Congressional investigations show that Pharmacia &

> Upjohn also utilized a large array of other inducements to stimulate product sales. These inducements, including "educational grants" and free goods, were designed to result in a lower net cost to the purchaser while concealing the actual price beneath a high invoice price. Through these means, drug purchasers were provided substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price – the price that corresponded to reported AWPs and inflated reimbursements from the government. Composite Exhibit "8" highlights these inducements:
>
> AOR/PHARMACIA & UPJOHN PARTNERSHIP PROPOSAL: Medical Education Grants. A $55,000 grant has been committed for 1997 for the AOR Partnership for excellence package including Education/Disease Management, Research Task Force, AOR Annual Yearbook. A $40,000 grant to sponsor the AOR monthly teleconference. This sponsorship was committed and complete in February 1997 . . .
>
> PHARMACIA & UPJOHN, INC. INTEROFFICE MEMO: If needed, you have a "free goods" program to support your efforts against other forms of generic doxorubicin . . .
>
> Use your "free goods" wisely to compete against other generic forms of Adriamycin, not to shift the customer to direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin (emphasis added by Rep. Stark).

(P007613-P007632).

445. Pharmacia's marketing pitches, as quoted by U.S. Rep. Pete Stark in a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, promoted a physician's ability to profit at the expense of Medicare and its beneficiaries:

> PHARMACIA: Some of the drugs on the multi-source list offer you savings of over 75% below list price of the drug. For a drug like Adriamycin, the reduced pricing offers AOR a reimbursement of over $8,000,000 profit when reimbursed at AWP. The spread from acquisition cost to reimbursement on the multi-source products offered on the contract give AOR a wide margin for profit.

(P007548-P007588).

446. In 1997, Pharmacia sent to a clinic a proposal listing the AWP and the contract price at which several drugs would be sold to the provider. The differences are staggering and just a few are noted below:

| Drug | AWP | Suggested New Contract Price |
|---|---|---|
| Adriamycin (10 mg) | 46.00 | 7.50 |
| Adriamycin (50 mg) | 230.00 | 37.50 |
| Neosar (2 g) | 86.00 | 18.00 |
| Toposar (1 g) | 1,330.75 | 120.00 |
| Vincasar (2 mg) | 741.50 | 7.50 |

(P007615).

### 5. Specific Pharmacia AWPs Documented by the DOJ

447. In a report published by the DHHS, the DOJ documented at least 43 instances where the published AWPs for various dosages of drugs manufactured by The Pharmacia Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Pharmacia Group in the 2001 *Red Book*.

| Drug | The Pharmacia Group's 2001 *Red Book* AWP | DOJ Determined Actual AWP | Difference | Spread |
|---|---|---|---|---|
| Amphotercin B | $36.26 | $16.00 | $20.26 | 127% |
| Bleomycin Sulfate | $309.98[9] | $158.67 | $151.31 | 96% |
| Clindamycin Phosphate | $93.60 | $61.20 | $32.40 | 53% |
| Cyclophospamide | $6.29 | $3.92 | $2.37 | 60% |
| Cytarabine | $8.98 | $4.06 | $4.92 | 122% |
| Doxorubicin HCL | $1104.13 | $150.86 | $953.27 | 632% |

[9] Calculation based on the AWP listed in the 2000 *Red Book*.

| | | | | |
|---|---|---|---|---|
| Etoposide | $157.65 | $9.47 | $148.18 | 1,565% |
| Fluorouracil | $3.20 | $1.47 | $1.73 | 118% |
| Hydrocortisone Sodium Succinate | $2.00 | $1.55 | $.45 | 29% |
| Metholprednisolone Sodium Succinate | $2.05 | $1.45 | $.60 | 41% |
| Testosterone Cypionate | $17.01 | $11.79 | $5.22 | 44% |
| Vincristine Sulfate | $43.23 | $5.10 | $38.13 | 748% |

448. In OIG report OEI-03-00-00310, the government noted that 20 mg of irinotecan, which according to the *Red Book* is manufactured only by The Pharmacia Group, had a Medicare Median of $117.81 and a Catalog Median of $98.63, resulting in a spread of 19.45%. (P006398-P006424).

449. The GAO issued a report entitled "Payments for Covered Outpatient Drugs Exceed Providers' Cost" (GAO-01-1118) wherein it found that irinotecan had an Average AWP of $141.32, the Average Widely Available Discount from AWP to physicians for irinotecan was 22.9%, and the drug constituted 2.0% of the total amount of Medicare spending in 1999. (P005546-P005578).

450. As of April 2000, another Pharmacia Group drug, Toposar® (etoposide), had an AWP of $28.38. The DOJ found that retailers were buying it for $1.70. (P006299-006316).

451. Similarly, by letter dated September 25, 2000 to the HCFA Administrator, the Chairman of the Commerce Committee revealed that:

> [I]n 1998, Pharmacia-Upjohn's Bleomycin had an AWP of $309.98, but health care providers could purchase it for $154.85. In 1997, Pharmacia-Upjohn's Vincasar could be purchased for $7.50, while the AWP was a staggering $741.50.

*See* letter dated May 25, 2000 from U.S. Rep. Thomas J. Bliley to Nancy-Ann Min DeParle, HCFA Administrator. (P007015-P007490).

452. Exhibit 1 to U.S. Rep. Pete Stark's September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, reveals that while the

AWP for 1 mg of Vincasar® (vincritine sulfate) was $370.75 in 1997, one physician group's (American Oncology Resources) price in 1997 was only $4.15. (P007515). Similarly, while the AWP for 2 mg of Vincasar® was $741.50, AOR's actual pre-April 1997 price was $7.75 (in fact, The Pharmacia Group had offered to reduce it to $7.50). *Id.* As of April 2000, Adriamycin had a reported AWP of $241.36, while the real wholesale price was $33.43.

**6. Inflated Pharmacia AWPs From Pharmacia's Price Lists**

453. According to Pharmacia's own documents, the published AWPs for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, the Pharmacia Group produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Pharmacia has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Table 1 are a number of those drugs with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of P&U drugs from a document entitled "Oncology Express CONTRACT PRICING" (PH011977) (Highly Confidential).

**Table 1**

| PRODUCT | LIST | AWP | CONTRACT PRICE | DIFFERENCE (between AWP and contract price) | PERCENTAGE SPREAD |
|---|---|---|---|---|---|
| Adriamycin | 883.80 | 1104.13 | 119.00 | 985.13 | 828% |
| Adrucil | 12.83 | 16.04 | 4.56 | 11.48 | 252% |
| Amphocin | 29.01 | 36.26 | 13.00 | 23.26 | 179% |
| Neosar | 80.22 | 100.28 | 16.15 | 84.13 | 521% |
| Toposar | 614.81 | 768.51 | 33.84 | 734.67 | 2,171% |

**7. The Pharmacia Group Provided Free Goods and Other Incentives**

454. In addition to marketing the spread, The Pharmacia Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to

result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, The Pharmacia Group provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

455. The government investigators also uncovered an October 3, 1996 internal memorandum wherein Pharmacia told three oncology sales representatives:

> Our competitive intelligence tells us that our pricing on Adriamycin, although higher than generics, is in the "ball park" for you to attain the customers Adriamycin business. If needed, you have a "free goods" program to support your efforts against other forms of generic doxorubicin.
>
> . . . .
>
> You should not have to use "free goods" to steer customer [sic] away from NSS or OTN. OTN and NSS Adriamycin pricing is competitive. Use your "free goods" wisely to compete against other generic forms of Adriamycin, not to shift the customer to direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin.

(PH 024315).

456. As set forth above, The Pharmacia Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

**O. The Schering-Plough Group (Schering-Plough and Warrick)**

457. The Schering Plough Group engages in an organization-wide and deliberate scheme to inflate AWPs. The Schering Plough Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of The Schering Plough Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| SCHERING-PLOUGH GROUP | Clarinex | desloratadine | Antihistamine<br>Used to relieve the symptoms of hay fever and hives of the skin |
| (Schering-Plough and Warrick) | Claritin | loratadine | Antihistamine<br>Used to relieve or prevent the symptoms of asthma |
| | Claritin-D | loratadine & pseudoephedrine | Antihistamine<br>Used to treat the nasal congestion, sneezing, and runny nose caused by colds and hay fever |
| | Diprolene | aug betamethasone dipropionate | Antipruritic (Skin & Mucous Membrane Agent)<br>Used to help relieve redness, swelling, itching, and discomfort of many skin problems |
| | Diprosone | betamethasone dipropionate | Antipruritic (Skin & Mucous Membrane Agent)<br>Used to help relieve redness, swelling, itching, and discomfort of many skin problems |
| | Elocon | mometasone furoate | Antipruritic (Skin & Mucous Membrane Agent)<br>Used to help relieve redness, swelling, itching, and discomfort of many skin problems |
| | Eulexin | flutamide | Antineoplastic<br>Used to treat cancer of the prostate gland |
| | Integrilin | eptifibatide | Cardiovascular Agent<br>Used in the treatment of patients with acute coronary syndrome |
| | Intron-A | interferon alfa-2b | Immunomodulator<br>Used in the treatment of hairy cell leukemia and chronic hepatitis B or C. |
| | Lotrisone | clotrimazole w/ betamethasone | Antifungal Agent (Anti-Infective Agent)<br>Used to treat fungus infections |
| | Nasonex | mometasone furoate (nasal) | Anti-Inflammatory Agent (Nasal Preparation)<br>Relieve the stuffy nose, irritation, and discomfort of hay fever and other allergies |
| | Peg-Intron | peginterferon alfa-2b | Biological Response Modifier<br>Used to treat chronic hepatitis C |
| | Proventil | albuterol sulfate | Bronchodilator (Respiratory Agent)<br>Used to treat the symptoms of asthma, chronic bronchitis, emphysema, and other lung diseases |
| | Rebetol | ribavirin | Biological Response Modifier<br>Used to treat hepatitis C |
| | Sebizon | sulfacetamide sodium | Anti-Infective Agent<br>Used in the treatment of conjunctivitis and other ocular infections |
| | Temodar | temozolomide | Antineoplastic<br>Used to treat a specific type of cancer of the brain in adults whose tumors have returned |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | Trinalin Rep | azatadine & pseudoephedrine | Antihistamine<br>Used to treat the nasal congestion, sneezing, and runny nose caused by colds and hay fever. |
| | Vanceril | beclomethosone (nasal) | Anti-Inflammatory Agent; Antiasthmatic<br>Used to help prevent the symptoms of asthma |
| | | albuterol | Bronchodilator (Respiratory Agent)<br>Used for relief of bronchospasm in asthma sufferers |
| | | clotrimazole | Antifungal Agent (Anti-Infective Agent)<br>Used to treat yeast (fungus) infections of the vagina |
| | | griseofulvin ultramicrocrystalline | Antifungal Agent (Anti-Infective Agent)<br>Used to treat fungus infections of the skin, hair, fingernails, and toenails |
| | | oxaprozin | Central Nervous System Agent; Antipyretic (Analgesic)<br>Used in the treatment of osteoarthritis and rheumatoid arthritis |
| | | perphenazine | Antiemetic (Gastrointestinal Agent); Antipsychotic Agent (Psychotherapeutic Agent)<br>Used to treat serious mental and emotional disorders. Also used to relieve moderate to severe pain in some hospitalized patients |
| | | potassium chloride | Electrolytic Agent<br>Used to prevent and treat potassium deficit secondary to diuretic or cortiocosteroid therapy |
| | | sodium chloride | Flush; Abortifacient<br>Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion |
| | | sulcrafate | Gastrointestinal agent<br>Used for short term treatment of duodenal ulcer |
| | | theophylline er | Bronchodilator (Respiratory Agent)<br>Used to treat and/or prevent the symptoms of bronchial asthma, chronic bronchitis, and emphysema |

### 1. The Schering Plough Group Has Been the Target of Government Investigations

458. In connection with its scheme to inflate AWPs, The Schering Plough Group has been investigated by the Department of Justice, Texas Attorney General, West Virginia Attorney General, California Attorney General, California Bureau of Medi-Cal Fraud and Elder Abuse,

and the Department of Health and Human Services Office of Inspector General, and the U.S. Attorney for the District of Massachusetts.

459. On May 30, 2003, Schering Plough announced that the U.S. Attorney for the District of Massachusetts had advised that its subsidiary, Schering Corporation, is the subject of a federal grand jury investigation. Schering Plough is the target of a criminal investigation involving: (i) providing remuneration, such as drug samples, to providers to induce the purchase of Schering products for which payment was made through federal health care programs; (ii) selling misbranded or unapproved drugs; (iii) submitting false wholesale pricing information for its pharmaceutical products to the government; and (iv) destroying evidence and obstructing justice relating to the government's investigation. *See* Schering Plough Press Release dated May 30, 2003, located at http://www.sch-plough.com/news/2003/business/20030530.html; "Schering Plough expects indictment," The Philadelphia Inquirer, at C3 (May 31, 2003). Moreover, according to Schering Plough's Form 10-K for the year 2000, this investigation has focused on "whether the AWP set by pharmaceutical companies for certain drugs improperly exceeds the average prices paid by dispensers . . . and other pricing and/or marketing practices."

460. A Medicaid investigation by the Texas Attorney General revealed that The Schering-Plough Group defrauded the State of Texas $14.5 million. Investigators determined that The Schering-Plough Group provided the greatest "spread" amongst the drug companies selling albuterol in Texas, and thereby obtained the largest market share for albuterol. The Schering-Plough Group sold a box of albuterol to pharmacies for $13.50, while it charged the Texas Medicaid program $40.30, a 200% increase. *See Cornyn Sues Three Drug Companies for Medicaid Fraud*, Press Release by the Office of the Attorney General, State of Texas, Sept. 7, 2000. (www.oag.state.tx.us.gov)

461. On October 11, 2001, the West Virginia Attorney General filed suit against Warrick, alleging that Warrick defrauded state agencies and citizens by deliberately overstating the AWP for certain drugs, including albuterol, from approximately 1995 until December 2000.

**2. The Schering Plough Group Controls the Published AWP for Its Products**

462. The Schering Plough Group has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, on February 23, 1995, Warrick sent a letter to First Data Bank, stating:

> Effective Friday, February 24, 1995, at 5:00 p.m., the price of Warrick Albuterol Solution 0.5% 20ml will increase as follows:
>
> | | NDC 59930- | AWP |
> |---|---|---|
> | Albuterol Solution 0.5% 20 ml | 1515-04 | $13.95 |

(WAR0024086) (Highly Confidential).

**3. The Schering Plough Group's AWP Manipulation Benefited Providers at the Expense of the Class**

463. A Schering Laboratories memorandum dated May 20, 1993 demonstrates Defendant's recognition that intermediaries choose drugs based on favorable AWP spreads. At the generic launch of albuterol, Schering stated:

> Proventil will stay listed at AWP; therefore, Proventil is a favored product for third party reimbursement that provides for the AWP minus 10% reimbursement rate to chains. Thus, they can buy off the Proventil deal and bill at AWP.

(WAR005419-20) (Highly Confidential).

464. According to Warrick's own documents, Warrick consistently maintained a spread between the AWPs and the direct prices it offered for its albuterol products. For example, a "Price Change" alert dated June 7, 1999 sent to Warrick customers provides:

| Product | Pkg. Size | NDC 59930 | AWP | Direct Price |
|---|---|---|---|---|
| Albuterol Inhalation Aerosol | 17 g | 1560-1 | $21.41 | $3.40 |
| Albuterol Aerosol Refill | 17 g | 1560-2 | $19.79 | $3.40 |

(WAR0000532) (Highly Confidential). Thus, Warrick touted a 529% spread on its albuterol inhalation aerosol and a 482% spread on the refill.

465. In a report to Congress, the GAO reported that albuterol sulfate was one of a small number of products that accounted for the majority of Medicare spending and volume. Albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than 400 covered drugs. Albuterol sulfate ranked first for volume of units covered, accounting for 65.8% of total units reimbursed. *See* GAO Report to Congressional Committees, "Payments for Covered Outpatient Drugs Exceed Providers' Cost," Tables 1 and 2, pp. 7-8 (GAO-01-0118 (P005546-005578)). The Schering Plough Group is one of three companies noted by the DOJ as manufacturing albuterol. *See* DHHS report, AB-00-86 (P006299-006316).

466. According to The Schering Plough Group's own documents, the published AWPs for most of its drugs were higher than the actual prices provided to wholesalers.

467. In response to government subpoenas, The Schering Plough Group produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Warrick has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1, 2 and 3 are a number of those drugs with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of Warrick drugs from a document entitled, "Amerisource" (WAR0022160) (Highly Confidential).

**TABLE 1**

| LABEL (MFG) | GENERIC NAME | AWP | INVOICE COST | DIFFERENCE | PERCENTAGE SPREAD |
|---|---|---|---|---|---|
| Warrick | Albuterol Inhaler | 21.41 | 5.75 | 15.66 | 272% |
| | Aug Beta Dip Oint 0.05% | 43.20 | 26.90 | 16.30 | 61% |
| | Griseofulvin | 82.47 | 37.22 | 45.25 | 122% |
| | Theophylline | 11.70 | 2.83 | 8.87 | 313% |

Table 2 is an analysis of certain dosages of Warrick drugs from a document entitled, "1997 Care Group Bid Proposal." (WAR0022122) (Highly Confidential).

**TABLE 2**

| **PRODUCT** | **AWP** | **INVOICE PRICE** | **NET PRICE (AFTER REBATE)** | **DIFFERENCE BETWEEN AWP AND INVOICE PRICE** | **PERCENTAGE SPREAD** |
|---|---|---|---|---|---|
| Clotrimazole | 22.25 | 7.77 | 6.99 | 14.48 | 186% |
| Perphenazine | 78.00 | 19.53 | 17.58 | 58.47 | 299% |

Table 3 is an analysis of certain dosages of Warrick drugs from a document entitled, "Managed Care Pricing," dated July 1, 2002. (WAR0054226) (Highly Confidential).

**TABLE 3**

| **Product** | **Minimum PBM/Mail Order/ Staff Price Guide** | **Target PBM/Mail Order/ Staff Price Guide** | **Minimum GPO Price Guide** | **Target GPO Price Guide** | **AWP** | **Difference** | **% Spread** |
|---|---|---|---|---|---|---|---|
| ISMN | 4.48 | 4.93 | 5.15 | 5.38 | 117.40 | 112.02 | 2,082% |
| Oxaprozin | 11.42 | 12.56 | 13.13 | 13.70 | 117.40 | 103.70 | 757% |
| Potassium Chloride | 9.67 | 10.64 | 11.12 | 11.60 | 65.00 | 53.40 | 460% |
| Sodium Chloride | 6.12 | 6.73 | 7.04 | 7.34 | 24.30 | 16.96 | 231% |
| Sulcrafate Tablets | 45.15 | 49.67 | 51.92 | 54.18 | 353.71 | 299.53 | 553% |

### 4. The DOJ Specifically Documented AWP Inflation for Albuterol Sulfate

468. In a report published by the DHHS (AB-00-86 (P006299-006316)), the DOJ documented at least one instance where the published AWPs for various dosages of albuterol sulfate manufactured by The Schering Plough Group were substantially higher than the actual

prices listed by wholesalers. The following figures compare the DOJ's determination of an accurate AWP for one particular dosage, based upon wholesalers' price lists, with the AWP reported by The Schering Plough Group in the 2001 *Red Book*: The Schering-Plough Group reported to *Red Book* an AWP of $30.25 for albuterol sulfate, yet the DOJ determined the actual AWP to be $9.16, or $21.09 less.

