

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

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

MASTER CONSOLIDATED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

| | Page |
|--|-------------|
| I. INTRODUCTION | 3 |
| II. JURISDICTION AND VENUE | 5 |
| III. PARTIES | 6 |
| 1. Individual Patients | 6 |
| 2. Third-Party Payors | 8 |
| 3. Non-Profit Associations Whose Members Purchased Prescription Drugs | 10 |
| IV. GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS..... | 32 |
| A. The AWP System..... | 32 |
| B. The Defendant Drug Manufacturers’ Use Of AWP Fraud To Increase Market Share For Their Drugs Covered By Medicare Part B | 34 |
| 1. The Medicare Insurance Program..... | 34 |
| 2. Congressional and Other Federal Investigations and Actions | 36 |
| 3. The Defendant Drug Manufacturers’ Fraudulent Conduct Within the Medicare Part B Program..... | 39 |
| a. Artificially Inflating AWPs..... | 39 |
| b. Improper Use of Free Samples | 40 |
| c. Other Hidden and Improper Inducements and Price Reductions..... | 40 |
| C. The Defendant Drug Manufacturers’ Use Of AWP Fraud To Increase And Maintain The High Price Of Their Brand Name Drugs Outside Of The Medicare Part B Context | 41 |
| D. Defendants’ Concealment of the Truth..... | 42 |
| E. Tolling of Applicable Statutes of Limitation | 44 |
| V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT | 44 |
| A. Abbott | 44 |
| B. Amgen..... | 46 |

| | | |
|-------|---|-----|
| C. | AstraZeneca | 47 |
| D. | The Aventis Group (Aventis, Pharma, Hoechst and Behring)..... | 50 |
| E. | Baxter | 52 |
| F. | Bayer..... | 54 |
| G. | The Boehringer Group (Boehringer, Ben Verue, Bedford) | 57 |
| H. | Braun..... | 58 |
| I. | The BMS Group (Bristol-Myers, OTN and Apothecon)..... | 59 |
| J. | Dey | 61 |
| K. | The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)..... | 63 |
| L. | The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Welcome)..... | 64 |
| | 1. Glaxo’s Zofran | 65 |
| | 2. SKB’s Kytril | 69 |
| | 3. General Counsel Correspondence between Glaxo and SKB | 71 |
| M. | Immunex | 73 |
| N. | The Johnson & Johnson Group (J&J, Centocor and Ortho)..... | 75 |
| O. | The Pharmacia Group (Pharmacia and P&U)..... | 76 |
| P. | The Schering-Plough Group (Schering-Plough and Warrick)..... | 82 |
| Q. | The Sicor Group (Sicor, Gensia and Gensia-Sicor)..... | 84 |
| R. | Watson | 85 |
| VI. | DIRECT DAMAGE SUSTAINED BY PLAINTIFFS AND THE MEMBERS OF THE CLASS | 86 |
| VII. | CLASS ACTION ALLEGATIONS | 87 |
| VIII. | PRAYER FOR RELIEF | 158 |
| IX. | DEMAND FOR JURY TRIAL | 159 |

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 most of the nation’s largest pharmaceutical companies (referred to as the “Defendant Drug Manufacturers”). One of the goals of this suit is to recover hundreds of millions of dollars overpaid as a result of Defendants’ fraudulent scheme to inflate and maintain the high reimbursement amounts upon which payments made by Plaintiffs and Class members for prescription drugs are based.

2. For the last decade, the Defendant Drug Manufacturers have conspired with others in the distribution chain, including but not limited to physicians and hospitals (hereafter “medical providers” or “providers”), 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 is deliberately set far above the prices that their drugs are available in the marketplace. The AWP 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 and brand name drugs administered outside of the Medicare context are priced based on the published AWP, the Defendant Drug Manufacturers inflate AWP reimbursement rates to enable providers and others to make secret profits through overcharges to patients and their insurers. This, in turn, incentivizes the providers to sell and administer the drugs with the most inflated AWP, resulting in increased market share and profit for the Defendant Drug

Manufacturers and inflated payments for drugs by individual patients and their insurers (through co-pays or direct payments).

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.

5. For brand name drugs administered outside of the Medicare Part B context, most patients and health plans pay based on the inflated AWP with an intermediary (for example, a pharmacy benefit manager or others) pocketing the "spread" between the AWP and the actual cost that the intermediaries pay for the brand name 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 by increasing the sales of their particular brand name drugs and their market share for that drug.

6. Thus, in a perversion of the type of competitive behavior expected in a market not subject to illegal restraints of trade, the Defendant Drug Manufacturers often promote their drugs not simply with lower prices, but with reimbursement rates based on a fictitious 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.

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 AWP for the drugs are deliberately overstated.

8. This suit, brought under the federal Racketeering and Corrupt Organizations Act and the consumer protection statutes of many states, is necessary to protect consumers, Medicare participants, health plans and insurers from Defendants' predatory and unlawful conduct.

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) because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-1968.

10. The Court has supplemental jurisdiction over the claims for violations of the consumer protection statutes alleged herein.

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

Plaintiffs

1. Individual Patients

13. Plaintiff Dr. Shirley Geller (“Geller”) is a resident of the State of California. During the Class Period, Dr. Geller’s clinician administered to her a Medicare Plan B covered prescription drug manufactured and distributed by the Defendant Drug Manufacturers, including Vancomycin. Dr. Geller, a Medicare Part B participant, paid the 20% co-payment for such drugs.

14. Plaintiff Leroy Townsend (“Townsend”) is a resident of the state of Florida. Townsend has prostate cancer and, during the Class Period, received injections of Zoladex from his physician. Townsend is a Medicare Part B participant and has been billed for and paid the Medicare Part B 20% co-payment.

15. Plaintiff Betty Sicher (“Sicher”) is a citizen and resident of the State of New York and a member of Plaintiff New York StateWide Senior Action Council. She resides in Spring Valley, New York. During the Class Period, Sicher’s clinician administered to her a Plan B covered prescription drug manufactured and distributed by Defendant Drug Manufacturers. Sicher, a Part B participant paid the 20% co-payment.