469. As stated in a May 4, 2000, letter from U.S. Rep. Tom Bliley, Chairman of the Congressional Committee on Commerce, to Raman Kapur, President of Warrick:

> I am writing to you because one of the drugs reflecting a significant variation between the AWP-based prices paid by Medicare and the prices generally charged to private sector purchasers is albuterol sulfate, a drug manufactured by Warrick Pharmaceuticals.

(P006938-006941).

470. In his May 4, 2000, letter, Bliley outlined The Schering Plough Group's scheme with respect to the prescription drug albuterol sulfate. The government's investigation uncovered a significant spread between the amount Medicare reimbursed for albuterol sulfate and the amount the Schering-Plough Group actually charged. U.S. Rep. Bliley stated:

> The OIG [Office of the Inspector General] has determined that the Medicare-allowed amount for albuterol sulfate, a pharmaceutical product sold by your company, in the Fiscal Year 1996 was $.42. The OIG further estimated that the actual wholesale price of this drug was $.15 and the highest available wholesale price that the OIG was able to identify was $.21.

*Id.*

**5. The Schering Plough Group Provided Free Goods and Other Incentives**

471. In addition to marketing the spread, The Schering Plough Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, The Schering Plough Group

provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

472. As set forth above, The Schering Plough Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

**P. The Sicor Group (Sicor, Gensia and Gensia Sicor)**

473. The Sicor Group engages in an organization-wide and deliberate scheme to inflate AWPs. The Sicor Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of The Sicor Group for which relief is sought in this case are set forth in Appendix A, and are identified below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| SICOR GROUP (Sicor, Gensia and Gensia-Sicor) | | acyclovir sodium | Anti-Infective Agent<br>Used in the treatment of herpes infections |
| | | amikacin sulfate | Antibiotic Agent (Anti-Infective Agent)<br>Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections |
| | | amphotercin b | Antifungal Agent (Anti-Infective Agent)<br>Used to help the body overcome serious fungus infections |
| | | doxorubicin hydrochloride | Antineoplastic<br>Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma |
| | | etoposide | Mitotic Inhibitor (Antineoplastic)<br>Used in the treatment of testicular neoplasm and small cell cancer of the lung |
| | | leucovorin calcium | Antianemic Agent (Blood Modifier)<br>Used in the treatment of anemia |
| | | pentamidine isethionate | Anti-Infective Agent<br>Used in the treatment of pneumonia |
| | | tobramycin sulfate | Antibiotic Agent (Anti-Infective Agent)<br>Used to treat severe infection |

**1. The Sicor Group Has Been the Target of Government Investigations**

474. In connection with its scheme to inflate AWPs, The Sicor Group has been investigated by the Department of Justice, Department of Health and Human Services Office of Inspector General, the Texas Department of Health, and the California Attorney General.

**2. The Sicor Group Controls the Published AWP for Its Products**

475. The Sicor Group has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, by letter dated February 21, 1994, Gensia advised MediSpan of the impending launch of its new product called "Etoposide" and stated: "I have also include [sic] some guidelines in this pack for establishing Gensia's AWPs for our Etoposide." (SICOR 00955) (Confidential). That same day, Gensia sent a second letter to MediSpan stating, in part:

> The following represents the detailed information for this product and the AWP that we would like MediSpan to use:

**ETOPOSIDE INJECTION**

| NDC # | PRODUCT DESC. | VIALSIZE | LIST PRICE | AWP |
|---|---|---|---|---|
| 0703-5643-01 | 20MG/ML (100MG) | 5ML | $105.16 | $131.30 |
| 0703-5646-01 | 20MG/ML (500MG) | 25ML | $483.74 | $638.76 |

(SICOR 00956).

476. Moreover, The Sicor Group has told its sales force to rely on the AWP information contained in the industry compendia when marketing to customers. For example, a memorandum dated April 6, 1994 to "Field Sales force" regarding "Average Wholesale Prices (AWP)" provides in pertinent part:

> Attached is a copy of Medi-Span's March 31, 1994 printout of product and AWP information for Gensia Laboratories. Since this information comes directly from Medi-Span's computer file, you will find it to be more accurate than the information that your customers are using from their reference texts. You will note, that the AWP information (listed in pack quantity) is found in the third column from the right. Additionally, the two columns to the immediate left of the AWP column represent: WAC (Wholesalers Acquisition Cost) and DP (Direct Price).

(SICOR 00753) (Highly Confidential).

### 3. The Sicor Group's AWP Manipulation Benefited Providers at the Expense of the Class

477. The Sicor Group has engaged in an ongoing deliberate scheme to inflate AWPs. For example, by letter dated September 25, 2000 to the HCFA administrator, the Chairman of the Commerce Committee revealed that: "[I]n 1998, a health care provider could buy Gensia's Etoposide for $14.00, while the AWP used to determine Medicare reimbursement was $141.97." (P007015-P007490).

478. The Sicor Group's marketing strategies further demonstrate its fraudulent practices. In a marketing document prepared by Gensia and obtained by the government in its investigation, Gensia stated:

> Concentrate field reps on the top 40 AIDS hospitals using a $54.00 price in conjunction with a 10% free goods program to mask the final price. Provides the account with an effective price of $48.60 per vial.

*See* letter dated September 28, 2000 from U.S. Rep. Pete Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America. (P007512).

479. Certain handwritten notations appear on this same marketing document comparing the AWP with other prices used for the same drug:

FSS $44.95

Whls $71.00

Distr. $51.50

AWP $109.20

(P007532).

480. Similarly, a document entitled "Comparison of AWPs" based on the 1996 *Red Book* contains the following handwritten notation:

Rob, Joe,

Tim suggested sending this info to the reps. Your thoughts?

B

(SICOR 00756) (Highly Confidential). Following this notation is a chart comparing the AWPs for certain drugs published by various manufacturers, including Gensia. One example follows:

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Doxurubicin** | | Abbott/ Adria | Bedford | FUSA | **Gensia** | | | |
| | | | | | **X** | | | |
| 10 | | $48.31 | $47.35 | $44.50 | **$49.29** | <Polymer | | |
| | | | | | **X** | | | |
| 50 | | $241.56 | $236.74 | $231.00 | **$246.46** | <Polymer | | |
| | | | | | **X** | | | |
| 200 | | $946.94 | $945.98 | NA | **$966.14** | <Polymer | | |

*Id.*

481. Moreover, Gensia disseminated advertisements that actually contained a comparison of the Contract Price with the AWP and set forth the resulting spread (SICOR 00751, 00752) (Highly Confidential), because Gensia knew that marketing the spread was in its best interests. Realizing this, one customer of Gensia, Opti Care, sent a memorandum to all its offices (with a copy to Gensia) stating: "Gensia's products offer a significant spread between AWP and contract price. This spread may be attractive, when a payor's reimbursement is based on AWP and the drug is not MAC'd. (SICOR 00758) (Highly Confidential).

**4. Specific Sicor Group AWPs Documented by the DOJ**

482. In a report published by the DHHS, the DOJ documented at least 17 instances where the published AWPs for various dosages of drugs manufactured by The Sicor Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Sicor Group in the 2001 *Red Book*.

| Drug | The Sicor Group's 2001 *Red Book* AWP | DOJ Determined Actual AWP | Difference | Spread |
|---|---|---|---|---|
| Acyclovir Sodium | $125.00[10] | $100.00 | $25.00 | 25% |
| Amikacin Sulfate | $87.50 | $72.68 | $14.82 | 20% |
| Tobramycin Sulfate | $342.19 | $6.98 | $335.21 | 4,802% |

(P006299-006316).

**5. Inflated Sicor Group AWPs From the Sicor Group's Price Lists**

483. According to The Sicor Group's own documents, the published AWPs for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, The Sicor Group produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that The Sicor Group has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of two Gensia drugs from a Medi-Span printout on which Gensia wanted its sales force to rely (the remaining drugs were redacted by The Sicor Group prior to production). (SICOR 00754-755) (Highly Confidential).

**Table 1**

| Product | WAC | DP | AWP | DIFFERENCE (between AWP and DP) | PERCENTAGE SPREAD |
|---|---|---|---|---|---|
| Etoposide Inj | 483.73 | 483.73 | 638.76 | 155.03 | 32% |
| Leucovorin CA Inj | 32.50 | 32.50 | 40.63 | 8.13 | 25% |

484. Table 2 is an analysis of certain dosages of four Gensia drugs from multiple Gensia price lists for a particular customer, Pharmaceutical Buyers, Inc., comparing the customer's Contract Price with the AWP and the resulting spread (the remaining drugs were

[10] Calculation based on the AWP listed in the 2000 *Red Book*.

redacted by The Sicor Group prior to production). (SICOR 00555, 573, 614, 633) (Highly Confidential).

**Table 2**

| Product | AWP | PBI CONTRACT | SPREAD | PERCENTAGE SPREAD |
|---|---|---|---|---|
| DOXURUBICIN HYDROCHLORIDE | 871.70 | 293.60 | 578.10 | 1,969% |
| ETOPOSIDE | 1207.33 | 456.00 | 751.33 | 1,648% |
| LEUCOVORIN CALCIUM | 39.00 | 4.58 | 34.42 | 752% |
| PENTAMIDINE ISETHIONATE | 468.00 | 193.75 | 274.25 | 1,415% |

**6. The Sicor Group Provided Free Goods and Other Incentives**

485. In addition to marketing the spread, The Sicor Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, such as free goods, The Sicor Group provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price. (SICOR 00718, 04182, 00689) (Highly Confidential).

486. As set forth above, The Sicor Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

**Q. Warrick**

487. Warrick has acted to inflate AWPs pursuant to the scheme identified above. The specific drugs are identified in Appendix A.

**R. Watson**

488. Watson engages in an organization-wide and deliberate scheme to inflate AWPs. Watson has stated fraudulent AWPs for all or almost all of its drugs, including: Ferrlecit, Verapamil HCL, Vinblastine Sulfate, Vincristine Sulfate, Dexamethasone, Diazepam,

Gentamicin, Testosterone Ethanate, Vancomycin, Fluphenazine, Gemfibrozil, Imipramine, Nadolol, and Perphenazine. The specific drugs of Watson for which relief is sought in this case are set forth in Appendix A or in the proposed class certification order, and are summarized below:

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| WATSON (Watson and Schein) | Ferrlecit | sodium ferric gluconate complex in sucrose injection | Iron Preparation (Blood modifier)<br>Used for treatment of anemia in patients undergoing hemodialysis |
| | InfeD | iron dextran | Iron Preparation (Blood modifier); Nutritional Supplement<br>Used for treatment of iron deficiency |
| | | dexamethasone acetate | Hormone; Glucocorticoid<br>Used to treat inflammatory conditions, hematologic disorders and cerebral adema |
| | | dexamethasone sodium phosphate | Hormone; Glucocorticoid<br>Used to treat inflammatory conditions, hematologic disorders and cerebral adema |
| | | diazepam | Central Nervous System Agent<br>Used to treat status eplipeticus and anxiety disorders. Also used as an amnesic prior to surgical procedures |
| | | estradiol | Estrogen (Hormone)<br>Used for treatment of menopausal symptoms and postmenopausal osteoporosis |
| | | fluphenazine hcl | Central Nervous System Agent; Psychotherapeutic Agent<br>Used to manage psychotic disorders |
| | | gemfibrozil | Antilipemic Agent (Cardiovascular Agent)<br>Used to lower cholesterol |
| | | gentamicin sulfate | Anti-Infective Agent<br>Used as a general antibiotic to treat serious gastrointestinal, respiratory, bone, skin and soft tissue infections |
| | | imipramine hcl | Central Nervous System Agent; Psychotherapeutic Agent<br>Used in the treatment of depression |
| | | lorazepam | Central Nervous System Agent<br>Used for treatment of anxiety disorders |
| | | nadolol | Antihypertensive (Cardiovascular Agent)<br>Used in the treatment of hypertension and management of angina |

| Manufacturer | Brand Name (if applicable) | Generic Name | Therapeutic Category/Usage |
|---|---|---|---|
| | | perphenazine | Central Nervous System Agent; Psychotherapeutic Agent<br>Used to manage psychotic disorders |
| | | propanolol hcl | Beta Adrenergic Blocking Agent (Cardiovascular Agent)<br>Used to treat hypertension |
| | | ranitidine hcl | Histamine Receptor Antagonist (Gastrointestinal Agent)<br>Used for treatment of duodenal ulcer, gastric ulcer, gastroesophagael disease and heartburn |
| | | vancomycin hcl | Antibiotic Agent (Anti-Infective Agent)<br>Used as a general antibiotic |
| | | verapamil hcl | Calcium Channel Blocker (Cardiovascular Agent)<br>Used in the treatment of tachyarrhythmia, angina and hypertension |

**1. Watson Has Been the Target of Government Investigations**

489. In connection with its scheme to inflate AWPs, Watson has been investigated by the Department of Justice, Department of Health and Human Services Office of Inspector General, and the State of California.

**2. Watson's Definition and Understanding of AWP**

490. Watson plainly recognizes that "AWP drives reimbursement." (MDLW12564) (Highly Confidential).

**3. Watson Controls the Published AWP for Its Products**

491. Watson has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In a memo, Watson states that it is faxing prices to various pricing services, but "not all pricing services received all of the prices listed on this letter. Most only received the AWP price…" The memo goes on to state that "AWP is the primary price being communicated in these faxes to establish a reference for reimbursement." (MDLW25203) (Highly Confidential).

492. A *Red Book* Product Listing Verification form asks for approval of changes to the stated AWP for Schein's (which was later acquired by Watson) Verapamil HCL, Vinblastine Sulfate and Vincristine Sulfate. A Schein executive okayed the changes and signed the *Red Book* form. (MDLW00887).

**4. Watson's AWP Manipulation Benefited Providers at the Expense of the Class**

493. When deciding where to set the price for its drug Ferrlecit, Watson recognized that, in a Medicare Reimbursement Mechanism, "margin drives AWP and ASP" and that a goal of setting the price is that "profit margin at the unit level must not decrease." Watson recognizes that 20% of reimbursement is patient co-pay, which can be private insurance, Medicaid or cash. (MDLW05457-05460) (Highly Confidential).

494. Watson was well aware that payors relied on the AWP, and was sensitive to avoid alerting payors to Watson's AWP manipulation. In the context of a pricing study, a Schein executive noted that "it would be great to get a read from some HCFA personnel regarding what level of price will set off alarms with reimbursement." (MDLW25216) (Highly Confidential).

495. In that same document, Watson acknowledges that AWP manipulation is the key to its customers' profits "if through reimbursement we can maintain or increase the money a unit makes on using this product does the price even matter?" (MDLW25216) (Highly Confidential).

**5. Specific Watson AWPs Documented by the DOJ**

496. In a report published by the DHHS (AB-00-86), the DOJ documented at least 12 instances where the published AWPs for various dosages drugs manufactured by Watson were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Watson in the *Red Book*.

| Drug | Watson's 1998-2001 *Red Book* AWPs | DOJ Determined Actual AWP | Difference | Spread |
|---|---|---|---|---|
| Dexamethasone Acetate | $46.45 (1998) | $11.50 | $34.95 | 304% |
| Dexamethasone Sodium Phosphate | $93.04 (2001) | $1.08 | $91.96 | 851% |
| Diazepam | $18.15 (2000) | $2.50 | $15.65 | 626% |
| Gentamicin Sulfate | $114.10 (1999) | $1.18 | $112.92 | 957% |
| Iron Dextran | $377.04 (2001) | $24.69 | $352.35 | 1,427% |
| Testosterone Ethanate | $42.10 (2001) | $13.39 | $28.71 | 214% |
| Vancomycin HCL | $70.00 (1998) | $3.84 | $60.16 | 1,567% |

(P006299-P006316).

### 6. Inflated Watson AWPs From Watson's Price Lists

497. In response to government subpoenas, Watson produced numerous price lists setting forth spreads between AWP and prices offered to wholesalers, providers and other intermediaries. A review of those lists indicates that Watson has consistently offered drugs to its customers at prices significantly below the published AWP, and that the spread was of great importance to Watson's customers. It is not practical to repeat every one of those drugs and the spread offered to specific customers. However, set forth below in Table 1 are a number of those drugs (not already referenced above) and the substantial spread offered to Watson customers.

498. Table 1 is an analysis of certain dosages of Schein drugs from a chart titled Schein Product Status Report, February 1996. (MDLW01237).

**Table 1**

| Drug | AWP | WAC | % Spread |
|---|---|---|---|
| Fluphenazine HCL 1mg | $46.08 | $15.71 | 193% |
| Gemfibrozil 600mg | $55.65 | $7.95 | 600% |
| Imipramine HCL 10mg | $4.45 | $1.32 | 237% |
| Nadolol 20mg | $85.32 | $42.95 | 98% |
| Perphenazine 2mg | $42.53 | $19.76 | 115% |

499. As set forth above, Watson's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

**7. Watson Provided Free Goods and Other Incentives**

500. In addition to marketing the spread, Watson has utilized other inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. In one instance in May 2000, Schein offered "Priority Customers" an additional 5% discount on Ferrlecit "off invoice" for all purchases made that month. (MDLW15896.) By utilizing "off-invoice" inducements, Watson provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

501. As set forth above, Watson's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

**8. Watson Concealed Its AWP Manipulation**

502. Watson deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, as noted above, Watson reported its AWP to various industry compendia, but disclosed WAC, direct price and average sale price to only a very few, if any, outside entities. (MDLW25204) (Highly Confidential). Also as noted above, Watson needed to keep the AWP high, but at a level that would not "set off alarms with reimbursement" (MDLW25216). Watson effectively hid the AWP spread from Plaintiffs and the Class.

## VI. DIRECT DAMAGE SUSTAINED BY PLAINTIFFS AND THE MEMBERS OF THE AWP CLASS

503. Plaintiffs and other Third-Party Payors who are members of the class reimburse health care providers for pharmaceuticals based upon the published AWP for brand name drugs

and based upon MAC, for generic drugs, which in turn is derived from AWP. Accordingly, plaintiffs and Third-Party Payors are directly damaged by fraudulent AWP pricing schemes for drugs covered by employee health and benefit plans. By virtue of the fact that AWP is the reimbursement benchmark for pricing of the AWPIDs at issue, such injury occurs in all aspects of the distribution chain for the AWPIDs, including the PBM segment, non-PBM purchases, Part B covered drugs and non-Part B covered drugs.