16. Plaintiff Joan Lee (“Lee”) is a citizen and resident of the State of California and a member of Plaintiff Gray Panthers of Sacramento and Plaintiff Congress of California Seniors. She resides in Sacramento, California. During the Class Period, Lee’s clinician administered to her a Plan B covered prescription drug manufactured and distributed by the

Defendant Drug Manufacturers. Lee, a Part B participant, paid the twenty percent (20%) co-payment.

17. Plaintiff John Bennett (“Bennett”) is a citizen and resident of the Commonwealth of Massachusetts and a member of Plaintiff Massachusetts Senior Action Counsel. He resides in Agawam, Massachusetts. During the Class Period, Bennett’s clinician administered to him a Plan B covered prescription drug manufactured and distributed by the Defendant Drug Manufacturers. Bennett, a Part B participant, paid the twenty percent (20%) co-payment.

18. Plaintiff Pearl Munic (“Munic”) is a citizen and resident of the State of Minnesota and a member of Plaintiff Minnesota Senior Federation. She resides in Duluth, Minnesota. During the Class Period, Munic’s clinician administered to her a Part B covered prescription drug manufactured and distributed by the Defendant Drug Manufacturers. Munic, a Plan B participant, paid the twenty percent (20%) co-payment.

19. Plaintiff Sue Miles (“Miles”) is a citizen and resident of the State of New York. She resides in New York City. During the Class Period, Miles’s clinician administered to her a Part B covered prescription drugs manufactured and distributed by the Defendant Drug Manufacturers. Miles, a Plan B participant, paid the twenty percent (20%) co-payment.

20. Plaintiff Jack Douglas (“Douglas”) is a citizen and resident of the State of New York. He resides in Elmhurst, New York. During the Class Period, Douglas’s clinicians administered to him Part B covered prescription drugs manufactured and distributed by the Defendant Drug Manufacturers. Douglas, a Plan B participant, paid the twenty percent (20%) co-payment.

21. Plaintiff Jean H. Aierstuck (“Aierstuck”) is a citizen and resident of the State of Pennsylvania. She resides in Leola, Pennsylvania. During the Class Period, Aierstuck’s clinicians administered to her Part B covered prescription drugs manufactured and distributed

by the Defendant Drug Manufacturers. Aierstuck, a Plan B participant, paid the twenty percent (20%) co-payment.

22. Each of the individual patient Plaintiffs overpaid for applicable drugs based on, and in reliance on, the AWP.

2. Third-Party Payors

23. 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 [or Medicare Part B 20% co-payments] for Covered Drugs and otherwise made payments for brand name drugs outside of the Medicare Part B context based on published AWP.

24. 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 Covered Drugs, including: Amgen's filgrastin; AstraZeneca's Zoladex; Aventis' Acthar; BMS' Mesnex, Taxol, Paraplatin, Blenoxane, Vepesid, Etopophos and Ifex; GSK's Navelbine, Kytril and Zofran; Immunex' Novantrone; Johnson & Johnson's Remicade; Pharmacia's Camptosar; and various generic drugs from several manufacturers. THWF also made payments for brand name drugs outside of the Medicare Part B context based on published AWP's.

25. Plaintiff Twin Cities Bakery Workers Health and Welfare Fund ("TCBW") is a jointly administered Taft-Hartley Fund established and maintained pursuant to § 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 Mendota Heights, 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 Covered Drugs, including: Dey's albuterol sulfate and cromolyn sodium; and Schering-Plough/Warrick's albuterol sulfate. TCBW also made payments for brand name drugs outside of the Medicare Part B context based on published AWP's.

26. 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 Covered Drugs, 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; Braun's sodium chloride; Aventis' Furosemide; Immunex' leucovorin calcium and Johnson & Johnson's Remicade. UFCW also made payments for brand name drugs outside of the Medicare Part B context based on published AWP.

27. Each of the Third-Party Payor Plaintiffs named overpaid for applicable drugs based on, and in reliance on, the AWP.

3. Non-Profit Associations Whose Members Purchased Prescription Drugs

28. 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, Ste. 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 co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, CCJ has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

29. 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 therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, CANY has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

30. Plaintiff Colorado Progressive Coalition ("CPC") is a statewide nonprofit, multiracial network of groups and individuals united for racial and economic justice. It is located at 1420 Ogden Street, 1st Floor, Denver, Colorado. During the Class Period, CPC's members purchased prescription pharmaceuticals manufactured and/or distributed by the

Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, CPC has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

31. Plaintiff Connecticut Citizen Action Group (“CCAG”) is a statewide membership organization dedicated to working with people to bring about social, economic and environmental justice. It is located at 139 Vanderbilt Avenue, West Hartford, Connecticut. During the Class Period, CCAG’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, CCAG has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

32. Plaintiff Florida Alliance for Retired Americans (“FLARA”) is a nonprofit umbrella organization formed in 1963 representing over 80 groups of retired Floridians with a cumulative membership of over 80,000 individuals. It is located at 12773 West Forest Hill Blvd., Ste. 1213, Wellington, Florida. During the Class Period, FLARA’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, FLARA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

33. Plaintiff Gray Panthers of Sacramento (“Gray Panthers”) is a non-profit organization devoted to advocating justice and equal access for its members and those who are powerless. It has an address at P.O. Box 19438, Sacramento, California 95834. During the Class Period, Gray Panther’s members purchased prescription pharmaceuticals manufactured and or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an

unincorporated association, Gray Panthers has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

34. Plaintiff Health Care For All, Inc. (“HCA”) is a non-profit organization devoted to making health care a right of all people. It is located at 30 Winter Street, 10th Floor, Boston, Massachusetts. During the Class Period, HCA’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, HCA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

35. Plaintiff Maine Consumers for Affordable Health Care (“MCAHC”) is a non-profit organization committed to helping the people of Maine obtain affordable, quality health care. It is located at One Weston Court, Level 1, Augusta, Maine. During the Class Period, MCAHC’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, MCAHC has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

36. Plaintiff Massachusetts Senior Action Council (“MSAC”) is a nonprofit advocacy group for seniors, especially championing health care issues. It has 3,000 individual members and over 60 affiliate organizations. It is located at 565 Warren Street, Boston, Massachusetts. During the Class Period, MSAC’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, MSAC has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

37. Plaintiff MASSPIRG is Massachusetts’ largest consumer advocacy group. It is located at 29 Temple Place, Boston, Massachusetts. During the Class Period, MASSPIRG’s

members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, MASSPIRG has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

38. Plaintiff Minnesota Senior Federation (“MSF”) is a statewide, Minnesota nonprofit and nonpartisan organization with 25,000 active members and 400 affiliated organizations, representing 100,000 individuals. It is located at 555 Park St., Ste. 110, St. Paul, Minnesota. During the Class Period, Plaintiff’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, MSF has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

39. Plaintiff New Jersey Citizen Action (“NJCA”) is the state’s largest independent citizen watchdog. It is located at 85 Raritan Ave., #100, Highland Park, New Jersey. During the Class Period, NJCA’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, NJCA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

40. 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 therefor, and were injured by the illegal conduct alleged herein. As

an unincorporated association, StateWide has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

41. Plaintiff North Carolina Fair Share (“NCFS”) is a non-profit grassroots organization. It is located at 3824 Barrett Drive, Suite 312, Raleigh, North Carolina. During the Class Period, NCFS’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, NCFS has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

42. Plaintiff Oregon Health Action Campaign (“OHAC”) is a non-profit public interest organization that works to enable Oregon citizens to become better health care consumers while maintaining affordable health care costs. It is located at 3896 Beverly Avenue, N.E., Building J-6, Salem, Oregon. During the Class Period, OHAC’s members purchased prescription pharmaceuticals manufactured and /or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged here. As an unincorporated association, OHAC has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

43. Oregon State Public Interest Research Group (“OSPIRG”) is a non-profit public interest research and advocacy group with 33,000 members throughout the State of Oregon. It is located at 1536 S.E. 11th Street, Portland, Oregon. During the Class Period, OSPIRG’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, OSPIRG has standing to pursue this action under Fed. R. Civ. P. 17 (b)(1).

44. Plaintiff Pennsylvania Alliance for Retired Americans (“PARA”) is a nonprofit, advocacy group committed to promoting affordable healthcare. It is located at 2116 Chestnut

St., Philadelphia, Pennsylvania. During the Class Period, PARA's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, PARA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

45. Plaintiff United Senior Action of Indiana, Inc. ("USAI") is a nonprofit advocacy group located at 1920 West Morris St., #246, Indianapolis, Indiana. During the Class Period, USAI's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, USAI has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

46. 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, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, VPIRG has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

47. Plaintiff West Virginia Citizen Action ("WVCA") is a nonprofit organization devoted to increase the voice of the average citizen in public affairs with an emphasis on health care reform. It is located at 1500 Dixie Street, Charlestown, West Virginia. During the Class Period, WVCA's members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, WVCA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

48. 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, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, WCA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

49. Action Alliance of Senior Citizens of Greater Philadelphia (“AASCGP”) is a non-profit corporation organized under the laws of the State of Pennsylvania and is located in Philadelphia County, Pennsylvania. During the Class Period, AASCGP’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefor, and were injured by the illegal conduct alleged herein. As an unincorporated association, AASCGP, has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

50. Each Plaintiff and all Class Members paid for the Covered Drugs and/or brand name drugs based upon and in reliance on the AWP’s published by each Defendant Drug Manufacturer for those drugs.

Defendants

51. 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.

52. 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.

Abbott

53. 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.

54. 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.

Amgen

55. Defendant Amgen Inc. (“Amgen”) is a California corporation with its principal place of business at Amgen Center, 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.

56. 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).

AstraZeneca

57. 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.

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

59. 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.

60. AstraZeneca, PLC, Zeneca, Inc., AstraZeneca Pharmaceuticals L.P. and AstraZeneca U.S. are collectively referred to as “AstraZeneca.”

61. 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.

62. 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).

The Aventis Group (Aventis, Pharma, Hoechst and Behring)

63. 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.

64. 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.

65. 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.

66. 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.

67. 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), Bioclata® (antihemo factor viii), Gammar® (immune globulin), Helixate® (antihemo factor viii), Humate-P® (antihemo factor viii), Mononine® (antihemo factor ix complex), Monoclata-P® (antihemo factor viii) and Taxotere® (docetaxel).

Baxter

68. 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.

69. 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.”

70. 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 year 2000 sales of \$6.9 billion.

71. 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.

Bayer

72. 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.

73. 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.

74. 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.

The Boehringer Group (Boehringer, Ben Venue, Bedford)

75. Defendant Boehringer Ingelheim Corp. (“Boehringer”), is a Nevada corporation with its principal place of business located at 900 Ridgefield Road, Ridgefield, Connecticut. Boehringer is a United States subsidiary of Pharma Investment Ltd., of Burlington, Canada, which in turn is a division of C.H. Boehringer Sohn Gurdstücksverwaltung GmbH & Co. KG of Ingelheim, Germany. Boehringer designs, manufactures and markets pharmaceuticals. Boehringer is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

76. Defendant Ben Venue Laboratories Inc. (“Ben Venue”) is a Delaware corporation with its principal place of business located at 300 Northfield Road, Bedford, Ohio. Ben Venue is a wholly owned subsidiary of Defendant Boehringer. Ben Venue is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

77. Bedford Laboratories (“Bedford”) is a division of Ben Venue with its principal place of business located at 300 Northfield Road, Bedford, Ohio. Bedford manufactures and markets injectable pharmaceuticals. Bedford is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. (Boehringer, Ben Venue, and Bedford are collectively referred to herein as the “Boehringer Group.”)

78. The pharmaceuticals manufactured by the Boehringer Group and covered by Medicare Part B include, but may not be limited to injectable forms of: acyclovir, bleomycin, cisplatin, cyclosporine, cytarabine, doxorubicin hydrochloride, doxorubicin hydrochloride,

doxycycline, etoposide, leucovorin calcium, leucovorin calcium, methotrexate, mitomycin, paclitaxel, pamidronate disodium, and vinblastine sulfate.