## VII. CLASS ACTION ALLEGATIONS FOR THE AWP PAYOR SCHEME

504. Plaintiffs bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of themselves Classes comprised of:

**Physician-Administered Drugs Class (Medicare Part B Co-Pay and Private System Physician-Administered Drugs)**

All persons or entities in the United States and its territories who (i) paid all or a portion of the co-insurance under Medicare Part B for an AWPID during the Class Period, and/or (ii) reimbursed another for a physician-administered AWPID under a contract or other payment scheme that expressly uses AWP as a pricing standard, along with all individual persons who paid coinsurance (*i.e.*, co-pays proportional to the reimbursed amount) under such circumstances for such AWPIDs, during the Class Period. Excluded from the Class are those who make flat co-pays and those whose co-pay was reimbursed by an insurer or other third party.

**Self-Administered and Specialty Pharmacy Drugs Class (Third-Party and Co-Payor Class for Self-Administered Drugs)**

All persons or entities in the United States and its territories who reimbursed another for any self-administered AWPID, or for any AWPID which was distributed through a specialty pharmacy, under a contract or other payment scheme that expressly uses AWP as a pricing standard, along with all individual persons who paid coinsurance (*i.e.*, co-pays proportional to the reimbursed amount) under such contracts for such AWPIDs. Excluded from the Class are those who make flat co-pays and those whose co-pay was reimbursed by an insurer or other third party.

The foregoing class is further subdivided into the following subclasses:

(a) brand name sub-class; and

(b) generic drug sub-class

**RICO Class for Self-Administered and Specialty Drugs**

All persons or entities in the United States and its territories who reimbursed another for any self-administered AWPID, or for any AWPID which was distributed through a specialty pharmacy, under a contract with Caremark, AdvancePCS, Express Scripts and/or Medco (or their predecessors), which contract expressly uses AWP as pricing standard, along with all individual persons who paid coinsurance (*i.e.*, co-pays proportional to the reimbursed amount) under such contracts for such AWPIDs. Excluded from the Class are those who make flat co-pays and those whose co-pay was reimbursed by an insurer or other third party.

The foregoing class is further subdivided into the following subclasses:

(a) brand name sub-class; and

(b) generic the sub-class

505. Plaintiffs also seek certification of each of the classes pursuant to Fed. R. Civ. P. 23 (b)(2) for Count III of the TAMCAC, in that 23 (b)(2) certification is appropriate as this Count seeks purely declaratory and injunctive relief. The class representatives for this Count are each of the plaintiffs, including the organizational plaintiffs.

506. The Class Period is January 1991 to the present.

507. Excluded from these classes are the defendants herein; any subsidiaries or affiliates of defendants; the officers and directors of defendants during the Class Period; members of the Individual Defendants' immediate families; any person, firm, trust, corporation, officer, director or any individual or entity in which any defendant has a controlling interest or which is related to, or affiliated with, any of the defendants; and the legal representatives, agents, affiliates, heirs, successors-in-interest or assigns of any such excluded party and governmental entities with respect to claims asserted for governmental damages.

508. The Classes consist of numerous individuals and entities throughout the United States, making individual joinder impractical, in satisfaction of Rule 23(a) (1). The disposition of the claims of the Class Members in a single class action will provide substantial benefits to all parties and to the Court.

509. The claims of the representative Plaintiffs are typical of the claims of the Class, as required by Rule 23(a) (3), in that the representative Plaintiffs include people and entities who, like all Class Members, purchased the AWPIDs at inflated prices based on AWPs. Such representative Plaintiffs, like all Class Members, have been damaged by Defendants' misconduct because, among other things, they paid prices for these drugs that were higher than they would have been but for Defendants' improper actions and have had medical providers make pharmacy decisions based on economic factors as opposed to purely medical factors.

510. The factual and legal bases of each Defendant's misconduct are common to the Class Members and represent a common thread of fraud and other misconduct resulting in injury to Plaintiffs and members of the Class.

511. There are many questions of law and fact common to Plaintiffs and the Class, and those questions predominate over any questions that may affect individual Class Members, within the meaning of and fulfilling Rules 23(a) (2) and 23(b)(2) and (3). Common questions of law and fact include, but are not limited to, the following:

a. Whether Defendants engaged in a fraudulent and/or deceptive scheme of improperly inflating the AWPs for the Drugs identified in Appendix A used by Plaintiffs and Class Members as the basis for reimbursement;

b. Whether Defendants artificially inflated the AWPs for these drugs;

c. Whether it was the policy and practice of Defendants to prepare marketing and sales materials that contained comparisons of the published AWPs and the spreads available;

d. Whether Defendants provided free samples of the AWPIDs to providers, and whether Defendants instructed them to bill Plaintiffs and the Class for those free samples;

e. Whether Defendants' provision of free samples to providers, with the intent that the providers bill Plaintiffs and the Class for the free samples, was unlawful;

f. Whether Defendants paid financial inducements to providers and other intermediaries, with the effect of lowering their costs for AWPIDs;

g. Whether Defendants engaged in a pattern and practice of paying illegal kickbacks, disguised as free goods, rebates, consulting fees, junkets and education grants to providers and other intermediaries;

h. Whether AWPs are used as a benchmark for negotiating payments by Third-Party Payors for the AWPIDs;

i. Whether Defendants engaged in a pattern and practice that caused Plaintiffs and Class Members to make inflated payments for the AWPIDs;.

j. Whether Defendants engaged in a pattern of deceptive and/or fraudulent activity intended to defraud Plaintiffs and the Class members;

k. Whether Defendants formed enterprises for the purpose of carrying out the AWP Scheme;

l. Whether Defendants used the U.S. mails and interstate wire facilities to carry out the AWP Scheme;

m. Whether Defendants' conduct violated RICO;

n. Whether Defendants are liable to Plaintiffs and the Class members for damages for conduct actionable under the various state consumer protection statutes.

512. Plaintiffs will fairly and adequately represent and protect the interests of the Class, as required by Rule 23(a)(4). Plaintiffs have retained counsel with substantial experience in prosecuting nationwide consumer class actions. Plaintiffs and their counsel are committed to

vigorously prosecuting this action on behalf of the Class, and have the financial resources to do so. Neither Plaintiffs nor their counsel have any interest adverse to those of the Class.

513. Plaintiffs and members of the Class have all suffered, and will continue to suffer, harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of this controversy under Rule 23(b)(3). Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the Courts and the litigants, and promotes consistency and efficiency of adjudication. Additionally, Defendants have acted and failed to act on grounds generally applicable to Plaintiffs and the Class and require Court imposition of uniform relief to ensure compatible standards of conduct toward the Class, thereby making appropriate equitable relief to the Class as a whole within the meaning of Rules 23(b)(1) and (b)(2).

**COUNT I[11]**

**VIOLATIONS OF 18 U.S.C. § 1962(C)**

**(AGAINST DEFENDANT DRUG MANUFACTURERS IDENTIFIED HEREIN FOR UNLAWFUL CONDUCT ASSOCIATED WITH AWPID DRUGS)**

514. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Amended Complaint.

[11] This Amended Complaint does not contain certain material struck or dismissed by the Court in its May 13, 2003 Memorandum and Order. For instance, many association plaintiffs and several RICO counts that were included in the MCC have not been included in this amended complaint in order to reduce the volume of an already lengthy pleading. However, plaintiffs incorporate by this reference, into this Complaint, material struck or dismissed by the Court in order to, if necessary, preserve appellate rights. Plaintiffs acknowledge that these allegations would be dismissed if reasserted.

515. This Count, which alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), is asserted against the Defendant Drug Manufacturers on behalf of the AWP classes with respect to all AWPID drugs not purchased through use of a PBM and includes drugs covered under Medicare Part B and those outside of Part B coverage. The pricing of all such AWPIDs was directly tied to the published AWPs

516. Plaintiffs, the members of Classes, and the Defendant Drug Manufacturers are each "persons," as that term is defined in 18 U.S.C. § 1961(3).

517. The following publishers of pharmaceutical industry compendia that periodically publish the AWPs, both in printed and electronic media, for various dosages of drugs are each "persons," as that term is defined in 18 U.S.C. § 1961(3): (a) **Thomson Medical Economics** ("Thomson Medical") is a division of Thomson Corporation, a Delaware corporation with its principal place of business located at One Station Place, Stamford, Connecticut, and it is the publisher of the *Drug Topics Red Book* (the "*Red Book*"); (b) **First DataBank, Inc.**, ("First DataBank") a Missouri corporation, with its principal place of business at 1111 Bayhill Drive, San Bruno, California, and it is the publisher of drug pricing information including, but not limited to, *American Druggist First Databank Annual Directory of Pharmaceuticals* and *Essential Directory of Pharmaceuticals*, commonly referred to as the *Blue Book*; (c) and **Facts & Comparisons, Inc.**, ("Facts & Comparisons") a division of Lippincott Williams & Wilkins, Inc., a Pennsylvania corporation which acquired all drug information reference products formerly published by Medi-Span, Inc. and which currently makes available drug pricing information, including, but not limited to, the Medi-Span *Master Drug Data Base*. These entities are sometimes collectively referred to herein as "the Publishers."

518. At all relevant times, in violation of 18 U.S.C. § 1962(c), the Defendant Drug Manufacturers conducted the affairs of certain association-in-fact enterprises identified herein, the affairs of which affected interstate commerce through a pattern of racketeering activity.

**The Manufacturer-Publisher Enterprises**

519. For purposes of this claim, certain RICO "enterprises" are associations-in-fact consisting of (a) one of the Publishers that reported AWPs for AWPIDs, and (b) a Defendant Drug Manufacturer, including its directors, employees and agents. These associations-in-fact are sometimes collectively referred to herein as the "Manufacturer-Publisher Enterprises." Each of the Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating pharmaceutical price information, which all too often includes disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to Plaintiffs and Class members, and (c) deriving profits from these activities. Each of the enterprises had a common purpose of perpetuating use of AWPs as a benchmark for reimbursement in the pharmaceutical industry, generally, and specifically for the drugs of that defendant. The manufacturing defendants have this as a purpose because without the AWP scheme, they would not be able to push the spread. The publishers agree to this scheme, because if they did not, the manufacturers could easily revert to the other methods of publishing prices or the publishers would have to independently investigate the AWP at significant expense. The Publishers also have an economic incentive to merely report the AWPs provided to them by the manufacturers, because to do otherwise would require the Publishers to spend money to extensively survey actual sales prices in the market. By simply republishing what is submitted to them by the drug manufacturers, the Publishers save on expenses and consequently reap greater profits. Thus, each of the Manufacturer-Publisher Enterprises has a common purpose of perpetuating the use of AWPs as a benchmark for reimbursement in the pharmaceutical industry.

520. Each of the Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities

between the Defendant Drug Manufacturer and the specific Publisher that are its associates. As to each of the Manufacturer-Publisher Enterprises, there is a common communication network by which the Defendant Drug Manufacturer and the specific Publisher share information on a regular basis. Typically this communication occurs by use of the wires and mails in which a manufacturer will instruct a publisher to list a certain AWP. As to each of the Manufacturer-Publisher Enterprises, the Defendant Drug Manufacturer and the specific Publisher functioned as a continuing unit. At all relevant times, each of the Manufacturer-Publisher Enterprises was operated by the specific Defendant Drug Manufacturer for criminal purposes, namely, carrying out the AWP Scheme.

521. At all relevant times, each one of the Publishers was aware of the Defendants Drug Manufacturers' AWP Scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme. Each of the publishing manufacturers is aware that the published AWPs are inflated. This awareness comes from the following sources: First, at some point prior to 1992 the publishers in many instances obtained AWPs themselves by survey. From their surveys of those in the distribution chain, they were and are aware that the reported AWPs were not accurate. Second, as various congressional bodies and government agencies reported on AWP inflation, the Publishers did not change or challenge the self-reported AWPs, but continued blindly accepting the requested AWPs. Third, when the State of Texas began prosecuting Dey for its AWP practices, and when other states began focusing on Dey, the Publishers stopped accepting Dey's reported AWPs and published a different, far lower AWP. They withdraw from the Dey enterprise due to fear that they would be sued if they continued to publish Dey's false AWPs. This prompted a lawsuit by Dey alleging that the Publishers were treating Dey differently than they were treating all other manufacturers. In other words, Dey was complaining of the others being allowed to continue the scheme while it could not.

522. The foregoing evidences the Publishers willing participation in the enterprise; their common purpose in the AWP scheme; and their agreement to a structure wherein the manufacturers made decisions as to what AWPs would be reported. This structure was the basis in which each of the enterprises was structured and its affairs conducted. The only exception occurred when the Publishers, fearing litigation, refused to accept Dey's instructions. The Publishers were willing participants in the scheme because if the truth were revealed the entire AWP reporting system would collapse.

523. For purposes of this count, the Manufacturer-Publisher Enterprises are identified as follows:

(a) *The Abbott Manufacturer-Publisher Enterprises:* The Abbott Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Abbott, and Abbott, including its directors, employees and agents: (1) the Abbott-Thomson Medical Enterprise; (2) the Abbott-First DataBank Enterprise; and (3) the Abbott-Facts & Comparisons Enterprise. Each of the Abbott Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Abbott Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Abbott and Thomson Medical, Abbott and First DataBank, and Abbott and Facts & Comparisons. As to each of these Abbott Manufacturer-Publisher Enterprises, there is a common

communication network by which Abbott and Thomson Medical, Abbott and First Data Bank, and Abbott and Facts & Comparisons share information on a regular basis. As to each of these Abbott-Manufacturer-Publisher Enterprises, Abbott and Thomson Medical, Abbott and First Data Bank, and Abbott and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Abbott Manufacturer-Publisher Enterprises was operated and conducted by Abbott for criminal purposes, namely, carrying out the AWP Scheme.

(b) *The Amgen Manufacturer-Publisher Enterprises:* The Amgen Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Amgen, and Amgen, including its directors, employees and agents: (1) the Amgen-Thomson Medical Enterprise; (2) the Amgen-First DataBank Enterprise; and (3) the Amgen-Facts & Comparisons Enterprise. Each of the Amgen Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Amgen Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Amgen and Thomson Medical, Abbott and First DataBank, and Abbott and Facts & Comparisons. As to each of these Amgen Manufacturer-Publisher Enterprises, there is a common communication network by which Amgen and Thomson Medical, Amgen and First Data Bank, and Amgen and Facts & Comparisons share information on a regular basis. As to

each of these Amgen-Manufacturer-Publisher Enterprises, Amgen and Thomson Medical, Amgen and First Data Bank, and Amgen and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Amgen Manufacturer-Publisher Enterprises was operated and conducted by Amgen for criminal purposes, namely, carrying out the AWP Scheme.

(c) *The AstraZeneca Manufacturer-Publisher Enterprises:* The AstraZeneca Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by AstraZeneca, and AstraZeneca, including its directors, employees and agents: (1) the AstraZeneca -Thomson Medical Enterprise; (2) the AstraZeneca -First DataBank Enterprise; and (3) the AstraZeneca -Facts & Comparisons Enterprise. Each of the AstraZeneca Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the AstraZeneca Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between AstraZeneca and Thomson Medical, AstraZeneca and First DataBank, and AstraZeneca and Facts & Comparisons. As to each of these AstraZeneca Manufacturer-Publisher Enterprises, there is a common communication network by which AstraZeneca and Thomson Medical, AstraZeneca and First Data Bank, and AstraZeneca and Facts & Comparisons share information on a regular basis. As to each of these AstraZeneca -Manufacturer-Publisher Enterprises, AstraZeneca and

Thomson Medical, AstraZeneca and First Data Bank, and AstraZeneca and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the AstraZeneca Manufacturer-Publisher Enterprises was operated and conducted by AstraZeneca for criminal purposes, namely, carrying out the AWP Scheme.

(d) *The Aventis Group Manufacturer-Publisher Enterprise:* The Aventis Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Aventis Group, and Aventis Group, including its directors, employees and agents: (1) the Aventis Group -Thomson Medical Enterprise; (2) the Aventis Group-First DataBank Enterprise; and (3) the Aventis Group-Facts & Comparisons Enterprise. Each of the Aventis Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Aventis Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Aventis Group and Thomson Medical, Aventis Group and First DataBank, and Aventis Group and Facts & Comparisons. As to each of these Aventis Group Manufacturer-Publisher Enterprises, there is a common communication network by which Aventis Group and Thomson Medical, Aventis Group and First Data Bank, and Aventis Group and Facts & Comparisons share information on a regular basis. As to each of these Aventis Group-Manufacturer-Publisher Enterprises, Aventis Group and Thomson Medical, Aventis Group and First Data Bank, and Aventis Group and Facts

& Comparisons functioned as continuing but separate units. At all relevant times, each of the Aventis Group Manufacturer-Publisher Enterprises was operated and conducted by Aventis Group for criminal purposes, namely, carrying out the AWP Scheme.

(e) *The Baxter Manufacturer-Publisher Enterprises:* The Baxter Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Baxter, and Baxter, including its directors, employees and agents: (1) the Baxter-Thomson Medical Enterprise; (2) the Baxter-First DataBank Enterprise; and (3) the Baxter Facts & Comparisons Enterprise. Each of the Baxter Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Baxter Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Baxter and Thomson Medical, Baxter and First DataBank, and Baxter and Facts & Comparisons. As to each of these Baxter Manufacturer-Publisher Enterprises, there is a common communication network by which Baxter and Thomson Medical, Baxter and First Data Bank, and Baxter and Facts & Comparisons share information on a regular basis. As to each of these Baxter-Manufacturer-Publisher Enterprises, Baxter and Thomson Medical, Baxter and First Data Bank, and Baxter and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Baxter Manufacturer-

Publisher Enterprises was operated and conducted by Baxter for criminal purposes, namely, carrying out the AWP Scheme.

(f) *The Bayer Manufacturer-Publisher Enterprises:* The Bayer Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Bayer, and Bayer, including its directors, employees and agents: (1) the Bayer-Thomson Medical Enterprise; (2) the Bayer-First DataBank Enterprise; and (3) the Bayer-Facts & Comparisons Enterprise. Each of the Bayer Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Bayer Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Bayer and Thomson Medical, Bayer and First DataBank, and Bayer and Facts & Comparisons. As to each of these Bayer Manufacturer-Publisher Enterprises, there is a common communication network by which Bayer and Thomson Medical, Bayer and First Data Bank, and Bayer and Facts & Comparisons share information on a regular basis. As to each of these Bayer Manufacturer-Publisher Enterprises, Bayer and Thomson Medical, Bayer and First Data Bank, and Bayer and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Bayer Manufacturer-Publisher Enterprises was operated and conducted by Bayer for criminal purposes, namely, carrying out the AWP Scheme.