Braun

79. Defendant B. Braun Medical Inc. (“Braun”) is a Pennsylvania corporation with its principal place of business located at 824 Twelfth Avenue, Bethlehem, PA. Braun designs, manufactures and markets medical devices and certain intravenous solutions. Braun is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

80. In 1997, Braun acquired McGaw, Inc. (“McGaw”), a Delaware corporation with a principal place of business in Irvine, CA. Upon information and belief, McGaw ceased to maintain a separate corporate entity upon the acquisition of McGaw by Braun. According to Braun’s own marketing materials, Braun accepts responsibility for McGaw’s former line of products, including the manufacture and marketing of certain intravenous solutions. Until its acquisition by Braun, McGaw was in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. (Braun and McGaw are collectively referred to herein as “Braun.”)

81. The pharmaceuticals manufactured by Braun and covered by Medicare Part B include, but may not be limited to intravenous solutions of dextrose, dextrose sodium chloride and sodium chloride.

The BMS Group

82. 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, BMS reported revenues of approximately \$20 billion and net earnings of \$4.7 billion.

83. 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.

84. 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.

85. 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.

86. Bristol-Myers, OTN and Apothecon are collectively referred to herein as the “BMS Group.”

87. 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), Cytosan® (cyclophosphamide), Rubex® (doxorubicin hydrochloride), Etopophos® (etoposide), Vepesid® (etoposide), TaxolV (paclitaxel) and Fungizone® (amphotericin B).

Dey

88. 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.

89. 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.

90. 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 metproterenol sulfate.

The Fujisawa Group (Fujisawa Healthcare, Fujisawa USA)

91. 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.

92. 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

93. 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.

The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

94. 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.

95. 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.

96. 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.

97. Defendants GlaxoSmithKline, SKB and Glaxo are referred to collectively as the “GSK Group.”

98. 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.

99. 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.

Hoffman-La Roche, Inc.

100. Defendant Hoffman-La Roche, Inc. (“Roche”) is a New Jersey corporation with its principal place of business at 340 Kingsland Street, Nutley, New Jersey. Roche, is a research-based company that develops, manufacturers and markets numerous prescription and non-prescription drugs.

101. Roche is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by Roche and covered by Medicare Part B include, but may not be limited to, Cellcept® (mycophenolate mofetil), Cytovene® (ganciclovir), Demadex® (torsemide), Kytril® (granisetron HCL), Rolcatrol® (calcitriol), Rocephin® (ceftriaxone), Roferon-A® (Interferon 2-alfa), Toradol® (ketorolac tromethamine), Valium® (diazepam), Versed® (midazolam), Xeloda® (capecitabine), Zenapx® (daclizumab), Rituxan® (rituximab), Herceptin® (trastuzumab) and Xeloda® (capecitabine).

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

Immunex

103. 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.

104. 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).

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

The Johnson & Johnson Group

106. 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.

107. 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.

108. 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.

109. The drugs manufactured by J&J, Centocor, and Ortho (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.

Merck & Co., Inc.

110. Defendant Merck & Co., Inc. (“Merck”) is a New Jersey corporation with its principal place of business located at One Merck Drive, Whitehouse Station, New Jersey. Merck is a global pharmaceutical company that develops, manufactures and markets numerous prescription and non-prescription drugs. Sales of pharmaceutical products by Merck totaled \$47.71 billion in 2001.

111. Merck is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by Merck and covered by Medicare Part B include, but may not be limited to, Aggrastat® (tirofiban hydrochloride).

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

Pfizer, Inc.

113. 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.

114. 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).

115. 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.

The Pharmacia Group

116. 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.

117. 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.

118. 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.

119. 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).

The Schering-Plough Group

120. 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.

121. 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.

122. 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.

123. The drugs manufactured by Schering-Plough and Warrick (collectively 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.

The Sicor Group

124. 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.

125. 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.

126. 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.

127. 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.

128. 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.

Watson

129. 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.

130. 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

131. The allegations contained herein apply generally to all defendants.

A. The AWP System

132. 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.

133. 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 insurance companies (the latter are included as members of the Class) rely on published AWP to reimburse providers for drugs. Use of the published AWP to establish reimbursement rates for drugs is an industry-wide practice in the insurance industry.

134. There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWP 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 AWP for the various dosage forms for drugs.

135. In periodically announcing the AWP for each drug, 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 AWP for each drug.

136. 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 that they could directly control and fabricate the AWP for their drugs at any time by forwarding to the Publishers a new and higher 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 AWP's should have been calculated) highly confidential and secret.

137. The AWP's for the drugs at issue here bore no relationship to the drugs' pricing in the marketplace. They were simply fabricated 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.

138. Plaintiffs and the members of the Class paid for the drugs based on and in reliance on the inflated AWP's reported by the Defendant Drug Manufacturers.

139. The Defendant Drug Manufacturers' pattern of fraudulent conduct in artificially inflating the AWP's 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.

140. 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) brand name drugs administered outside of the Medicare context.

B. The Defendant Drug Manufacturers' Use Of AWP Fraud To Increase Market Share For Their Drugs Covered By Medicare Part B

1. The Medicare Insurance Program

141. 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.

142. 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.

143. 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.

144. 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.

145. 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.

146. 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.

147. 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.”

148. 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.

149. 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.

150. 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.

2. Congressional and Other Federal Investigations and Actions

151. 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.

152. 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.

153. 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.

154. The DOJ and Congressional investigations are ongoing.

155. On October 13, 2001, the United States Attorney in Boston, Massachusetts announced that TAP Pharmaceutical Products Inc., a corporation that arose from a partnership between Takeda Chemical Industries, Ltd. and Abbott Laboratories, had agreed to pay \$875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing practices for the drug named Lupron®. As part of the agreement:

(a) TAP agreed to plead guilty to a conspiracy to violate the Prescription Drug Marketing Act, 21 U.S.C. §§ 331(t) and 333(b), and to pay a \$290 million

criminal fine, the largest criminal fine ever in a health care fraud prosecution. The plea agreement between the United States and TAP specifically stated that TAP's criminal conduct caused the Government losses of \$145,000,000;

(b) TAP agreed to pay the United States Government \$559,483,560 for filing false and fraudulent claims with the Medicare and Medicaid programs as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct;

(c) TAP agreed to pay the fifty states and the District of Columbia \$25,516,440 for filing false and fraudulent claims with the States, as a result of TAP's drug pricing and marketing misconduct, and for TAP's failure to provide state Medicaid programs TAP's best price for Lupron®, as required by law;

(d) TAP agreed to comply with the terms of a sweeping Corporate Integrity Agreement that, among other things, significantly changes the manner in which TAP supervises its marketing and sales staff and ensures that TAP will report to the Medicare and Medicaid programs the true average sale price for drugs reimbursed by those programs;

(e) Abbott and Takeda agreed to cooperate fully with the ongoing government investigation of TAP and its former officers and employees in exchange for the United States declining prosecution of Abbott and Takeda for conduct relating to Lupron®; and

(f) An Indictment was unsealed in the District of Massachusetts against six current or former TAP employees (including an account executive, three District Managers, a National Accounts Manager and the former Vice President of Sales), and a urologist, alleging that they conspired to (i) bill Medicare for free samples of Lupron® and (ii) market Lupron® using the "spread" and the "return to practice" program.

The TAP defendants have been sued in a separate class action in connection with their fraudulent pricing and marketing practices for Lupron®.

156. At a hearing in the criminal matter, which has an extensive record, United States District Court Judge William G. Young found:

This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

United States v. TAP Pharmaceutical Products, Inc., No. CR-01-10354-WGY (D. Mass, Dec. 6, 2001).

3. The Defendant Drug Manufacturers' Fraudulent Conduct Within the Medicare Part B Program

157. The Defendant Drug Manufacturers each perpetrated the alleged fraudulent scheme by using some and/or all of the following practices:

a. Artificially Inflating AWP

158. Each Defendant Drug Manufacturer provided AWP for each of its drugs to the *Red Book*, the *Blue Book*, *Medi-Span* and other pharmaceutical compendia.

159. During the Class Period, the Defendant Drug Manufacturers deliberately and intentionally published AWP 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 AWP and earn a substantial profit from the "spread" between the real cost and the various AWP-related reimbursement rates.

160. 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 AWP of the drugs. Because the Defendant Drug Manufacturers controlled the AWP 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.

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

b. Improper Use of Free Samples

162. 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.

163. 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.

164. 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 AWP 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

165. 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 grants. All of these incentives were designed to lower the providers' net cost of purchasing the Defendant Drug Manufacturers' Covered Drugs.

C. The Defendant Drug Manufacturers' Use Of AWP Fraud To Increase And Maintain The High Price Of Their Brand Name Drugs Outside Of The Medicare Part B Context

166. The Defendant Drug Manufacturers' AWP fraud strikes well beyond Medicare Part B, adversely impacting health plans and their participants with respect to purchases of brand name drugs.

167. 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 typically priced at AWP less a certain percentage "discount."

168. A 1996 study commissioned by HCFA reported that the price that health plans pay for brand-name, patented drugs typically fell in the range of AWP less 10 to 15%, with AWP less 13% a popular level. A 1999 survey conducted by Wyeth-Ayerst of 375 employers revealed that the average payment "discount" off AWP for brand name drugs was 13.2%. A 1999 Novartis Pharmacy Benefit Report revealed that, for the 108 HMOs that it surveyed in 1998, the average paid by the HMOs was with a 14.3% "discount" from AWP.

169. The Defendant Drug Manufacturers know that there are significant discrepancies between (i) the AWP reported by them and therefore published by the Publishers, and (ii) the prices actually paid by providers and PBMs for those same drugs. However, Defendant Drug Manufacturers continue to foster the use of the published AWP as representing the true average price from wholesalers to retailers or providers.

170. Over 70% of all Americans, or more than 200 million people, have their purchases of prescription drug products controlled through the use of a formulary program established by a PBM. The ability of a drug manufacturer to effectively market its drug

product depends on securing favorable formulary and reimbursement status from the PBMs in the market.

171. Just as the Defendant Drug Manufacturers incentivize providers under Medicare Part B to use (and submit reimbursement claims for) the drugs with the highest-inflated AWP, the Defendant Drug Manufacturers incentivize PBMs to place the brand name drugs with the highest-inflated AWPs on the PBMs' formularies by marketing the spread that the PBMs can retain the purchases of those drugs by the participants in health plans that have contracted with PBMs.

172. The Defendant Drug Manufacturers incentivize placement of their brand name drugs on formularies by marketing the spread between (i) the discounted AWP that the PBM agrees to pay retail pharmacies, and (ii) the AWP at which the health plans reimburse the PBM. Pursuant to the Defendant Drug Manufacturers' suggestion, the PBMs retain the proceeds of this "spread" without disclosure. Consequently, the PBMs are incentivized by the Defendant Drug Manufacturers to market the brand name drugs (by including those drugs on their formularies) with the highest AWPs in order to benefit from the artificial spread. Moreover, the PBMs negotiate rebates with the Defendant Drug Manufacturers at a percentage of the drug's list price or AWP. Thus, the Defendant Drug Manufacturers further inflate AWPs in order to create additional proceeds that are then passed back to the PBMs as "rebates."

D. Defendants' Concealment of the Truth

173. 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.

174. Each Defendant closely guarded its pricing structures and sales figures for their Covered Drugs and brand name drugs.

175. 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.

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

177. 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.

178. 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 Covered Drugs and brand name drugs), (ii) it was manipulating the AWPs of the Covered Drugs and brand name drugs, and (iii) the AWPs bore no relationship to the prices paid for, or the pricing structure of, the Covered Drugs and brand name drugs as they were sold to providers and others.

179. Plaintiffs and the Class, unaware of the true facts about the pricing of these drugs, have paid and continued to pay for them based upon and in reliance on the AWPs, which were the only publicly available pricing figures.

180. 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.

E. Tolling of Applicable Statutes of Limitation

181. 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 AWP's.

182. Defendants were and continue to be under a continuing duty to disclose to Plaintiffs and the Class the fact that the published AWP's 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 AWP's, Defendants are estopped from relying on any statutes of limitations.

V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

183. 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.

A. Abbott

184. Abbott has engaged in an ongoing deliberate scheme to inflate AWP's. According to 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 for 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.