(g) *The BMS Group Manufacturer-Publisher Enterprises:* The BMS Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by BMS Group, and BMS Group, including its directors, employees and agents: (1) the BMS Group-Thomson Medical Enterprise; (2) the BMS Group-First DataBank Enterprise; and (3) the BMS Group-Facts & Comparisons Enterprise. Each of the BMS Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the BMS Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between BMS Group and Thomson Medical, BMS Group and First DataBank, and BMS Group and Facts & Comparisons. As to each of these BMS Group Manufacturer-Publisher Enterprises, there is a common communication network by which BMS Group and Thomson Medical, BMS Group and First Data Bank, and BMS Group and Facts & Comparisons share information on a regular basis. As to each of these BMS Group Manufacturer-Publisher Enterprises, BMS Group and Thomson Medical, BMS Group and First Data Bank, and BMS Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the BMS Group Manufacturer-Publisher Enterprises was operated and conducted by BMS Group for criminal purposes, namely, carrying out the AWP Scheme.

(h) *The Dey Manufacturer-Publisher Enterprises:* The Dey Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Dey, and Dey, including its directors, employees and agents: (1) the Dey-Thomson Medical Enterprise; (2) the Dey-First DataBank Enterprise; and (3) the Dey-Facts & Comparisons Enterprise. Each of the Dey Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Dey Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Dey and Thomson Medical, Dey and First DataBank, and Dey and Facts & Comparisons. As to each of these Dey Manufacturer-Publisher Enterprises, there is a common communication network by which Dey and Thomson Medical, Dey and First Data Bank, and Dey and Facts & Comparisons share information on a regular basis. As to each of these Dey Manufacturer-Publisher Enterprises, Dey and Thomson Medical, Dey and First Data Bank, and Dey and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Dey Manufacturer-Publisher Enterprises was operated and conducted by Dey for criminal purposes, namely, carrying out the AWP Scheme.

(i) *The Fujisawa Group Manufacturer-Publisher Enterprises:* The Fujisawa Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided

to them by Fujisawa Group, and Fujisawa Group, including its directors, employees and agents: (1) the Fujisawa Group-Thomson Medical Enterprise; (2) the Fujisawa Group-First DataBank Enterprise; and (3) the Fujisawa Group-Facts & Comparisons Enterprise. Each of the Fujisawa Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Fujisawa Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Fujisawa Group and Thomson Medical, Fujisawa Group and First DataBank, and Fujisawa Group and Facts & Comparisons. As to each of these Fujisawa Group Manufacturer-Publisher Enterprises, there is a common communication network by which Fujisawa Group and Thomson Medical, Fujisawa Group and First Data Bank, and Fujisawa Group and Facts & Comparisons share information on a regular basis. As to each of these Fujisawa Group Manufacturer-Publisher Enterprises, Fujisawa Group and Thomson Medical, Fujisawa Group and First Data Bank, and Fujisawa Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Fujisawa Group Manufacturer-Publisher Enterprises was operated and conducted by Dey for criminal purposes, namely, carrying out the AWP Scheme.

(j) *The GSK Group Manufacturer-Publisher Enterprises:* The GSK Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by

GSK Group, and GSK Group, including its directors, employees and agents: (1) the GSK Group-Thomson Medical Enterprise; (2) the GSK Group-First DataBank Enterprise; and (3) the GSK Group-Facts & Comparisons Enterprise. Each of the GSK Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the GSK Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between GSK Group and Thomson Medical, GSK Group and First DataBank, and GSK Group and Facts & Comparisons. As to each of these GSK Group Manufacturer-Publisher Enterprises, there is a common communication network by which GSK Group and Thomson Medical, GSK Group and First Data Bank, and GSK Group and Facts & Comparisons share information on a regular basis. As to each of these GSK Group Manufacturer-Publisher Enterprises, GSK Group and Thomson Medical, GSK Group and First Data Bank, and GSK Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the GSK Group Manufacturer-Publisher Enterprises was operated and conducted by GSK Group for criminal purposes, namely, carrying out the AWP Scheme.

(k) *The Hoffman-La Roche Manufacturer-Publisher Enterprises:* The Hoffman-La Roche Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Hoffman-La Roche, and Hoffman-La Roche, including its

directors, employees and agents: (1) the Hoffman-La Roche-Thomson Medical Enterprise; (2) the Hoffman-La Roche-First DataBank Enterprise; and (3) the Hoffman-La Roche-Facts & Comparisons Enterprise. Each of the Hoffman-La Roche Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Hoffman-La Roche Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Hoffman-La Roche and Thomson Medical, Hoffman-La Roche and First DataBank, and Hoffman-La Roche and Facts & Comparisons. As to each of these Hoffman-La Roche Manufacturer-Publisher Enterprises, there is a common communication network by which Hoffman-La Roche and Thomson Medical, Hoffman-La Roche and First Data Bank, and Hoffman-La Roche and Facts & Comparisons share information on a regular basis. As to each of these Hoffman-La Roche Manufacturer-Publisher Enterprises, Hoffman-La Roche and Thomson Medical, Hoffman-La Roche and First Data Bank, and Hoffman-La Roche and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Hoffman-La Roche Manufacturer-Publisher Enterprises was operated and conducted by Hoffman-La Roche for criminal purposes, namely, carrying out the AWP Scheme.

(l) *The Immunex Manufacturer- Publisher Enterprises:* The Immunex Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by

Immunex, and Immunex, including its directors, employees and agents: (1) the Immunex-La Roche-Thomson Medical Enterprise; (2) the Immunex-First DataBank Enterprise; and (3) the Immunex-Facts & Comparisons Enterprise. Each of the Immunex Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Immunex Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Immunex and Thomson Medical, Immunex and First DataBank, and Immunex and Facts & Comparisons. As to each of these Immunex Manufacturer-Publisher Enterprises, there is a common communication network by which Immunex and Thomson Medical, Immunex and First Data Bank, and Immunex and Facts & Comparisons share information on a regular basis. As to each of these Immunex Manufacturer-Publisher Enterprises, Immunex and Thomson Medical, Immunex and First Data Bank, and Immunex and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Immunex Manufacturer-Publisher Enterprises was operated and conducted by Immunex for criminal purposes, namely, carrying out the AWP Scheme.

(m) *The Johnson & Johnson Group Manufacturer-Publisher Enterprise:* The Johnson & Johnson Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Johnson & Johnson Group, and Johnson & Johnson Group,

including its directors, employees and agents: (1) the Johnson & Johnson Group-La Roche-Thomson Medical Enterprise; (2) the Johnson & Johnson Group-First DataBank Enterprise; and (3) the Johnson & Johnson Group-Facts & Comparisons Enterprise. Each of the Johnson & Johnson Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Johnson & Johnson Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Johnson & Johnson Group and Thomson Medical, Johnson & Johnson Group and First DataBank, and Johnson & Johnson Group and Facts & Comparisons. As to each of these Johnson & Johnson Group Manufacturer-Publisher Enterprises, there is a common communication network by which Johnson & Johnson Group and Thomson Medical, Johnson & Johnson Group and First Data Bank, and Johnson & Johnson Group and Facts & Comparisons share information on a regular basis. As to each of these Johnson & Johnson Group Manufacturer-Publisher Enterprises, Johnson & Johnson Group and Thomson Medical, Johnson & Johnson Group and First Data Bank, and Johnson & Johnson Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Johnson & Johnson Group Manufacturer-Publisher Enterprises was operated and conducted by Johnson & Johnson Group for criminal purposes, namely, carrying out the AWP Scheme.

(n) *The Pfizer Manufacturer-Publisher Enterprises:* The Pfizer Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Pfizer, and Pfizer, including its directors, employees and agents: (1) the Pfizer-La Roche-Thomson Medical Enterprise; (2) the Pfizer-First DataBank Enterprise; and (3) the Pfizer-Facts & Comparisons Enterprise. Each of the Pfizer Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Pfizer Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Pfizer and Thomson Medical, Pfizer and First DataBank, and Pfizer and Facts & Comparisons. As to each of these Pfizer Manufacturer-Publisher Enterprises, there is a common communication network by which Pfizer and Thomson Medical, Pfizer and First Data Bank, and Pfizer and Facts & Comparisons share information on a regular basis. As to each of these Pfizer Manufacturer-Publisher Enterprises, Pfizer and Thomson Medical, Pfizer and First Data Bank, and Pfizer and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Pfizer Manufacturer-Publisher Enterprises was operated and conducted by Pfizer for criminal purposes, namely, carrying out the AWP Scheme.

(o) *The Pharmacia Group Manufacturer-Publisher Enterprises:* The Pharmacia Group Manufacturer-Publisher Enterprises are three separate associations-in-

fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Pharmacia Group, and Pharmacia Group, including its directors, employees and agents: (1) the Pharmacia Group-Thomson Medical Enterprise; (2) the Pharmacia Group-First DataBank Enterprise; and (3) the Pharmacia Group-Facts & Comparisons Enterprise. Each of the Pharmacia Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Pharmacia Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Pharmacia Group and Thomson Medical, Pharmacia Group and First DataBank, and Pharmacia Group and Facts & Comparisons. As to each of these Pharmacia Group Manufacturer-Publisher Enterprises, there is a common communication network by which Pharmacia Group and Thomson Medical, Pharmacia Group and First Data Bank, and Pharmacia Group and Facts & Comparisons share information on a regular basis. As to each of these Pharmacia Group Manufacturer-Publisher Enterprises, Pharmacia Group and Thomson Medical, Pharmacia Group and First Data Bank, and Pharmacia Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Pharmacia Group Manufacturer-Publisher Enterprises was operated and conducted by Pharmacia Group for criminal purposes, namely, carrying out the AWP Scheme.

(p) *The Schering-Plough Group Manufacturer-Publisher Enterprises:* The Schering-Plough Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Schering-Plough Group, and Schering-Plough Group, including its directors, employees and agents: (1) the Schering-Plough Group-Thomson Medical Enterprise; (2) the Schering-Plough Group-First DataBank Enterprise; and (3) the Schering-Plough Group-Facts & Comparisons Enterprise. Each of the Schering-Plough Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Schering-Plough Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Schering-Plough Group and Thomson Medical, Schering-Plough Group and First DataBank, and Schering-Plough Group and Facts & Comparisons. As to each of these Schering-Plough Group Manufacturer-Publisher Enterprises, there is a common communication network by which Schering-Plough Group and Thomson Medical, Schering-Plough Group and First Data Bank, and Schering-Plough Group and Facts & Comparisons share information on a regular basis. As to each of these Schering-Plough Group Manufacturer-Publisher Enterprises, Schering-Plough Group and Thomson Medical, Schering-Plough Group and First Data Bank, and Schering-Plough Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Schering-Plough Group

Manufacturer-Publisher Enterprises was operated and conducted by Schering-Plough Group for criminal purposes, namely, carrying out the AWP Scheme.

(q) *The Sicor Group Manufacturer-Publisher Enterprises:* The Sicor Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Sicor Group, and Sicor Group, including its directors, employees and agents: (1) the Sicor Group-Thomson Medical Enterprise; (2) the Sicor Group-First DataBank Enterprise; and (3) the Sicor Group-Facts & Comparisons Enterprise. Each of the Sicor Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Sicor Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Sicor Group and Thomson Medical, Sicor Group and First DataBank, and Sicor Group and Facts & Comparisons. As to each of these Sicor Group Manufacturer-Publisher Enterprises, there is a common communication network by which Sicor Group and Thomson Medical, Sicor Group and First Data Bank, and Sicor Group and Facts & Comparisons share information on a regular basis. As to each of these Sicor Group Manufacturer-Publisher Enterprises, Sicor Group and Thomson Medical, Sicor Group and First Data Bank, and Sicor Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Sicor

Group Manufacturer-Publisher Enterprises was operated and conducted by Sicor Group for criminal purposes, namely, carrying out the AWP Scheme.

(r) *The Watson Manufacturer-Publisher Enterprises:* The Watson Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Watson, and Watson, including its directors, employees and agents: (1) the Watson-Thomson Medical Enterprise; (2) the Watson-First DataBank Enterprise; and (3) the Watson-Facts & Comparisons Enterprise. Each of the Watson Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Watson Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Watson and Thomson Medical, Watson and First DataBank, and Watson and Facts & Comparisons. As to each of these Watson Manufacturer-Publisher Enterprises, there is a common communication network by which Watson and Thomson Medical, Watson and First Data Bank, and Watson and Facts & Comparisons share information on a regular basis. As to each of these Watson Manufacturer-Publisher Enterprises, Watson and Thomson Medical, Watson and First Data Bank, and Watson and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Watson Manufacturer-Publisher Enterprises was operated and conducted by Watson for criminal purposes, namely, carrying out the AWP Scheme.

(s) *The Warrick Manufacturer-Publisher Enterprises*: The Warrick Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Warrick, and Warrick, including its directors, employees and agents: (1) the Warrick-Thomson Medical Enterprise; (2) the Warrick-First DataBank Enterprise; and (3) the Warrick-Facts & Comparisons Enterprise. Each of the Warrick Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Warrick Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Warrick and Thomson Medical, Warrick and First DataBank, and Warrick and Facts & Comparisons. As to each of these Warrick Manufacturer-Publisher Enterprises, there is a common communication network by which Warrick and Thomson Medical, Warrick and First Data Bank, and Warrick and Facts & Comparisons share information on a regular basis. As to each of these Warrick Manufacturer-Publisher Enterprises, Warrick and Thomson Medical, Warrick and First Data Bank, and Warrick and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Warrick Manufacturer-Publisher Enterprises was operated and conducted by Warrick for criminal purposes, namely, carrying out the AWP Scheme.

**The Defendant Drug Manufacturers' Use of the U.S. Mails and Interstate Wire Facilities**

524. Each of the Manufacturer-Publisher Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: The transmission and publication of false and misleading information concerning AWPs; the sale, purchase and/or administration of AWPIDs; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission and/or receipt of invoices, statements and payments related to the use or administration of AWPIDs.

525. During the Class Period, the Defendants Drug Manufacturers' illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products and funds by the U.S. mails and interstate wire facilities.

526. The nature and pervasiveness of the Defendant Drug Manufacturers' AWP Scheme, which was orchestrated out of the corporate headquarters of the Defendant Drug Manufacturers, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with the various local district managers overseeing the sales force(s), the numerous pharmaceutical sales representatives who, in turn, directly communicated with providers and employees who communicated with the Publishers.

527. Many of the precise dates of Defendant Drug Manufacturers' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to these Defendants' books and records. Indeed, an essential part of the successful operation of the AWP Scheme alleged herein depended upon secrecy, and as alleged above, the Defendant Drug Manufacturers took deliberate steps to conceal their wrongdoing. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the AWP Scheme and do so below.

528. The Defendant Drug Manufacturers' use of the U.S. mails and interstate wire facilities to perpetrate the AWP Scheme involved thousands of communications throughout the Class Period including, *inter alia*:

(a) Marketing materials about the AWPs for AWPIDs and the available spread, which were sent by the Defendant Drug Manufacturers to health care providers located across the country;

(b) Written representations of the AWPs made by the Defendant Drug Manufacturers to the Publishers, which were made at least annually and in many cases several times during a single year;

(c) Documents providing information or incentives designed to lessen the prices that health care providers paid for AWPIDs and/or to conceal those prices or the AWP Scheme alleged here;

(d) Written communications, relating to rebates, kickbacks, or other financial inducements included, but not limited to, checks, as detailed herein;

(e) Written and oral communications directed to U.S. Government agencies and private insurers that fraudulently misrepresented what the AWPs were, or that were intended to deter investigations into the true nature of the AWPs or to forestall changes to reimbursement based on something other than AWPs;

(f) Written and oral communications with health insurers and patients, including Plaintiffs and members of the Class, inducing payments for the drugs that were made in reliance on AWPs; and

(g) Receipts of money sent on tens of thousands of occasions through the U.S. mails and interstate wire facilities – the wrongful proceeds of the Defendant Drug Manufacturers' AWP Scheme.

(h) In addition to the above-referenced RICO predicate acts, it was foreseeable to the Defendant Drug Manufacturers that the Publishers would distribute their publications containing false AWPs through the U.S. mails and by interstate wire facilities. Further, the Defendant Drug Manufacturers' corporate headquarters have, in furtherance of the AWP Scheme, communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions. These uses of the U.S. mails include some of the documents referenced in this Amended Complaint.

**Conduct of the RICO Enterprises' Affairs**

529. During the Class Period, the Defendant Drug Manufacturers have exerted control over their Manufacturer-Publisher Enterprises and, in violation of Section 1962(c) of RICO, the Defendant Drug Manufacturers have conducted or participated in the conduct of the affairs of those RICO enterprises, directly or indirectly, in the following ways:

(a) Each of the Defendant Drug Manufacturers has directly controlled the price for its AWPIDs;

(b) Each of the Defendant Drug Manufacturers has directly controlled the AWPs that are reported by the Publishers;

(c) Each of the Defendant Drug Manufacturers has directly controlled the creation and distribution of marketing, sales, and other materials used to inform health care providers nationwide of the profit potential of its AWPIDs;

(d) Each of the Defendant Drug Manufacturers has controlled and participated in the affairs of its Manufacturer-Publisher Enterprises by using a fraudulent scheme to manufacture, market and sell its AWPIDs on the basis of AWPs that each of the Defendant Drug Manufacturers provides to the Publishers;

(e) Each of the Defendant Drug Manufacturers intended that each of the Publishers would (and did) distribute their publications containing false AWPs through the U.S. mails and by interstate wire facilities; and

(f) Each of the publishers has allowed these Defendants to exert control over their organizations knowing that the AWPs were inflated and were not real numbers. Each publisher did so because the reporting of AWPs was, and is, a major part of its business.

530. Each of the Manufacturer-Publisher Enterprises had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer. The Defendant Drug Manufacturers issued instructions on how its AWPs were to be reported and each publisher accepted those instructions despite knowing of their falsity.

531. In violation of Section 1962(c) of RICO, each of the Defendant Drug Manufacturers have conducted the affairs of each of the Manufacturer-Publisher Enterprises with which they associated by reporting fraudulently inflated AWPs for AWPIDs that were then published by the Publishers and disseminated nationwide.

**The Defendant Drug Manufacturers' Pattern of Racketeering Activity**

532. Each of the Defendant Drug Manufacturers have conducted and participated in the affairs of their above-referenced Manufacturer-Publisher Enterprises through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The Defendant Drug Manufacturers' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their AWP Scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which the

Defendant Drug Manufacturers intended to defraud Plaintiffs, members of the Classes and other intended victims of the AWP Scheme.

533. The Defendants Drug Manufacturers' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWPs for their AWPIDs, thereby creating a "spread" based on the inflated figure in order to induce others to advocate and favor that Defendant Drug Manufacturer's AWPIDs. Further, others would bill their clients for the Defendant Drug Manufacturers' AWPIDs based on the inflated AWPs, which did not reflect the true price paid for the AWPIDs.

534. The AWP Scheme was calculated and intentionally crafted to ensure that Plaintiffs and members of the Classes would be over-billed for the drugs. In designing and implementing the AWP Scheme, at all times the Defendant Drug Manufacturers were cognizant of the fact that those in the distribution chain who are not part of the industry rely on the integrity of the Defendant Drug Manufacturers in setting the AWPs, as reported by the Publishers.