185. At least one publisher, Medi-Span, has challenged the manner in which Abbott sets its AWP. The following statement appeared in a February 9, 1996 faxed letter to Abbott from a representative of Medi-Span regarding Abbott's drug vancomycin:

It appears that the only difference between the two products listed is the vial it comes in. If so, why the \$400 difference in AWP? This 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 costs.

186. 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* February 25, 2000 letter from U.S. Rep. Tom Bliley to the Honorable Nancy-Ann Min DeParle, Administrator of the Health Care Financing Administration.

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

188. And Abbott's AWP inflation scheme is not limited to vancomycin. 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).

189. Further, in a report published by the DHHS, the DOJ documented at least 81 instances where the published AWP for drugs manufactured by Abbott were substantially higher than the actual prices listed by wholesalers.

190. The chart below sets forth 16 examples where Abbott deliberately inflated AWP that it reported for Abbott's Covered Drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

| Drug | Abbott's 2001 <i>Red Book</i> AWP | DOJ Determined Actual AWP | Difference | 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% |

191. As set forth above, Abbott's scheme to inflate its reported AWP 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

192. Amgen has engaged in an ongoing deliberate scheme to inflate AWP. Amgen has reported fraudulently inflated AWP for both epoetin alfa (sold by Amgen as Epogen®)

and filgrastim (sold by Amgen as Neupogen®). Amgen is identified in various annual *Red Book* publications as the sole manufacturer for filgrastim and as one of two sources for epoetin alfa. The other source for epoetin alfa is Defendant Johnson & Johnson.¹

193. 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.

194. As set forth above, Amgen’s scheme to inflate its reported AWP 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

195. AstraZeneca has engaged in an ongoing deliberate scheme to inflate AWP. 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%.

196. Internal AstraZeneca documents reveal that AstraZeneca was directly marketing the spread to physicians.

197. 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 |
| | | | |

¹ Under a licensing agreement between Defendant Amgen and Defendant Johnson & Johnson, Amgen markets Epoetin Alfa for use in the treatment of dialysis patients while licensing the right to market Epoetin Alfa for all other uses to Defendant J&J.

| | | | |
|---------------|----|---------|--------|
| 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.”

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.

198. 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 |

199. 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%

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

| <u>ZOLADEX</u> | | |
|---|-------------------------|------------------------------|
| <u>Direct Pricing</u> | <u>Medicare AWP</u> | <u>\$\$Return / % Return</u> |
| 72+ \$244.88 | \$358.55 | \$133.67 59% |
| 72x\$224.88=\$16,191.38 | 72x\$358.55=\$25,815.60 | \$9,624.24 59% |
| <i>based on your use of 480 depots annually, with our 2% discount these are the comparisons</i> | | |
| \$107,942.40 | \$172,104.00 | \$64,161.60 59% |

201. 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.

202. 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."

203. As set forth above, AstraZeneca's scheme to inflate its reported AWP, 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.

204. 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®.

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

205. The Aventis Group has engaged in an ongoing deliberate scheme to inflate AWP. For example, by letter dated May 4, 2000 to the CEO of Behring, U.S. Rep. Thomas J. Bliley states:

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.

206. The government's investigation revealed similar inflated pricing implemented by The Aventis Group 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 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. |

207. The government investigation further revealed that the Aventis Group's fraudulent AWP scheme gave them the intended advantage over their competitors. An internal GlaxoWellcome, Inc. memo describes some of the effects:

GLAXO: "There is a decline in Zofran [Glaxo's competing product] usage at Louisiana Oncology in Baton Rouge, Louisiana. Kevin Turner ...has seen a drastic decline in Zofran usage at this clinic over the last few months. The reason for this decline is strictly a reimbursement issue. This clinic has started using Anzemet because it is more profitable. Kevin has learned that this clinic is buying Anzemet for \$58.00 for a 100 mg vial, which gives them a \$84.29 profit from Medicare. They are buying a 40 mg vial of Zofran for \$145.28. If they use 32 mg of Zofran, which is \$3.63 per mg, this will net this clinic \$69.60 from Medicare reimbursement. Clearly Anzemet has a reimbursement advantage over Zofran...."

208. The government's investigation has uncovered substantial evidence that the Aventis Group's fraudulent practices are widespread. For example, in a report published by DHHS, the DOJ documented at least 15 instances where the published AWPs for drugs manufactured by the Aventis Group were substantially higher than the actual prices listed by wholesalers.

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

| Drug | The Aventis Group's 2001 <i>Red Book</i> AWP | DOJ Determined Actual AWP | Difference | Spread |
|-------------------------------|---|----------------------------------|-------------------|---------------|
| Dolasetron Mesylate (Anzemet) | \$166.50 | \$74.08 | \$92.42 | 125% |
| Factor VIII/Bioclalte | \$1.25 | \$.91 | \$.34 | 37% |
| Factor VIII/Helixate | \$1.18 | \$.78 | \$.40 | 51% |
| Immune Globulin (Gammar) | \$400.00 | \$296.67 | \$103.33 | 35% |

210. The OIG (*see* OEI-03-00-00310) 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%.

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

E. Baxter

212. Baxter has engaged in an ongoing deliberate scheme to inflate AWP's in order to increase the market share of its products. Baxter's AWP scheme is widespread and the government investigation has documented substantially inflated AWP's associated with Baxter.

213. A Baxter document made public as a result of the congressional investigation entitled, "Confidential – Baxter Internal Use Only," acknowledged that: "Increasing AWP's 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 AWP.²

214. Another Baxter document explains the basis of the AWP scheme:

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.

215. 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.

216. In a report published by DHHS, the DOJ documented at least 41 instances where the published AWP for drugs manufactured by Baxter were substantially higher than the actual prices listed by wholesalers.

217. The chart below sets forth four examples where Baxter deliberately inflated AWP that it reported for Baxter drugs. These figures compare the DOJ’s determination of an accurate AWP, based upon wholesalers’ price lists, with the AWP reported by Baxter in the 2001 *Red Book*.

| Drug in Lowest Dosage Form | Baxter’s 2001 <i>Red Book</i> 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% |

² Stark 9/28/00 letter, Exh. 3.

³ Bliley 9/25/00 letter, Exh. 6.

| Drug in Lowest Dosage Form | Baxter's 2001 Red Book AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|-----------------------------------|-----------------------------------|----------------------------------|-------------------|--------------------------|
| Factor VIII | \$1.28 | \$.92 | \$.36 | 39% |

218. 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."

219. As set forth above, Baxter's scheme to inflate its reported AWP's, 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

220. Bayer has engaged in an ongoing deliberate scheme to inflate AWP's. 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's participation in a scheme to artificially inflate the AWP's for their 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."

221. Bayer, which recently was the subject of an investigation by the DOJ, agreed to settle claims asserted by the U.S. 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 the product to doctors at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit from reimbursement paid to them by the government.

The Bayer AWP, at issue in the investigation, involved several of 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 has the effect of discouraging market competition from manufacturers that do not inflate AWP as a way of inducing doctors to purchase their products.

222. The government’s investigation has uncovered substantial evidence that Bayer’s fraudulent practices are widespread. For example, in a report published by DHHS, the DOJ documented at least 10 instances where the published AWP for drugs manufactured by Bayer were substantially higher than the actual prices listed by wholesalers.

223. The chart below sets forth two examples where Bayer deliberately inflated AWP that it reported for Bayer drugs. These figures compare the DOJ’s determination of an accurate AWP, based upon wholesalers’ price lists, with the AWP reported by Bayer in the 2001 *Red Book*.

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

224. In a DHHS OIG report (*see* OEI-03-00-00310), 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%.

225. 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.

226. 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."

227. As part of its settlement of government claims in 2000, Bayer is required, under the terms of a corporate integrity agreement, to provide the state and federal governments 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.

228. 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.

G. The Boehringer Group

229. The Boehringer Group has engaged in an ongoing deliberate scheme to inflate AWP's in order to increase the market share of its products. Although each of the injectable form of the drugs marketed by the Boehringer Group is also available from other pharmaceutical manufacturers and are not brand name pharmaceuticals, the government's investigation has uncovered substantial evidence of the Boehringer Group's fraudulent pricing practices with respect to its generic pharmaceuticals.

230. The Boehringer Group's AWP Scheme is widespread and the government investigation has documented substantially inflated AWP's associated with the Boehringer Group. For example, in a report published by DHHS, the DOJ documented at least 32 instances where the published AWP's for injectable pharmaceuticals manufactured and marketed by the Boehringer Group were substantially higher than the actual prices listed by wholesalers.

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

| Drug | The Boehringer Group's 2001 Red Book AWP | DOJ Determined Actual AWP | Difference | Spread |
|--------------------|---|----------------------------------|-------------------|---------------|
| Acyclovir Sodium | \$ 528.00 | \$ 207.00 | \$ 321.00 | 155% |
| Amikacin Sulfate | \$ 437.50 | \$ 65.33 | \$ 372.17 | 570% |
| Mitomycin | \$ 128.05 | \$ 51.83 | \$ 76.22 | 147% |
| Cytarabine | \$ 62.50 | \$ 3.55 | \$ 58.95 | 1,661% |
| Doxorubicin HCL | \$ 945.98 | \$ 139.75 | \$ 806.23 | 577% |
| Etoposide | \$ 110.00 | \$ 8.45 | \$ 101.55 | 1,202% |
| Leucovorin Calcium | \$ 184.40 | \$ 2.76 | \$ 181.64 | 6,581% |

| Drug | The Boehringer Group's 2001 Red Book AWP | DOJ Determined Actual AWP | Difference | Spread |
|---------------------|---|----------------------------------|-------------------|---------------|
| Methotrexate Sodium | \$ 68.80 | \$ 2.63 | \$ 66.17 | 2,516% |
| Vinblastine Sulfate | \$ 212.50 | \$ 8.19 | \$ 204.31 | 2,495% |

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

H. Braun

233. Braun has engaged in an ongoing deliberate scheme to inflate AWP's in order to increase the market share of its products. Although each of the intravenous solutions marketed by Braun is also available from other pharmaceutical manufacturers and are not brand name pharmaceuticals, the government's investigation has uncovered substantial evidence of Braun's fraudulent practices with respect to certain generic pharmaceuticals.

234. Braun's AWP scheme is widespread and the government investigation has documented substantially inflated AWP's associated with Braun. For example, in a report published by DHHS, the DOJ documented at least 23 instances where the published AWP's for intravenous solutions manufactured and marketed by Braun were substantially higher than the actual prices listed by wholesalers.

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

| Drug | Braun's 2001 Red Book AWP | DOJ Determined Actual AWP | Difference | Spread |
|--------------------------|----------------------------------|----------------------------------|-------------------|---------------|
| Dextrose | \$11.28 | \$1.61 | \$9.67 | 601% |
| Dextrose Sodium Chloride | \$11.34 | \$1.89 | \$9.45 | 500% |
| Sodium Chloride | \$11.33 | \$1.49 | \$9.84 | 660% |

236. As set forth above, Braun’s scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

I. The BMS Group (Bristol-Myers, OTN and Apothecan)

237. The BMS Group has engaged in an ongoing deliberate scheme to inflate AWP. For example, in a report published by DHHS, the DOJ documented at least 12 instances where the published AWP for drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers.

238. The chart below sets forth five examples where the BMS Group deliberately inflated AWP 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 <i>Red Book</i> AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|---------------------|---------------------|---|--|-------------------|------------------------------|
| Amikacin Sulfate | Apothecan | \$32.89 | \$17.31 | \$15.58 | 90% |
| Amphotercin B | Apothecan | \$17.84 | \$6.20 | \$11.64 | 188% |
| Bleomycin Sulfate | BMS | \$609.20 | \$509.29 | \$99.91 | 20% |
| Cyclophosphamide | BMS | \$102.89 | \$45.83 | \$57.06 | 125% |
| Etoposide (Vepesid) | BMS | \$136.49 | \$34.30 | \$102.19 | 298% |

239. In 1997, an OIG Report identified three other Medicare Part B drugs with inflated AWP – 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.

240. 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

241. 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."

242. 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.

243. While the BMS Group and other Defendants have placed the blame for setting published AWP's on the publications in which the AWP's are contained, another BMS Group document demonstrates that publications reporting AWP's had no discretion to set AWP's, 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.