535. Each of the plaintiffs, to the extent they purchased drugs outside of the PBM context, made purchases with the price being tied to AWP.

536. By intentionally and artificially inflating the AWPs, and by subsequently failing to disclose such practices to the individual patients, health plans and their insurers, the Defendant Drug Manufacturers engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

537. The Defendant Drug Manufacturers' racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive Plaintiffs and members of the Classes. Each separate use of the U.S. mails and/or interstate wire facilities employed by the Defendant Drug Manufacturers was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the Classes. Each of the Defendant Drug

Manufacturers has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its particular Manufacturer-Publisher Enterprises.

**The Defendant Drug Manufacturers' Motive**

538. The Defendant Drug Manufacturers' motive in creating and operating the AWP Scheme and conducting the affairs of the Manufacturer-Publisher Enterprises described herein was to fraudulently obtain sales of and profits from their AWPIDs.

539. The AWP Scheme was designed to, and did, encourage others, including health care providers, to advocate the use of the Defendant Drug Manufacturers' AWPIDs. Thus, each of the Defendant Drug Manufacturers used the AWP Scheme to sell more of its drugs, thereby fraudulently gaining sales and market share and profits.

**Damages Caused by the Defendant Drug Manufacturers' AWP Scheme**

540. The Defendant Drug Manufacturers' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and members of the Classes to be injured in their business or property because Plaintiffs and members of the Classes have paid many hundreds of millions of dollars in inflated reimbursements or other payments for AWPIDs.

541. The Defendant Drug Manufacturers sent billing statements through the U.S. mails or by interstate wire facilities and reported AWPs and other information by the same methods in furtherance of their AWP Scheme. Plaintiffs and members of the Classes have made inflated payments for AWPIDs based on and/or in reliance on reported and false AWPs.

542. Under the provisions of Section 1964(c) of RICO, the Defendant Drug Manufacturers are jointly and severally liable to Plaintiffs and members of the Classes for three times the damages that Plaintiffs and the Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

**COUNT II**

**VIOLATIONS OF 18 U.S.C. § 1962(C)**

**(AGAINST DEFENDANT DRUG MANUFACTURERS IDENTIFIED HEREIN)**

543. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Amended Complaint.

544. This Count, which alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), is asserted against the Defendant Drug Manufacturers identified below on behalf of AWP Classes by the AWP Class representatives.

545. Plaintiffs, the members of Classes, and the Defendant Drug Manufacturers are each "persons," as that term is defined in 18 U.S.C. § 1961(3).

546. The following pharmacy benefit managers (collectively "PBMs") are each "persons," as that term is defined in 18 U.S.C. § 1961(3): (a) **AdvancePCS** ("Advance PCS"), a Delaware corporation with its principal place of business located at 750 West John Carpenter Freeway, Suite 1200, Irving, Texas; Advance PCS is the largest PBM in the United States and currently serves more than 75 million health plan members; (b) **Caremark, Rx, Inc.** ("Caremark Rx"), a Delaware corporation with its principal place of business located at 300 Galloria Tower, Suite 1000, Birmingham, Alabama; Caremark Rx is one of the largest pharmaceutical services companies in the United States with net revenues of approximately $5.6 billion in 2001; (c) **Express Scripts, Inc.** ("Express Scripts"), a Delaware corporation with its principal place of business located at 13900 Riverpoint Drive, Maryland Heights, Missouri; Express Scripts is the third largest PBM in North America; and (d) **Medco Health Solutions, Inc.** ("Medco Health"), a successor-in-interest to Merck-Medco Managed Care, L.L.C., is a Delaware corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey; since its acquisition in 1993, Medco Health has been a wholly-owned subsidiary of Defendant Drug Manufacturer Merck.

**The Manufacturer-PBM RICO Enterprises**

547. For purposes of this claim, the RICO "enterprises" are associations-in-fact consisting of (a) one of the PBMs that administered purchases of a Defendant Drug Manufacturer's brand name drugs and billed its members on the basis of the Defendant Drug Manufacturer's reported AWPs, and (b) a Defendant Drug Manufacturer, including its directors, employees and agents. These associations-in-fact are collectively referred to herein as the "Manufacturer-PBM Enterprises."

548. Each of the Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Classes that comprise health and welfare plans, and deriving profits from these activities.

549. Each of the Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between the Defendant Drug Manufacturer and the specific PBM that are associates. As to each of the Manufacturer-PBM Enterprises, there is a common communication network by which the Defendant Drug Manufacturer and the specific PBM share information on a regular basis. As to each of the Manufacturer-PBM Enterprises, the Defendant Drug Manufacturer and the specific PBM functioned as a continuing unit. At all relevant times, each of the Manufacturer-PBM Enterprises was operated by the specific Defendant Drug Manufacturer for criminal purposes, namely, carrying out the AWP Scheme.

550. Each manufacturer-PBM enterprise had a common purpose of perpetuating use of AWPs as a benchmark for reimbursement in the pharmaceutical industry. The manufacturing defendants had this as a purpose, because without the use of inflated AWPs as an industry price setting benchmark, they would not be able to push the spread to those in the distribution chain.

The PBMs share this common purpose, because they are subject to a great deal of control from the manufacturers. PBMs are now turning to drug manufacturers for hidden profit-making schemes, because PBM clients are no longer allowing PBMs to collect as much for claims administration. Thus, as a result, PBMs have, with the knowing and willful participation and assistance of the drug manufacturers, engaged in hidden profit-making schemes falling into three general categories: (i) garnering rebates and other "soft dollars" from drug manufacturers that the PBM Defendants, to a large extent, keep without disclosing to their health plans the true amounts of the rebates; (ii) pocketing secret spreads between actual drug costs and the prices charged to health plans and their members; and (iii) keeping secret discounts provided by the drug manufacturers in association with the PBMs' mail order operations.

551. The existence and magnitude of PBM rebates and accompanying profits at the expense of PBM clients is acknowledged within the PBM industry. For example, a recent industry report observed:

> [R]ebates paid to the PBMs by pharmaceutical companies continue to increase, as evidenced by the increasing PBM profits . . . . [T]his should hold true so long as the PBMs add value [apparently to the drug makers] by moving market share within drug classes.

552. Thus, PBMs were willing participants in the enterprise, and each participant in the enterprise shared many common purposes.

553. Further, as a result of their reliance on the manufacturers, PBMs took instructions and commands from the manufacturers regarding the use of AWP, not only so that they could keep part of the spread, but also so as to continue to earn from the manufacturers: (i) ***Access rebates*** for placement of products on the PBMs' formulary; (ii) ***Market share rebates*** for garnering higher market share than established targets; (iii) ***Administrative fees*** for assembling data to verify market share results; and (iv) ***Other fees and grants*** in an effort to promote products.

554. In order to garner all of these fees from the drug manufacturers, the PBMs each meet on a frequent basis to discuss drug prices, spreads, marketing opportunities and coordination of all of the above.

555. There is a common communication network between each PBM and each manufacturer for the purpose of implementing the AWP spread scheme and for the exchange of financial rewards for the PBMs activities that benefit the drug company manufacturers.

556. At all relevant times, each one of the PBMs was aware of the Defendants Drug Manufacturers' AWP Scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme.

557. For purposes of this count, the Manufacturer-PBM Enterprises are identified as follows:

(a) *The Abbott Manufacturer-PBM Enterprises:* The Abbott Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Abbott's AWPIDs and billed its members on the basis of Abbott's reported AWPs, and Abbott, including its directors, employees and agents: (1) the Abbott-AdvancePCS Enterprise; (2) the Abbott-Caremark Rx Enterprise; (3) the Abbott-Express Scripts Enterprise; and (4) the Abbott-Medco Health Enterprise. Each of the Abbott Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Abbott Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Abbott and AdvancePCS, Abbott and Caremark Rx, Abbott and Express Scripts, and Abbott and Medco Health. As to each of these Abbott

Manufacturer-PBM Enterprises, there is a common communication network by which Abbott and AdvancePCS, Abbott and Caremark Rx, Abbott and Express Scripts, and Abbott and Medco Health share information on a regular basis. As to each of these Abbott-Manufacturer-PBM Enterprises, Abbott and AdvancePCS, Abbott and Caremark Rx, Abbott and Express Scripts, and Abbott and Medco Health functioned as continuing but separate units. At all relevant times, each of the Abbott Manufacturer-PBM Enterprises was operated and conducted by Abbott for criminal purposes, namely, carrying out the AWP Scheme.

(b) *The Amgen Manufacturer-PBM Enterprises:* The Amgen Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Amgen's AWPIDs and billed its members on the basis of Amgen's reported AWPs, and Amgen, including its directors, employees and agents: (1) the Amgen-AdvancePCS Enterprise; (2) the Amgen-Caremark Rx Enterprise; (3) the Amgen-Express Scripts Enterprise; and (4) the Amgen-Medco Health Enterprise. Each of the Amgen Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Amgen Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Amgen and AdvancePCS, Amgen and Caremark Rx, Amgen and Express Scripts, and Amgen and Medco Health. As to each of these Amgen Manufacturer-PBM Enterprises, there is a common communication network by which Amgen and AdvancePCS, Amgen and Caremark Rx, Amgen and Express Scripts, and Amgen and Medco Health share information on a regular basis. As to each of these

Amgen-Manufacturer-PBM Enterprises, Amgen and AdvancePCS, Amgen and Caremark Rx, Amgen and Express Scripts, and Amgen and Medco Health functioned as continuing but separate units. At all relevant times, each of the Amgen Manufacturer-PBM Enterprises was operated and conducted by Amgen for criminal purposes, namely, carrying out the AWP Scheme.

(c) *The AstraZeneca Manufacturer-PBM Enterprises:* The AstraZeneca Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of AstraZeneca's AWPIDs and billed its members on the basis of AstraZeneca's reported AWPs, and AstraZeneca, including its directors, employees and agents: (1) the AstraZeneca-AdvancePCS Enterprise; (2) the AstraZeneca-Caremark Rx Enterprise; (3) the AstraZeneca-Express Scripts Enterprise; and (4) the AstraZeneca-Medco Health Enterprise. Each of the AstraZeneca Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the AstraZeneca Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between AstraZeneca and AdvancePCS, AstraZeneca and Caremark Rx, AstraZeneca and Express Scripts, and AstraZeneca and Medco Health. As to each of these AstraZeneca Manufacturer-PBM Enterprises, there is a common communication network by which AstraZeneca and AdvancePCS, AstraZeneca and Caremark Rx, AstraZeneca and Express Scripts, and AstraZeneca and Medco Health share information on a regular basis. As to each of these AstraZeneca-Manufacturer-PBM Enterprises, AstraZeneca and AdvancePCS, AstraZeneca and Caremark Rx, AstraZeneca and Express Scripts, and

AstraZeneca and Medco Health functioned as continuing but separate units. At all relevant times, each of the AstraZeneca Manufacturer-PBM Enterprises was operated and conducted by AstraZeneca for criminal purposes, namely, carrying out the AWP Scheme.

(d) *The Aventis Group Manufacturer-PBM Enterprise:* The Aventis Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Aventis Group's AWPIDs and billed its members on the basis of Aventis Group's reported AWPs, and Aventis Group, including its directors, employees and agents: (1) the Aventis Group-AdvancePCS Enterprise; (2) the Aventis Group-Caremark Rx Enterprise; (3) the Aventis Group-Express Scripts Enterprise; and (4) the Aventis Group-Medco Health Enterprise. Each of the Aventis Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Aventis Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Aventis Group and AdvancePCS, Aventis Group and Caremark Rx, Aventis Group and Express Scripts, and Aventis Group and Medco Health. As to each of these Aventis Group Manufacturer-PBM Enterprises, there is a common communication network by which Aventis Group and AdvancePCS, Aventis Group and Caremark Rx, Aventis Group and Express Scripts, and Aventis Group and Medco Health share information on a regular basis. As to each of these Aventis Group-Manufacturer-PBM Enterprises, Aventis Group and AdvancePCS, Aventis Group and Caremark Rx, Aventis Group and Express Scripts, and Aventis Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Aventis Group

Manufacturer-PBM Enterprises was operated and conducted by Aventis Group for criminal purposes, namely, carrying out the AWP Scheme.

(e) *The Baxter Manufacturer-PBM Enterprises:* The Baxter Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Amgen's AWPIDs and billed its members on the basis of Baxter's reported AWPs, and Baxter, including its directors, employees and agents: (1) the Baxter-AdvancePCS Enterprise; (2) the Baxter-Caremark Rx Enterprise; (3) the Baxter-Express Scripts Enterprise; and (4) the Baxter-Medco Health Enterprise. Each of the Baxter Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Baxter Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Baxter and AdvancePCS, Baxter and Caremark Rx, Baxter and Express Scripts, and Baxter and Medco Health. As to each of these Baxter Manufacturer-PBM Enterprises, there is a common communication network by which Baxter and AdvancePCS, Baxter and Caremark Rx, Baxter and Express Scripts, and Baxter and Medco Health share information on a regular basis. As to each of these Baxter-Manufacturer-PBM Enterprises, Baxter and AdvancePCS, Baxter and Caremark Rx, Baxter and Express Scripts, and Baxter and Medco Health functioned as continuing but separate units. At all relevant times, each of the Baxter Manufacturer-PBM Enterprises was operated and conducted by Baxter for criminal purposes, namely, carrying out the AWP Scheme.

(f) *The Bayer Manufacturer-PBM Enterprises:* The Bayer Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Bayer's AWPIDs and billed its members on the basis of Bayer's reported AWPs, and Bayer, including its directors, employees and agents: (1) the Bayer-AdvancePCS Enterprise; (2) the Bayer-Caremark Rx Enterprise; (3) the Bayer-Express Scripts Enterprise; and (4) the Bayer-Medco Health Enterprise. Each of the Bayer Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Bayer Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Bayer and AdvancePCS, Bayer and Caremark Rx, Bayer and Express Scripts, and Bayer and Medco Health. As to each of these Bayer Manufacturer-PBM Enterprises, there is a common communication network by which Bayer and AdvancePCS, Bayer and Caremark Rx, Bayer and Express Scripts, and Bayer and Medco Health share information on a regular basis. As to each of these Bayer-Manufacturer-PBM Enterprises, Bayer and AdvancePCS, Bayer and Caremark Rx, Bayer and Express Scripts, and Bayer and Medco Health functioned as continuing but separate units. At all relevant times, each of the Bayer Manufacturer-PBM Enterprises was operated and conducted by Bayer for criminal purposes, namely, carrying out the AWP Scheme.

(g) *The BMS Group Manufacturer-PBM Enterprises:* The BMS Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of BMS Group's AWPIDs and billed its members on the basis of BMS Group's reported AWPs, and BMS Group, including its

directors, employees and agents: (1) the BMS Group-AdvancePCS Enterprise; (2) the BMS Group-Caremark Rx Enterprise; (3) the BMS Group-Express Scripts Enterprise; and (4) the BMS Group-Medco Health Enterprise. Each of the BMS Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the BMS Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between BMS Group and AdvancePCS, BMS Group and Caremark Rx, BMS Group and Express Scripts, and BMS Group and Medco Health. As to each of these BMS Group Manufacturer-PBM Enterprises, there is a common communication network by which BMS Group and AdvancePCS, BMS Group and Caremark Rx, BMS Group and Express Scripts, and BMS Group and Medco Health share information on a regular basis. As to each of these BMS Group-Manufacturer-PBM Enterprises, BMS Group and AdvancePCS, BMS Group and Caremark Rx, BMS Group and Express Scripts, and BMS Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the BMS Group Manufacturer-PBM Enterprises was operated and conducted by BMS Group for criminal purposes, namely, carrying out the AWP Scheme.

(h) *The Fujisawa Group Manufacturer-PBM Enterprise:* The Fujisawa Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Fujisawa Group's AWPIDs and billed its members on the basis of Fujisawa Group's reported AWPs, and Fujisawa Group, including its directors, employees and agents: (1) the Fujisawa Group-AdvancePCS Enterprise; (2) the Fujisawa Group-Caremark Rx Enterprise; (3) the Fujisawa Group-

Express Scripts Enterprise; and (4) the Fujisawa Group-Medco Health Enterprise. Each of the Fujisawa Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Fujisawa Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Fujisawa Group and AdvancePCS, Fujisawa Group and Caremark Rx, Fujisawa Group and Express Scripts, and Fujisawa Group and Medco Health. As to each of these Fujisawa Group Manufacturer-PBM Enterprises, there is a common communication network by which Fujisawa Group and AdvancePCS, Fujisawa Group and Caremark Rx, Fujisawa Group and Express Scripts, and Fujisawa Group and Medco Health share information on a regular basis. As to each of these Fujisawa Group-Manufacturer-PBM Enterprises, Fujisawa Group and AdvancePCS, Fujisawa Group and Caremark Rx, Fujisawa Group and Express Scripts, and Fujisawa Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Fujisawa Group Manufacturer-PBM Enterprises was operated and conducted by Fujisawa Group for criminal purposes, namely, carrying out the AWP Scheme.

(i) *The GSK Group Manufacturer-PBM Enterprises:* The GSK Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of GSK Group's AWPIDs and billed its members on the basis of GSK Group's reported AWPs, and GSK Group, including its directors, employees and agents: (1) the GSK Group-AdvancePCS Enterprise; (2) the GSK Group-Caremark Rx Enterprise; (3) the GSK Group-Express Scripts Enterprise; and (4) the GSK Group-Medco Health Enterprise. Each of the GSK Group Manufacturer-

PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the GSK Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between GSK Group and AdvancePCS, GSK Group and Caremark Rx, GSK Group and Express Scripts, and GSK Group and Medco Health. As to each of these GSK Group Manufacturer-PBM Enterprises, there is a common communication network by which GSK Group and AdvancePCS, GSK Group and Caremark Rx, GSK Group and Express Scripts, and GSK Group and Medco Health share information on a regular basis. As to each of these GSK Group-Manufacturer-PBM Enterprises, GSK Group and AdvancePCS, GSK Group and Caremark Rx, GSK Group and Express Scripts, and GSK Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the GSK Group Manufacturer-PBM Enterprises was operated and conducted by GSK Group for criminal purposes, namely, carrying out the AWP Scheme.

(j) *The Hoffman-La Roche Manufacturer-PBM Enterprises:* The Hoffman-La Roche Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Hoffman-La Roche's AWPIDs and billed its members on the basis of Hoffman-La Roche's reported AWPs, and Hoffman-La Roche, including its directors, employees and agents: (1) the Hoffman-La Roche-AdvancePCS Enterprise; (2) the Hoffman-La Roche-Caremark Rx Enterprise; (3) the Hoffman-La Roche-Express Scripts Enterprise; and (4) the Hoffman-La Roche-Medco Health Enterprise. Each of the Hoffman-La Roche Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and

individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Hoffman-La Roche Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Hoffman-La Roche and AdvancePCS, Hoffman-La Roche and Caremark Rx, Hoffman-La Roche and Express Scripts, and Hoffman-La Roche and Medco Health. As to each of these Hoffman-La Roche Manufacturer-PBM Enterprises, there is a common communication network by which Hoffman-La Roche and AdvancePCS, Hoffman-La Roche and Caremark Rx, Hoffman-La Roche and Express Scripts, and Hoffman-La Roche and Medco Health share information on a regular basis. As to each of these Hoffman-La Roche Manufacturer-PBM Enterprises, Hoffman-La Roche and AdvancePCS, Hoffman-La Roche and Caremark Rx, Hoffman-La Roche and Express Scripts, and Hoffman-La Roche and Medco Health functioned as continuing but separate units. At all relevant times, each of the Hoffman-La Roche Manufacturer-PBM Enterprises was operated and conducted by Hoffman-La Roche for criminal purposes, namely, carrying out the AWP Scheme.

(k) *The Immunex Manufacturer-PBM Enterprises:* The Immunex Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Immunex's AWPIDs and billed its members on the basis of Immunex's reported AWPs, and Immunex, including its directors, employees and agents: (1) the Immunex-AdvancePCS Enterprise; (2) the Immunex-Caremark Rx Enterprise; (3) the Immunex-Express Scripts Enterprise; and (4) the Immunex-Medco Health Enterprise. Each of the Immunex Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both

corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Immunex Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Immunex and AdvancePCS, Immunex and Caremark Rx, Immunex and Express Scripts, and Immunex and Medco Health. As to each of these Immunex Manufacturer-PBM Enterprises, there is a common communication network by which Immunex and AdvancePCS, Immunex and Caremark Rx, Immunex and Express Scripts, and Immunex and Medco Health share information on a regular basis. As to each of these Immunex Manufacturer-PBM Enterprises, Immunex and AdvancePCS, Immunex and Caremark Rx, Immunex and Express Scripts, and Immunex and Medco Health functioned as continuing but separate units. At all relevant times, each of the Immunex Manufacturer-PBM Enterprises was operated and conducted by Immunex for criminal purposes, namely, carrying out the AWP Scheme.

(l) *The Johnson & Johnson Group Manufacturer-PBM Enterprise:* The Johnson & Johnson Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Johnson & Johnson Group's AWPIDs and billed its members on the basis of Johnson & Johnson Group's reported AWPs, and Johnson & Johnson Group, including its directors, employees and agents: (1) the Johnson & Johnson Group-AdvancePCS Enterprise; (2) the Johnson & Johnson Group-Caremark Rx Enterprise; (3) the Johnson & Johnson Group-Express Scripts Enterprise; and (4) the Johnson & Johnson Group-Medco Health Enterprise. Each of the Johnson & Johnson Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are

and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Johnson & Johnson Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Johnson & Johnson Group and AdvancePCS, Johnson & Johnson Group and Caremark Rx, Johnson & Johnson Group and Express Scripts, and Johnson & Johnson Group and Medco Health. As to each of these Johnson & Johnson Group Manufacturer-PBM Enterprises, there is a common communication network by which Johnson & Johnson Group and AdvancePCS, Johnson & Johnson Group and Caremark Rx, Johnson & Johnson Group and Express Scripts, and Johnson & Johnson Group and Medco Health share information on a regular basis. As to each of these Johnson & Johnson Group-Manufacturer-PBM Enterprises, Johnson & Johnson Group and AdvancePCS, Johnson & Johnson Group and Caremark Rx, Johnson & Johnson Group and Express Scripts, and Johnson & Johnson Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Johnson & Johnson Group Manufacturer-PBM Enterprises was operated and conducted by Johnson & Johnson Group for criminal purposes, namely, carrying out the AWP Scheme.

(m) *The Pfizer Manufacturer-PBM Enterprises:* The Pfizer Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Pfizer's AWPIDs and billed its members on the basis of Pfizer's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the Pfizer-AdvancePCS Enterprise; (2) the Pfizer-Caremark Rx Enterprise; (3) the Pfizer-Express Scripts Enterprise; and (4) the Pfizer-Medco Health Enterprise. Each of the Pfizer Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been

associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Pfizer Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Pfizer and AdvancePCS, Pfizer and Caremark Rx, Pfizer and Express Scripts, and Pfizer and Medco Health. As to each of these Pfizer Manufacturer-PBM Enterprises, there is a common communication network by which Pfizer and AdvancePCS, Pfizer and Caremark Rx, Pfizer and Express Scripts, and Pfizer and Medco Health share information on a regular basis. As to each of these Pfizer Manufacturer-PBM Enterprises, Pfizer and AdvancePCS, Pfizer and Caremark Rx, Pfizer and Express Scripts, and Pfizer and Medco Health functioned as continuing but separate units. At all relevant times, each of the Pfizer Manufacturer-PBM Enterprises was operated and conducted by Pfizer for criminal purposes, namely, carrying out the AWP Scheme.

(n) *The Pharmacia Group Manufacturer-PBM Enterprises:* The Pharmacia Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Pharmacia Group's AWPIDs and billed its members on the basis of Pharmacia Group's reported AWPs, and Pharmacia Group, including its directors, employees and agents: (1) the Pharmacia Group-AdvancePCS Enterprise; (2) the Pharmacia Group-Caremark Rx Enterprise; (3) the Pharmacia Group-Express Scripts Enterprise; and (4) the Pharmacia Group-Medco Health Enterprise. Each of the Pharmacia Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Pharmacia Group Manufacturer-PBM Enterprises has a

systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Pharmacia Group and AdvancePCS, Pharmacia Group and Caremark Rx, Pharmacia Group and Express Scripts, and Pharmacia Group and Medco Health. As to each of these Pharmacia Group Manufacturer-PBM Enterprises, there is a common communication network by which Pharmacia Group and AdvancePCS, Pharmacia Group and Caremark Rx, Pharmacia Group and Express Scripts, and Pharmacia Group and Medco Health share information on a regular basis. As to each of these Pharmacia Group-Manufacturer-PBM Enterprises, Pharmacia Group and AdvancePCS, Pharmacia Group and Caremark Rx, Pharmacia Group and Express Scripts, and Pharmacia Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Pharmacia Group Manufacturer-PBM Enterprises was operated and conducted by Pharmacia Group for criminal purposes, namely, carrying out the AWP Scheme.

(o) *The Schering-Plough Group Manufacturer-PBM Enterprises:* The Schering-Plough Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Schering-Plough Group's AWPIDs and billed its members on the basis of Schering-Plough Group's reported AWPs, and Schering-Plough Group, including its directors, employees and agents: (1) the Schering-Plough Group-AdvancePCS Enterprise; (2) the Schering-Plough Group-Caremark Rx Enterprise; (3) the Schering-Plough Group-Express Scripts Enterprise; and (4) the Schering-Plough Group-Medco Health Enterprise. Each of the Schering-Plough Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from

these activities. Each of the Schering-Plough Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Schering-Plough Group and AdvancePCS, Schering-Plough Group and Caremark Rx, Schering-Plough Group and Express Scripts, and Schering-Plough Group and Medco Health. As to each of these Schering-Plough Group Manufacturer-PBM Enterprises, there is a common communication network by which Schering-Plough Group and AdvancePCS, Schering-Plough Group and Caremark Rx, Schering-Plough Group and Express Scripts, and Schering-Plough Group and Medco Health share information on a regular basis. As to each of these Schering-Plough Group-Manufacturer-PBM Enterprises, Schering-Plough Group and AdvancePCS, Schering-Plough Group and Caremark Rx, Schering-Plough Group and Express Scripts, and Schering-Plough Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Schering-Plough Group Manufacturer-PBM Enterprises was operated and conducted by Schering-Plough Group for criminal purposes, namely, carrying out the AWP Scheme.

(p) *The Sicor Group Manufacturer-PBM Enterprises:* The Sicor Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Sicor Group's AWPIDs and billed its members on the basis of Sicor Group's reported AWPs, and Sicor Group, including its directors, employees and agents: (1) the Sicor Group-AdvancePCS Enterprise; (2) the Sicor Group-Caremark Rx Enterprise; (3) the Sicor Group-Express Scripts Enterprise; and (4) the Sicor Group-Medco Health Enterprise. Each of the Sicor Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering

AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Sicor Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Sicor Group and AdvancePCS, Sicor Group and Caremark Rx, Sicor Group and Express Scripts, and Sicor Group and Medco Health. As to each of these Sicor Group Manufacturer-PBM Enterprises, there is a common communication network by which Sicor Group and AdvancePCS, Sicor Group and Caremark Rx, Sicor Group and Express Scripts, and Sicor Group and Medco Health share information on a regular basis. As to each of these Sicor Group-Manufacturer-PBM Enterprises, Sicor Group and AdvancePCS, Sicor Group and Caremark Rx, Sicor Group and Express Scripts, and Sicor Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Sicor Group Manufacturer-PBM Enterprises was operated and conducted by Sicor Group for criminal purposes, namely, carrying out the AWP Scheme.

(q) *The Watson Manufacturer-PBM Enterprises:* The Watson Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Watson's AWPIDs and billed its members on the basis of Watson's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the Watson-AdvancePCS Enterprise; (2) the Watson-Caremark Rx Enterprise; (3) the Watson-Express Scripts Enterprise; and (4) the Watson-Medco Health Enterprise. Each of the Watson Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Watson Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of

activities between Watson and AdvancePCS, Watson and Caremark Rx, Watson and Express Scripts, and Watson and Medco Health. As to each of these Watson Manufacturer-PBM Enterprises, there is a common communication network by which Watson and AdvancePCS, Watson and Caremark Rx, Watson and Express Scripts, and Watson and Medco Health share information on a regular basis. As to each of these Watson Manufacturer-PBM Enterprises, Watson and AdvancePCS, Watson and Caremark Rx, Watson and Express Scripts, and Watson and Medco Health functioned as continuing but separate units. At all relevant times, each of the Watson Manufacturer-PBM Enterprises was operated and conducted by Watson for criminal purposes, namely, carrying out the AWP Scheme.

(r) *The Warrick Manufacturer-PBM Enterprises:* The Warrick Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Warrick's AWPIDs and billed its members on the basis of Warrick's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the Warrick-AdvancePCS Enterprise; (2) the Warrick-Caremark Rx Enterprise; (3) the Warrick-Express Scripts Enterprise; and (4) the Warrick-Medco Health Enterprise. Each of the Warrick Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Warrick Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Warrick and AdvancePCS, Warrick and Caremark Rx, Warrick and Express Scripts, and Warrick and Medco Health. As to each of these Warrick Manufacturer-PBM Enterprises, there is a common communication network by

which Warrick and AdvancePCS, Warrick and Caremark Rx, Warrick and Express Scripts, and Warrick and Medco Health share information on a regular basis. As to each of these Warrick Manufacturer-PBM Enterprises, Warrick and AdvancePCS, Warrick and Caremark Rx, Warrick and Express Scripts, and Warrick and Medco Health functioned as continuing but separate units. At all relevant times, each of the Warrick Manufacturer-PBM Enterprises was operated and conducted by Warrick for criminal purposes, namely, carrying out the AWP Scheme.

(s) *The Dey Manufacturer-PBM Enterprises:* The Dey Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Dey's AWPIDs and billed its members on the basis of Dey's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the Dey-AdvancePCS Enterprise; (2) the Dey-Caremark Rx Enterprise; (3) the Dey-Express Scripts Enterprise; and (4) the Dey-Medco Health Enterprise. Each of the Dey Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Dey Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Dey and AdvancePCS, Dey and Caremark Rx, Dey and Express Scripts, and Dey and Medco Health. As to each of these Dey Manufacturer-PBM Enterprises, there is a common communication network by which Dey and AdvancePCS, Dey and Caremark Rx, Dey and Express Scripts, and Dey and Medco Health share information on a regular basis. As to each of these Dey Manufacturer-PBM Enterprises, Dey and AdvancePCS, Dey and Caremark Rx, Dey and Express Scripts, and Dey and Medco Health functioned

as continuing but separate units. At all relevant times, each of the Dey Manufacturer-PBM Enterprises was operated and conducted by Dey for criminal purposes, namely, carrying out the AWP Scheme.

**The Defendant Drug Manufacturers' Use of the U.S. Mails and Interstate Wire Facilities**

558. Each of the Manufacturer-PBM Enterprises and Medco Health engaged in and affected interstate commerce because they engage in the following activities across state boundaries: The sale, purchase and/or administration of drugs; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission to patients of individual prescriptions for drugs by mail-order pharmacies; and/or the transmission and/or receipt of invoices, statements and payments related to the use or administration of drugs. During the Class Period, the Manufacturer-PBM Enterprises and Medco Health participated in the administration of prescription drugs to millions of individuals located throughout the United States.

559. During the Class Period, the Defendants Drug Manufacturers' illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products and funds by the U.S. mails and interstate wire facilities.

560. The nature and pervasiveness of the Defendant Drug Manufacturers' AWP Scheme, which was orchestrated out of the corporate headquarters of the Defendant Drug Manufacturers, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with the various local district managers overseeing the sales force(s), the numerous pharmaceutical sales representatives who, in turn, directly communicated with providers and employees who communicated with the PBMs, including Medco Health.

561. Many of the precise dates of Defendant Drug Manufacturers' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to these Defendants' books and records. Indeed, an essential part of the successful operation of the AWP Scheme alleged herein depended upon secrecy, and as alleged above, the Defendant Drug Manufacturers took deliberate steps to conceal their wrongdoing. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the AWP Scheme and do so below.

562. The Defendant Drug Manufacturers' use of the U.S. mails and interstate wire facilities to perpetrate the AWP Scheme involved thousands of communications throughout the Class Period including, *inter alia*:

(a) Marketing materials about the AWPs for brand name drugs and the available spread, which were sent by the Defendant Drug Manufacturers to PBMs (including Medco Health) located across the country;

(b) Written representations of the AWPs made by the Defendant Drug Manufacturers to the Publishers, which were made at least annually and in many cases several times during a single year;

(c) Thousands of written and oral communications discussing, negotiating and confirming the placement of a Defendant Drug Manufacturer's drugs on a particular PBM's formulary;

(d) Documents providing information or incentives designed to lessen the prices that each of the PBMs paid for drugs, and/or to conceal those prices or the AWP Scheme;

(e) Written communications, including checks, relating to rebates, kickbacks or other financial inducements paid to each of the PBMs to persuade them to advocate one Defendant Drug Manufacturers' drug over a drug manufactured by a competitor;

(f) Written and oral communications with U.S. Government agencies and private insurers that fraudulently misrepresented what the AWPs were, or that were intended to deter investigations into the true nature of the AWPs or to forestall changes to reimbursement based on something other than AWPs;

(g) Written and oral communications with health insurers and patients;

(h) Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities – the wrongful proceeds of the Defendant Drug Manufacturers' AWP Scheme; and

(i) In addition to the above-referenced RICO predicate acts, Defendants' corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions, in furtherance of the AWP Scheme. These mails include some of the documents referenced in this Amended Complaint.

**Conduct of the RICO Enterprises' Affairs**

563. During the Class Period, each of the Defendant Drug Manufacturers have exerted control over the Manufacturer-PBM Enterprises with which they were associated and, in violation of Section 1962(c) of RICO, each of the Defendant Drug Manufacturers have conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation was carried out in the following ways:

(a) Each of the Defendant Drug Manufacturers has directly controlled the price for its AWPIDs, which determines the amount of each of the PBMs' compensation;

(b) Each of the Defendant Drug Manufacturers has directly controlled the AWPs that are reported by the Publishers;

(c) Each of the Defendant Drug Manufacturers has directly controlled the creation and distribution of marketing, sales, and other materials used to inform each of the PBMs of the profit potential of its AWPIDs;

(d) Each of the Defendant Drug Manufacturers has relied upon its employees and agents to promote the AWP Scheme through the U.S. mails, through interstate wire facilities, and through direct contacts with providers and the PBMs; and

(e) Each of the Defendant Drug Manufacturers has controlled and participated in the affairs of the Manufacturer-PBM Enterprises with which they are associated by providing or receiving rebates (as detailed above) or other inducements to place a certain Defendant Drug Manufacturer's AWPIDs on a PBM formulary or advocate the use of a certain AWPID. These inducements include drug manufacturers' payment to PBMs of: (i) access rebates for placement of products on the PBMs' formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) administrative fees for assembling data to verify market share results; and (iv) other fees and grants. Although PBMs typically agree to share rebates in some form with clients, they link the rebates to formulary savings in such a manner that the PBM often is able to secretly retain all of the rebates. Furthermore, PBMs refuse to disclose specific rebate amounts to clients in any fashion other than in the aggregate compared to performance standards, thereby preventing the client from learning the true amount of rebates that the PBM has received in connection with the health plan client.

564. Each of the Manufacturer-PBM Enterprises identified above had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer.

565. In violation of Section 1962(c) of RICO, each of the Defendant Drug Manufacturers has conducted the affairs of each of the Manufacturer-PBM Enterprises with which they associated by reporting fraudulently inflated AWPs for AWPIDs and by submitting false and misleading invoices to Plaintiffs and members of the Classes, thereby inducing Plaintiffs and Class members to pay inflated amounts for AWPIDs.

**The Defendant Drug Manufacturers' Pattern of Racketeering Activity**

566. Each of the Defendant Drug Manufacturers has conducted and participated in the affairs of their respective Manufacturer-PBM Enterprises through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The Defendant Drug Manufacturers' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their AWP Scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1) (B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which the Defendant Drug Manufacturers intended to defraud Plaintiffs, members of the Classes and other intended victims of the AWP Scheme.

567. The Defendant Drug Manufacturers' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWPs for their AWPIDs, thereby creating a "spread" based on the inflated figure in order to induce each of the PBMs to advocate and favor that particular Defendant Drug Manufacturer's drugs to the members of that PBM's clients. Further, each of the PBMs billed their clients for the particular Defendant Drug Manufacturers' AWPIDs based on the inflated AWPs, which did not reflect the true price paid by the PBMs for the AWPIDs.

568. The AWP Scheme was calculated and intentionally crafted to ensure that Plaintiffs and members of the Classes would be over-billed for AWPIDs. In designing and implementing the AWP Scheme, at all times the Defendant Drug Manufacturers were cognizant of the fact those in the distribution chain that were not part of the enterprise relied upon the integrity of the Defendant Drug Manufacturers in setting the AWPs, as reported by the Publishers.

569. By intentionally and artificially inflating the AWPs, and by subsequently failing to disclose such practices to the individual patients and their insurers, each of the Defendant Drug Manufacturers engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

570. The Defendant Drug Manufacturers' racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive Plaintiffs and members of the Classes. Each separate use of the U.S. mails and/or interstate wire facilities employed by each of the Defendant Drug Manufacturers was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the Classes. Each of the Defendant Drug Manufacturers has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the respective Manufacturer-PBM Enterprises with which each of them is and was associated-in-fact.

**The Defendant Drug Manufacturers' Motive**

571. The Defendant Drug Manufacturers' motive in creating and operating the AWP Scheme and conducting the affairs of the Manufacturer-PBM Enterprises described herein was to fraudulently obtain sales of and profits from their AWPIDs.

572. The AWP Scheme was designed to, and did, encourage others, including health care providers, to advocate the use of the Defendant Drug Manufacturers' AWPIDs. Thus, each

of the Defendant Drug Manufacturers used the AWP Scheme to sell more of its drugs, thereby fraudulently gaining sales and market share and profits.

**Damages Caused by the Defendant Drug Manufacturers' AWP Scheme**

573. The Defendant Drug Manufacturers' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and members of the Classes to be injured in their business or property because Plaintiffs and Class members have paid many hundreds of millions of dollars in inflated reimbursements for AWPIDs.

574. The Defendant Drug Manufacturers sent billing statements through the U.S. mails or by interstate wire facilities and reported AWPs and other information by the same methods in furtherance of their AWP Scheme. Plaintiffs and members of the Classes have made inflated payments for AWPIDs based on and/or in reliance on reported and false AWPs.

575. Under the provisions of Section 1964(c) of RICO, the Defendant Drug Manufacturers are jointly and severally liable to Plaintiffs and members of the Classes for three times the damages that Plaintiffs and Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

**COUNT III**

**DECLARATORY AND OTHER RELIEF PURSUANT TO 28 U.S.C. §§ 2201, 2002**

**(AGAINST DEFENDANT DRUG MANUFACTURERS FOR UNLAWFUL CONDUCT ASSOCIATED WITH PHYSICIAN-ADMINISTERED AND MEDICARE PART B COVERED DRUGS)**

576. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint. This Court is asserted under Fed. R. Civ. P. 23(b)(2) by all Plaintiffs for the physician-administered-Medicare Part B drug class, including all consumers who made co-payments for Part B covered drugs; all TPP's making payments for Part B covered drugs; and all consumers and TPPs making payments for physician-administered drugs.

577. An actual case and controversy exists between the Plaintiffs and each of the Defendant Drug Manufacturers with respect to the Defendant Drug Manufacturers' conduct of inflating the published reimbursement rates for AWPIDs. The Plaintiffs contend that setting stated reimbursement prices above the actual average wholesale price for AWPIDs is unlawful, and that each Defendant Drug Manufacturer does so in violation of applicable law, knowing that Medicare beneficiaries and other end payors will incur similarly inflated co-payments and payments for AWPIDs.

578. Each Defendant Drug Manufacturer contends to the contrary. Each of the Defendant Drug Manufacturers, either by itself or through groups or its trade association, contend that they may exploit the Medicare reimbursement system without limit, and regardless of its effect on Medicare beneficiaries and their insurers.

579. The Plaintiffs, on behalf of themselves, their constituent members and all others similarly situated, are entitled to a judgment declaring that the practice of the Defendant Drug Manufacturers of inflating stated reimbursement rates for AWPIDs is unlawful, and are entitled to further relief pursuant to 28 U.S.C. § 2202.

**COUNT IV**

**VIOLATIONS OF CONSUMER PROTECTION STATUTES**

580. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint. This Count is in the TAMCAC to preserve Plaintiffs' right to appease the home state issues.

581. This Count is asserted by each Class by each class representative.

582. Defendants are incorporated, or maintain their principal places of business, in either California, Delaware, Illinois, New Jersey, Pennsylvania or Washington. In addition, individual Patient and Third-Party Payor Plaintiffs reside in either California, Florida, New

York, Minnesota, Louisiana, Pennsylvania or Texas. Each of these states has enacted statutes to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition and false advertising. The statutes of these states, legally and substantively common, provide consumers with a private right of action, as follows:

| | |
|---|---|
| *California*: | Cal. Civ. Code §§ 1750, Bus. & Prof. Code § 17200, *et seq.* and 17500, *et seq.* |
| *Delaware*: | 6 Del. Code §§ 2511-2537 |
| *Florida*: | Fla. Stat. Stat. §§ 501.201-501.213 |
| *Illinois*: | 815 ILCS § 505/1, *et seq.* |
| *Louisiana:* | La. Rev. Stat. Ann. § 51:1405 |
| *Minnesota:* | Minn. Stat. Ann. §§ 325D.09 - 325D.16, § 325F.67 - 69 |
| *New Jersey*: | N.J. Stat. Ann. §§ 56:8-1 - 56:8-24 |
| *New York*: | N.Y. Gen. Bus. L. §§ 349-350 |
| *Pennsylvania*: | 73 Pa. Stat. § 201-1 *et seq.* |
| *Texas:* | Tex. Bus. & Com. Code §§ 17.41 B 17.63 |
| *Washington:* | RCW 19.86.010, *et seq.* |

These statutes do not require a showing of either scienter or individual reliance.

583. Defendants' conduct, as alleged in this Complaint, constitutes unfair and deceptive acts or practices, unconscionable practices, fraud, false pretense, false promise, misrepresentation, concealment, suppression or omission of material fact in violation of these statutes. Defendants' continuing violations include:

> (a) Failing to disclose material facts in the conduct of trade or commerce in that they have not disclosed that the AWP does not reflect the true average wholesale price of the drugs they sell, and that the published AWPs are instead deliberately inflated in order to (1) increase the prices paid by Plaintiffs and the members of the Classes; (2) increase the profitability of the Defendant Drug Manufacturer's drugs to the providers who prescribe or dispense them, and to the other intermediaries that promote them; and thereby (3) increase Defendants' market shares and profits;

(b) Making false or misleading statements of fact concerning the price of goods in that they have not reported the true AWP paid for their medications in order to accomplish the goals described above;

(c) Knowingly making false representations in a transaction by representing that the AWP is an accurate reflection of the average wholesale price paid for their drugs when AWP is, in reality, a fictitious and inflated amount;

(d) Publishing fictitious and inflated AWPs in the *Red Book* and other publications;

(e) Encouraging Medicare Part B providers to use drugs based upon the "spread" as opposed to medicines being prescribed based on medical reasons; and

(f) Providing PBMs with a cut on the spread in return for the PBMs' participation in the AWP scheme.

584. Defendants willfully engaged in such practices knowing them to be deceptive and with the intent that Plaintiffs and the Class would rely thereon.

585. The wrongful conduct alleged in this Complaint occurs, and continues to occur, in the ordinary course of Defendants' business or occupation and has caused great harm to Plaintiffs and the Class, who were foreseeable and direct victims.

586. Defendants have injured the public interest, and Defendants' actions continue to pose a threat to the public.

587. As a direct and legal result of Defendants' misleading, deceptive, unfair, false and fraudulent trade practices, Plaintiffs and the Class have sustained damages.

## COUNT V

## VIOLATION OF CONSUMER PROTECTION LAWS – MEDICARE PART B CO-PAY SUB-CLASS

588. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein, and this Count is asserted in the event that the Court does not apply the laws asserted as applicable in Count IV.

589. This Count is asserted on behalf of a nationwide class of these persons who made a co-payment for a Part B covered drug manufactured by any defendant.

590. For the purposes of Track 1 proceedings, the following individuals are proposed class representatives for this class: Leroy Townsend (AstraZeneca); Susan Aaronson (GSK, J&J, BMS); David Clark (GSK, J&J); Robert Howe (AstraZeneca, GSK); James Shepley (J&J, Astra); Estate of Patricia Young (BMS, J&J); Estate of William Newell (AstraZeneca, J&J, BMS). With respect to Schering, plaintiffs proffer UFCW and SMW Health Fund made co-payments for Part B covered drugs and have the same incentive as any individual co-payor would have to represent this Class. To the extent that the Court finds any of these Plaintiffs inadequate, then Plaintiffs assert that the UFCW should be declared an adequate representative rather than leave the Class uncertified due to a lack of a plaintiff representative who made a co-payment under Medicare Part B. Alternatively, the following individuals also made co-payments based upon AWP for drugs manufactured by Track 1 defendants: Cynthia Byrski (BMS, GSK); Estate of William Barnewolt (J&J, Amgen, Abbott, Watson); Cheryl Barreca (J&J, BMS, GSK); Mary Cauble (BMS); Anna Choice (BMS, GSK); Joyce Dison (BMS); Tracy Garcia (BMS, Schering); Donna Kendall (GSK, BMS, J&J); Sandra Leef (BMS, Aventis, Abbott, Fujisawa); Gerald Miller (BMS); Constance Nelson (BMS, GSK); Andrea Palenica (BMS, GSK); Scott Tell (GSK, BMS); Pauline Vernick (BMS, Aventis); Mardolyn Vescovi (BMS, J&J); Kathleen Weaver-Zech (J&J); Susan Wessels (Astra); Joseph Miller (GSK, Baxter, Abbott); Regina Shoemaker (BMS); Kenneth Vanderwal (J&J); Rebecca Hopkins (BMS); and George Baker Thomson (Astra). They each have the same incentive as any Part B victim to recover damages and/or obtain injunctive relief.

591. For the purposes of Track 2 proceedings, the following individuals are proposed representatives: Susan Aaronson (Abbott, Amgen, Aventis, Baxter, Dey, Fujisawa, Pfizer, Pharmacia, Schering-Plough, Sicor and Watson); Harold Carter (Abbott, Amgen and Fujisawa);

Roger Clark (Baxter, Abbott, Amgen, Fujisawa, Pfizer, Sicor and Watson); Robert Howe (Abbott, Amgen, Aventis, Baxter, Fujisawa, Immunex, Sicor and Watson); James Monk (Aventis); Virginia Newell (Amgen and Aventis); Oral Roots (Dey, Pfizer); Hunter G. Walters (Dey); Larry Young (Abbott, Amgen, Aventis, Bayer, Baxter, Fujisawa, Immunex, Pfizer, Pharmacia, Sicor and Watson).

592. Certification of this sub-class is sought pursuant to Fed. R. Civ. P. 23(b)(3) for the damage claims and (b)(2) for the injunctive relief claims.

593. As described herein, each Defendant has intentionally and repeatedly used deception, fraud, false pretense, false promise, misrepresentation, and/or concealment, suppression or omission of material facts in connection with the sale or advertisement of AWPIDs. It was the intent of each Defendant that others rely on said concealment, suppression or omissions.

594. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state consumer protection statutes listed below:

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*, 1770;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

(n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

(w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

(ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*;

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

(ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, § 245 1, *et seq.*;

(ll) Defendants have engaged in unfair competition or unfair, deceptive acts or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

(mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.18, *et seq.*; and

(oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*

595. Plaintiffs provided notice of this litigation as follows: On January 9, 2002, to the Attorneys General of New Jersey, New York, Arizona, of Case 01-C-8828; of Case 01-CV-5427, of Case CV-N-H-01666, 01-5548, SA-01-1029; 01-4466, 01-1917, 01-CU-5790, 01-4303, 01-CU-5978, and 01-C-8827. The foregoing are cases against Baxter, Warrick, Aventis, Sicor, Dey, Immunex, GSK, BMS, Bayer and Abbott.

596. In addition, on October 6, 2005, notice was sent to each Attorney General in each of the states requiring notice and where demand on a defendant is required, such demand was made on or about October 6, 2005.

597. On October 6, 2005, plaintiffs sent notice pursuant to California Civil Code § 1782; Georgia Code § 10-1-399; Indiana Code § 24-5-0.5-5(a); Maine Revised Statutes, Title 5, § 50-634(g); Massachusetts General Laws Chapter 93A, § 9(3); Texas Business & Commercial Code § 17.505; West Virginia Code § 46A-6-106(b); and Wyoming Statutes § 40-12-109 to: Schering-Plough, J&J, BMS, GSK, and AstraZeneca for all classes.

598. On October 6, 2005, plaintiffs sent letters to Utah AG, Illinois AG, Washington AG, Oregon AG, New Jersey AG, Missouri AG, Mississippi AG, Kansas AG, Connecticut AG, Connecticut Commissioner, Louisiana AG notifying them of the filing of the SAC.

599. On November 17, 2005, plaintiffs sent demand letters pursuant to Mass. Gen. Laws Ch. 93A § 9(3) to: AZ, BMS, GSK, J&J, and Schering-Plough for Classes 2 & 3 for BCBS with damage amounts.

600. On July 10, 2006, plaintiffs sent demand letters pursuant to Mass. Gen. Laws Ch. 93A § 9(3) to: Dey, Immunex, Aventis, Fujisawa, Pfizer, Pharmacia, Bayer, Baxter, Amgen, Abbott, Watson and Sicor (Track 2 Defendants) for the "putative classes as defined in plaintiffs' proposed order in the *AWP Litigation*" (all classes).

601. On March 27, 2007, plaintiffs sent demand letters for all classes to all defendants. Each defendant has failed to respond to the demand letter and such response was made in bad

faith with reason to know that the acts complained of violated the consumer protection law of the applicable state and was an unfair and deceptive act or practice.

**COUNT VI**

**(VIOLATIONS OF CONSUMER PROTECTION LAWS – THIRD-PARTY PAYORS PART B MEDIGAP CLASS)**

602. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein, and this Count is asserted in the event that the Court does not apply the laws asserted as applicable in Count IV.

603. This Count is asserted on behalf of a nationwide class of third-party payors ("TPPs") who made a payment for drugs covered by Medicare Part B. The proposed class representatives are UFCW, PMBT, SMW Health Fund and BCBS of Massachusetts for Track 1. To the extent the Court limits this claim as a certified class for Massachusetts only for test purposes, each of these representatives is adequate. To the extent defendants assert that a non-Massachusetts entity cannot be an adequate class representative and the Court agrees, then the Court should allow the test case to be based on the law of the home state of the class representatives: Illinois and Tennessee.

604. In addition, for Track 1, Blue Cross and Blue Shield of Massachusetts and Sheet Metal Worker National Health Fund are proposed class representatives. In addition, for Track 2, SMW Health Fund is a proposed class representative for Class 2.

605. Plaintiffs seek to certify this class under Fed. R. Civ. P. 23(b)(3) for Plaintiffs' damage claims and Fed. R. Civ. P. (b)(2), for injunctive relief.

606. As described herein, defendant has intentionally and repeatedly used deception, fraud, false pretense, false promise, misrepresentation, and/or concealment, suppression or omission of material facts in connection with the sale or advertisement of AWPIDs. It was the intent of defendant that others rely on said concealment, suppression or omissions.

607. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state consumer protection statutes. Pursuant to the Court's Order of August 16, 2005, Plaintiffs identify the states that permit TPP claims under the consumer protection laws as set forth below.

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*, including 4-88-113(f), and 4-8-102(5);

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*, including § 6-1-113(1)© and § 6-1-102(b);

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*, including § 42-110(a)(3);

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq*, including 6 Del. Code § 2512;

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*, including § 28-390(1);

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*, including § 481A-2;

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*, including § 48-602;

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

(n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*, including § 13-101(h);

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*, including § 445-902(c);

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*, including § 407.010(5);

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*, including § 59-160(1);

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*, including § 358A:1(1);

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*, § 56:8-1(d);

(w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.,* including § 51-15-01(4);

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.,* including § 1345.01(B);

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*, including § 646.605(4);

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.,* including § 201-2(2);

(ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.,* including § 6-13.1(3);

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*, including § 39-5-10(9);

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.,* including § 37-24-1(8);

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.,* including § 47-18-103(9);

(ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.,* including § 17.45(4);

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, § 245 1, *et seq.*;

(ll) Defendants have engaged in unfair competition or unfair, deceptive acts or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.,* including § 19.86.010(1);

(mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.18, *et seq.*; and

(oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.,* including § 40-12-102(a)(i).

608. Plaintiffs provided notice of this litigation as follows: On January 9, 2002, to the Attorneys General of New Jersey, New York, Arizona, of Case 01-C-8828; of Case 01-CV-5427, of Case CV-N-H-01666, 01-5548, SA-01-1029; 01-4466, 01-1917, 01-CU-5790, 01-4303, 01-CU-5978, and 01-C-8827. The foregoing are cases against Baxter, Warrick, Aventis, Sicor, Dey, Immunex, GSK, BMS, Bayer and Abbott.

609. In addition, on October 6, 2005, notice was sent to each Attorney General in each of the states requiring notice and where demand on a defendant is required, such demand was made on October 6, 2005.

610. On October 6, 2005, plaintiffs sent notice pursuant to California Civil Code § 1782; Georgia Code § 10-1-399; Indiana Code § 24-5-0.5-5(a); Maine Revised Statutes,

Title 5, § 50-634(g); Massachusetts General Laws Chapter 93A, § 9(3); Texas Business & Commercial Code § 17.505; West Virginia Code § 46A-6-106(b); and Wyoming Statutes § 40-12-109 to: Schering-Plough, J&J, BMS, GSK, and AstraZeneca for all classes.

611. On October 6, 2005, plaintiffs sent letters to Utah AG, Illinois AG, Washington AG, Oregon AG, New Jersey AG, Missouri AG, Mississippi AG, Kansas AG, Connecticut AG, Connecticut Commissioner, Louisiana AG notifying them of the filing of the SAC.

612. On November 17, 2005, plaintiffs sent demand letters pursuant to Mass. Gen. Laws Ch. 93A § 9(3) to: AZ, BMS, GSK, J&J, and Schering-Plough for Classes 2 & 3 for BCBS with damage amounts.

613. On July 10, 2006, plaintiffs sent demand letters pursuant to Mass. Gen. Laws Ch. 93A § 9(3) to: Dey, Immunex, Aventis, Fujisawa, Pfizer, Pharmacia, Bayer, Baxter, Amgen, Abbott, Watson and Sicor (Track 2 Defendants) for the "putative classes as defined in plaintiffs' proposed order in the *AWP Litigation*" (all classes).

614. On March 27, 2007, plaintiffs sent demand letters for all classes to all defendants. Each defendant has failed to respond to the demand letter and such response was made in bad faith with reason to know that the acts complained of violated the consumer protection law of the applicable state and was an unfair and deceptive act or practice.

**COUNT VII**

**(VIOLATIONS OF CONSUMER PROTECTION LAWS – PHYSICIAN-ADMINISTERED CLASS FOR CONSUMERS AND TPPS)**

615. Plaintiffs incorporate by reference the preceding allegations as if fully set forth herein, and this Count is asserted in the event that the Count does not apply the laws asserted as applicable in Count IV.

616. Plaintiffs seek certification of this class pursuant to Fed. R. Civ. P. 23(b)(3) for damage claims and (b)(2) for injunctive relief claims.

617. The proposed consumer class representatives for this claim as to the Track 1 defendants are: Cynthia Byrski (BMS, GSK); Estate of William Barnewolt (J&J, Amgen, Abbott, Watson); Cheryl Barreca (J&J, BMS, GSK); Mary Cauble (BMS); Anna Choice (BMS, GSK); Joyce Dison (BMS); Tracy Garcia (BMS, Schering); Donna Kendall (GSK, BMS, J&J); Sandra Leef (BMS, Aventis, Abbott, Fujisawa); Gerald Miller (BMS); Constance Nelson (BMS, GSK); Andrea Palenica (BMS, GSK); Scott Tell (GSK, BMS); Pauline Vernick (BMS, Aventis); Mardolyn Vescovi (BMS, J&J); Kathleen Weaver-Zech (J&J); Susan Wessels (AstraZeneca); Joseph Miller (GSK, Baxter, Abbott); Regina Shoemaker (BMS); Kenneth Vanderwal (J&J); Rebecca Hopkins (BMS); and George Baker Thomson (AstraZeneca).

618. The TPP class representatives for this claim are: United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW"); Board of Trustees of Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund (CMHV); Teamsters Health & Welfare Fund of Philadelphia and Vicinity ("THWF"); Philadelphis Federation of Teachers Health and Welfare Fund ("PFTHW"); Man-U Service Contract Trust Fund ("Man-U"); and Twin Cities Bakery Workers Health and Welfare Fund ("TCBW").

619. The TPP class representatives for this class, to the extent it is limited to Massachusetts and BCBS of Massachusetts for Track 1, are Pipefitters Local 537 Trust Fund.

620. Since the Court did not require consumer representatives for Class 3, plaintiffs do not offer any but reserve the right to do so.

621. This sub-class is asserted for consumers and TPPs for physician-administered AWPIDs.

622. The consumer class groups its claims as follows:

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*, 1770;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

(n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

(w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

(ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*;

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

(ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, § 245 1, *et seq.*;

(ll) Defendants have engaged in unfair competition or unfair, deceptive acts or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

(mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.18, *et seq.*; and

(oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*

623. The TPP class groups its claims as set forth below:

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*, including 4-88-113(f), and 4-8-102(5);

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*, including § 6-1-113(1)© and § 6-1-102(b);

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*, including § 42-110(a)(3);

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq*, including 6 Del. Code § 2512;

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*, including § 28-390(1);

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*, including § 481A-2;

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*, including § 48-602;

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

(n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*, including § 13-101(h);

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*, including § 445-902(c);

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*, including § 407.010(5);

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*, including § 59-160(1);

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*, including § 358A:1(1);

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*, § 56:8-1(d);

(w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.,* including § 51-15-01(4);

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.,* including § 1345.01(B);

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.,* including § 646.605(4);

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.,* including § 201-2(2);

(ee) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.,* including § 6-13.1(3);

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*, including § 39-5-10(9);

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*, including § 37-24-1(8);

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*, including § 47-18-103(9);

(ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*, including § 17.45(4);

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, § 245 1, *et seq.*;

(ll) Defendants have engaged in unfair competition or unfair, deceptive acts or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*, including § 19.86.010(1);

(mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.18, *et seq.*; and

(oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*, including § 40-12-102(a)(i).

624. As described herein, Defendants have intentionally and repeatedly used deception, fraud, false pretense, false promise, misrepresentative, and/or concealment, suppression or omission of material facts in connection with the sale or advertisement of

AWPIDs. It was the intent of Defendants that others rely on said concealment, suppression or omissions.

625. On October 6, 2005, plaintiffs sent notice pursuant to California Civil Code § 1782; Georgia Code § 10-1-399; Indiana Code § 24-5-0.5-5(a); Maine Revised Statutes, Title 5, § 50-634(g); Massachusetts General Laws Chapter 93A, § 9(3); Texas Business & Commercial Code § 17.505; West Virginia Code § 46A-6-106(b); and Wyoming Statutes § 40-12-109 to: Schering-Plough, J&J, BMS, GSK, and AstraZeneca for all classes.

626. On October 6, 2005, plaintiffs sent letters to Utah AG, Illinois AG, Washington AG, Oregon AG, New Jersey AG, Missouri AG, Mississippi AG, Kansas AG, Connecticut AG, Connecticut Commissioner, Louisiana AG notifying them of the filing of the SAC.

627. On November 17, 2005, plaintiffs sent demand letters pursuant to Mass. Gen. Laws Ch. 93A § 9(3) to: AZ, BMS, GSK, J&J, and Schering-Plough for Classes 2 & 3 for BCBS with damage amounts.

628. On July 10, 2006, plaintiffs sent demand letters pursuant to Mass. Gen. Laws Ch. 93A § 9(3) to: Dey, Immunex, Aventis, Fujisawa, Pfizer, Pharmacia, Bayer, Baxter, Amgen, Abbott, Watson and Sicor (Track 2 Defendants) for the "putative classes as defined in plaintiffs' proposed order in the *AWP Litigation*" (all classes).

629. On March 27, 2007, plaintiffs sent demand letters for all classes to all defendants. Each defendant has failed to respond to the demand letter and such response was made in bad faith with reason to know that the acts complained of violated the consumer protection law of the applicable state and was an unfair and deceptive act or practice.

**COUNT VIII**

**CIVIL CONSPIRACY**

**(AGAINST ALL DEFENDANTS IDENTIFIED HEREIN FOR CONSPIRING WITH PBMS)**

630. Plaintiffs incorporate the preceding allegations as if fully set forth above.

631. This Court is asserted on behalf of the AWP Payor class by class representative CMHV and the Court has diversity jurisdiction over this claim.

632. Each of the defendants named below, for the purpose of implementing the AWP scheme, and thereby causing plaintiffs and the Class to overpay for AWPIDs, conspired with each of the four major PBMs: AdvancePCS, Caremark, Rx, Inc., Express Scripts, Inc. and Medco Health Solutions. The conspiratorial arrangements are as follows:

(a) *The Abbott Manufacturer-PBM Conspiracies:* The Abbott Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Abbott's AWPIDs and billed its members on the basis of Abbott's reported AWPs, and Abbott, including its directors, employees and agents: (1) the Abbott-AdvancePCS; (2) the Abbott-Caremark Rx; (3) the Abbott-Express Scripts; and (4) the Abbott-Medco Health. Each of the Abbott Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(b) *The Amgen Manufacturer-PBM Conspiracies:* The Amgen Manufacturer-PBM Conspiracies are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Amgen's AWPIDs and billed its members on the basis of Amgen's reported AWPs, and Amgen, including its directors, employees and agents: (1) the Amgen-AdvancePCS; (2) the Amgen-Caremark Rx; (3) the Amgen-Express Scripts; and (4) the Amgen-Medco Health. Each of the Amgen Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of

selling, purchasing, prescribing and administering AWPID drugs to individual Plaintiffs and Class members.

(c) *The AstraZeneca Manufacturer-PBM Conspiracies:* The AstraZeneca Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of AstraZeneca's AWPIDs and billed its members on the basis of AstraZeneca's reported AWPs, and AstraZeneca, including its directors, employees and agents: (1) the AstraZeneca-AdvancePCS; (2) the AstraZeneca-Caremark Rx; (3) the AstraZeneca-Express Scripts; and (4) the AstraZeneca-Medco Health. Each of the AstraZeneca Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(d) *The Aventis Group Manufacturer-PBM Conspiracies:* The Aventis Group Manufacturer-PBM Conspiracies are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Aventis Group's AWPIDs and billed its members on the basis of Aventis Group's reported AWPs, and Aventis Group, including its directors, employees and agents: (1) the Aventis Group-AdvancePCS; (2) the Aventis Group-Caremark Rx; (3) the Aventis Group-Express Scripts; and (4) the Aventis Group-Medco Health. Each of the Aventis Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(e) *The Baxter Manufacturer-PBM Conspiracies:* The Baxter Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Baxter's AWPIDs and billed its members on the basis of

Baxter's reported AWPs, and Baxter, including its directors, employees and agents: (1) the Baxter-AdvancePCS; (2) the Baxter-Caremark Rx; (3) the Baxter-Express Scripts; and (4) the Baxter-Medco Health. Each of the Baxter Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(f) *The Bayer Manufacturer-PBM Conspiracies:* The Bayer Manufacturer-PBM Conspiracy are four separate conspiracies consisting of each of the PBMs that administered purchases of Bayer's AWPIDs and billed its members on the basis of Bayer's reported AWPs, and Bayer, including its directors, employees and agents: (1) the Bayer-AdvancePCS; (2) the Bayer-Caremark Rx; (3) the Bayer-Express Scripts; and (4) the Bayer-Medco Health. Each of the Bayer Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(g) *The BMS Group Manufacturer-PBM Conspiracies:* The BMS Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of BMS Group's AWPIDs and billed its members on the basis of BMS Group's reported AWPs, and BMS Group, including its directors, employees and agents: (1) the BMS Group-AdvancePCS; (2) the BMS Group-Caremark Rx; (3) the BMS Group-Express Scripts; and (4) the BMS Group-Medco Health. Each of the BMS Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been

associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(h) *The GSK Group Manufacturer-PBM Conspiracies:* The GSK Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of GSK Group's AWPIDs and billed its members on the basis of GSK Group's reported AWPs, and GSK Group, including its directors, employees and agents: (1) the GSK Group-AdvancePCS; (2) the GSK Group-Caremark Rx; (3) the GSK Group-Express Scripts; and (4) the GSK Group-Medco Health. Each of the GSK Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(i) *The Hoffman-La Roche Manufacturer-PBM Conspiracies:* The Hoffman-La Roche Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Hoffman-La Roche's AWPIDs and billed its members on the basis of Hoffman-La Roche's reported AWPs, and Hoffman-La Roche, including its directors, employees and agents: (1) the Hoffman-La Roche-AdvancePCS; (2) the Hoffman-La Roche-Caremark Rx; (3) the Hoffman-La Roche-Express Scripts; and (4) the Hoffman-La Roche-Medco Health. Each of the Hoffman-La Roche Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(j) *The Immunex Manufacturer-PBM Enterprises:* The Immunex Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the

PBMs that administered purchases of Immunex's AWPIDs and billed its members on the basis of Immunex's reported AWPs, and Immunex, including its directors, employees and agents: (1) the Immunex-AdvancePCS; (2) the Immunex-Caremark Rx; (3) the Immunex-Express Scripts; and (4) the Immunex-Medco Health. Each of the Immunex Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(k) *The Johnson & Johnson Group Manufacturer-PBM Conspiracies:* The Johnson & Johnson Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Johnson & Johnson Group's AWPIDs and billed its members on the basis of Johnson & Johnson Group's reported AWPs, and Johnson & Johnson Group, including its directors, employees and agents: (1) the Johnson & Johnson Group-AdvancePCS; (2) the Johnson & Johnson Group-Caremark Rx; (3) the Johnson & Johnson Group-Express Scripts; and (4) the Johnson & Johnson Group-Medco Health. Each of the Johnson & Johnson Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(l) *The Pfizer Manufacturer-PBM Conspiracies:* The Pfizer Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Pfizer's AWPIDs and billed its members on the basis of Pfizer's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the Pfizer-AdvancePCS; (2) the Pfizer-Caremark Rx; (3) the Pfizer-Express Scripts;

and (4) the Pfizer-Medco Health. Each of the Pfizer Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(m) *The Pharmacia Group Manufacturer-PBM Conspiracies:* The Pharmacia Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Pharmacia Group's AWPIDs and billed its members on the basis of Pharmacia Group's reported AWPs, and Pharmacia Group, including its directors, employees and agents: (1) the Pharmacia Group-AdvancePCS; (2) the Pharmacia Group-Caremark Rx; (3) the Pharmacia Group-Express Scripts; and (4) the Pharmacia Group-Medco Health. Each of the Pharmacia Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(n) *The Schering-Plough Group Manufacturer-PBM Conspiracies:* The Schering-Plough Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Schering-Plough Group's AWPIDs and billed its members on the basis of Schering-Plough Group's reported AWPs, and Schering-Plough Group, including its directors, employees and agents: (1) the Schering-Plough Group-AdvancePCS; (2) the Schering-Plough Group-Caremark Rx; (3) the Schering-Plough Group-Express Scripts; and (4) the Schering-Plough Group-Medco Health. Each of the Schering-Plough Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals

that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(o) *The Sicor Group Manufacturer-PBM Conspiracies:* The Sicor Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Sicor Group's AWPIDs and billed its members on the basis of Sicor Group's reported AWPs, and Sicor Group, including its directors, employees and agents: (1) the Sicor Group-AdvancePCS; (2) the Sicor Group-Caremark Rx; (3) the Sicor Group-Express Scripts; and (4) the Sicor Group-Medco Health. Each of the Sicor Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(p) *The Watson Manufacturer-PBM Conspiracies:* The Watson Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Watson's AWPIDs and billed its members on the basis of Watson's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the Watson-AdvancePCS; (2) the Watson-Caremark Rx; (3) the Watson-Express Scripts; and (4) the Watson-Medco Health. Each of the Watson Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(q) *The Warrick Manufacturer – PBM Conspiracies:* The Warrick Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the

PBMs that administered purchases of Warrick's AWPIDs and billed its members on the basis of Warrick's reported AWPs, and Pfizer, including its directors, employees and agents: (1) Warrick-AdvancePCS; (2) Warrick-Caremark Rx; (3) Warrick-Express Scripts; and (4) Warrick-Medco Health. Each of the Warrick Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(r) *The Dey-PBM Conspiracies:* The Dey-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Dey's AWPIDs and billed its members on the basis of Dey's reported AWPs, and Pfizer, including its directors, employees and agents: (1) Dey -AdvancePCS; (2) Dey-Caremark Rx; (3) Dey -Express Scripts; and (4) Dey -Medco Health. Each of Dey-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(s) *The Fujisawa-PBM Conspiracies:* The Fujisawa-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Fujisawa's AWPIDs and billed its members on the basis of Fujisawa's reported AWPs, and Pfizer, including its directors, employees and agents: (1) Fujisawa-AdvancePCS; (2) Fujisawa-Caremark Rx; (3) Fujisawa-Express Scripts; and (4) Fujisawa-Medco Health. Each of Fujisawa-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the

common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

633. Defendants consciously conspired and deliberately pursued a common plan or design to commit tortious acts, with each PBM that was part of its conspiracy, subjecting each to joint liability. Each Defendant Drug Manufacturer and each PBM had the common purpose of perpetuating a reimbursement system based on AWP, because such a system financially benefits ***both*** the manufacturer and the PBM. The Defendant Drug Manufacturers deliberately and fraudulently overstate the AWPs for their AWPIDs, thereby creating a "spread" based on the inflated figure in order to obtain each of the PBM agreement to advocate and favor that particular Defendant Drug Manufacturer's drugs to the members of that PBM's clients. Each of the PBMs then billed their clients for the particular Defendant Drug Manufacturers' AWPIDs based on the inflated AWPs, which did not reflect the true price paid by the PBMs for the AWPIDs. All of these acts – and more – were done as part of a conspiracy to deceive payors, in violation of applicable state consumer protection laws and the common law of fraud. All of these acts were done in violation of Medicare anti-fraud kickback statutes and were done pursuant to acts of wire and mail fraud.

634. Defendants each committed an unlawful act or acts in furtherance of this conspiracy, including:

(a) Issuing false marketing materials about the AWPs for AWPIDs and the available spread, which were sent by the Defendant Drug Manufacturers to PBMs (including Medco Health) located across the country;

(b) Written representations of the AWPs made by the Defendant Drug Manufacturers to the Publishers, which were made at least annually and in many cases several times during a single year and which the PBMs knew were false;

(c) Thousands of written and oral communications discussing, negotiating and confirming the placement of a Defendant Drug Manufacturer's brand name drugs on a particular PBM's formulary;

(d) Documents providing information or incentives designed to lessen the prices that each of the PBMs paid for AWPIDs, and/or to conceal those prices or the AWP Scheme;

(e) Written communications, including checks, relating to rebates, kickbacks or other financial inducements paid to each of the PBMs to persuade them to advocate one Defendant Drug Manufacturers' AWPIDs over a drug manufactured by a competitor;

(f) Written and oral communications with U.S. Government agencies and private insurers that fraudulently misrepresented what the AWPs were, or that were intended to deter investigations into the true nature of the AWPs or to forestall changes to reimbursement based on something other than AWPs;

(g) Written and oral communications with health insurers and patients, including Plaintiffs and the members of Classes, inducing payments for the drugs that were made in reliance on AWPs; and

(h) Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities – the wrongful proceeds of the Defendant Drug Manufacturers' AWP Scheme.

635. All of these acts were done as part of a conspiracy to deceive end payors, in violation of applicable state consumer protection laws and the common law of fraud. All of these acts were also committed in violation of applicable Medicare anti-fraud kickback statutes, and were committed pursuant to acts of unlawful instances of mail and wire fraud.

636. Plaintiffs are entitled to a presumption of reliance on the false representations, concealments and nondisclosures by Defendants. The Class Members were ignorant of

Defendants' representations and were ignorant of the full and true facts suppressed by Defendants, and such reliance was justified.

637. As a direct, proximate result of this conspiracy, Plaintiffs and Class Members have been injured, as they have suffered and continue to suffer economic losses and general and specific damages, all in an amount to be determined according to proof.

**COUNT IX**

**COMMON LAW FRAUD**

**(AGAINST ALL DEFENDANTS AND ON BEHALF OF CLASS 1)**

638. Plaintiffs, on behalf of themselves and all others similarly, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs.

639. This Count, which alleges common law fraud, is asserted against all Defendants on behalf of the members of Class 1.

640. Defendants have committed fraud as follows:

(a) Defendants' publication and distribution of AWPs constituted representations;

(b) Those representations were false in that the AWPs were not actual averages and did not reflect discounts and other cost advantages given to physicians;

(c) The representations were material in that they were sufficiently important to influence a reasonable person's actions;

(d) Defendants knew that the representations were false;

(e) Defendants intended that Plaintiffs would act upon the representations in the manner reasonably contemplated by Defendants (that is, by making Medicare Part B co-payments based on Defendants' AWPs);

(f) Plaintiffs did not know that the representations were false;

(g) Plaintiffs relied on the truth of the representations in making their Medicare Part B co-payments;

(h) Plaintiffs' reliance was reasonable and justified under the circumstances; and

(i) As a direct and proximate result, Plaintiffs and the members of Class 1 have been damaged by making inflated Medicare Part B co-payments.

## VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that:

A. The Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for declaratory, equitable and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages, and declaring Plaintiffs as representatives of the Classes and their counsel as counsel for the Classes;

B. The conduct alleged herein be declared, adjudged and decreed to be unlawful;

C. Plaintiffs and the Classes be granted an award of damages in such amount to be determined at trial to the full extent to all remedies as provided by law, with trebling where permitted by law;

D. Plaintiffs and the Classes be granted an award of punitive damages in such amount to be determined at trial;

E. Defendants be enjoined from continuing the illegal activities alleged herein;

F. Plaintiffs and the Classes recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and

G. Plaintiffs and the Classes be granted such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

## IX. DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all issues so triable.

DATED: February 17, 2009

By **/s/ Steve W. Berman**
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**CERTIFICATE OF SERVICE**

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing, **REVISED FIFTH AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT**, to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on February 17, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

**/s/ Steve W. Berman**
Steve W. Berman