244. 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®.)

245. As set forth above, the BMS Group’s scheme to inflate its reported AWP, 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.

J. Dey

246. Dey has engaged in an ongoing deliberate scheme to inflate AWP. Although one of the drugs Dey sells, albuterol sulfate, is also available from other pharmaceutical manufacturers, the government’s investigation has uncovered substantial evidence of Dey’s fraudulent pricing practices with respect to this drug.

247. Albuterol sulfate, 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.

248. 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.

249. 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.

250. The government's investigation has uncovered substantial evidence that Dey's fraudulent practices are widespread. For example, in a report published by DHHS, the DOJ documented at least 15 instances where the published AWP for drugs manufactured by Dey were substantially higher than the actual prices listed by wholesalers.

251. The chart below sets forth several drugs for which Dey reported inflated AWP. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by Dey in the 2001 *Red Book*.

| Drug in Lowest Dosage Form | 2001 <i>Red Book</i> 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% |

252. As part of the scheme, Dey regularly manipulated the spread by changing either the AWP or the actual sales price for its drugs. Thus, Dey's spread for albuterol sulfate 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.

253. The federal government is not the only entity to investigate Dey's scheme to inflate AWP's. The Attorneys General of Texas and West Virginia recently discovered that due to over inflated AWP's, 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.

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

K. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)

255. The Fujisawa Group has engaged in an ongoing deliberate scheme to inflate AWP's. An internal marketing memo references its blatant manipulation of the AWP:

Many thanks to Rick and Brace for adjusting the AWP on the five gram Vanco [Vancomycin Hydrochloride]. This should lead to more business . . . 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?

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.

256. The government's investigation has uncovered substantial evidence that the Fujisawa Group's fraudulent practices are widespread. For example, in a report published by

DHHS, the DOJ documented at least 35 instances where the published AWP for drugs manufactured by the Fujisawa Group's were substantially higher than the actual prices listed by wholesalers.

257. The chart below sets forth six drugs for which the Fujisawa Group reported inflated AWP. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by The Fujisawa Group.

| Drug | The Fujisawa Group's 2001 <i>Red Book</i> AWP | DOJ Determined Actual AWP | Difference | Spread |
|--------------------------------|--|----------------------------------|-------------------|---------------|
| <i>Acyclovir Sodium</i> | \$565.10 ⁴ | \$371.50 | \$193.60 | 52% |
| Dexamethasone Sodium Phosphate | \$1.04 ⁵ | \$.66 | \$.38 | 58% |
| Fluorouracil | \$2.87 ⁶ | \$1.20 | \$1.67 | 139% |
| Gentamacin Sulfate | \$12.64 | \$5.40 | \$7.24 | 134% |
| Pentamidine Isethionate | \$98.75 | \$36.00 | \$62.75 | 174% |
| Vancomycin Hydrochloride | \$10.97 ⁷ | \$7.00 | \$3.97 | 57% |

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

L. The GSK Group

259. The GSK Group has engaged in an ongoing deliberate scheme to inflate AWP and to market the spread to increase the sales of its products. For example, in a report published by DHHS, the DOJ documented at least five instances where the published AWP for drugs manufactured by the GSK Group or its related entities were substantially higher than the actual prices listed by wholesalers.

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*.

⁷ Calculation based on the AWP listed in the 1998 *Red Book*.

260. The chart below sets forth examples of drugs for which the GSK Group reported inflated AWP. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the GSK Group in the 2001 *Red Book*.

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

261. Perhaps the most flagrant example of the GSK Group's fraudulent manipulation of AWP 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. As detailed below, much of that competition concerned which product could generate *the greater spread*, or profit, for prescribers; not over which product was better for patients.

1. Glaxo's Zofran®

262. 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

263. 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."

264. 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% \$214.76 to \$233.78 (8.5%) |
| 3% Wholesaler (chargeback) | \$187.02 to \$172.92 |
| Rebate (11/14/94 - 1/31/95) | \$179.92 to \$167.31 (rebate) |

265. 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.

266. 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.

267. 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.

268. 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.

269. 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.

270. 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:

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.

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?*

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? (Emphasis added.)

271. 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

272. 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.”

273. 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 | \$110.41 | \$195.00 | 84.59 | \$13,957,350 | 76.6% |

| | | | | | |
|---------------------|----------|----------|-------|--------------|-------|
| 3mg bag | | | | | |
| Kytril 1 mg vial | \$102.73 | \$175.00 | 72.27 | \$11,924,000 | 70.3% |

274. 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.

275. 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.* (Emphasis added.)

276. 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.

2. SKB’s Kytril

277. 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.

278. 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 5h3 5 times a day = \$2,340.00 month. \$28,000.00 a year more!

279. 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®.

280. 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.

281. 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.”

282. 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.

3. General Counsel Correspondence between Glaxo and SKB

283. 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.

284. 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.”

285. 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.* (Emphasis added.) 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.* (Emphasis added.)

286. 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."

287. 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 Class.

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

M. Immunex

289. Immunex has been engaged in an ongoing deliberate scheme to inflate AWP's and has deliberately attempted to hide its participation in the scheme. In a letter dated September 28, 2000, to the president of a national pharmaceutical trade group, Representative Stark exposed Immunex's scheme, stating:

The documents further expose the fact that certain of your members deliberately concealed and misrepresented the source of AWP's:

In a 1996 Barron's article entitled "Hooked On Drugs," the following quote from Immunex appeared (Composite Exhibit #11):

IMMUNEX: "But Immunex, with a thriving generic cancer-drug business, says its average wholesale prices aren't its own. The drug manufacturers have no control over the AWP's published . . ." says spokeswoman, Valerie Dowell. (IMNX003079)

However, Immunex's own internal documents indisputably establish the knowledge of the origin of their AWP's and their active concealment:

LETTER FROM RED BOOK TO IMMUNEX:

Kathleen Stamm
Immunex Corporation . . .

Dear Kathleen:

This letter is a confirmation letter that we have received and entered your latest AWP price changes in our system. The price changes that were effective January 3, 1996 were posted in our system on January 5, 1996. I have enclosed an updated copy of your Red Book listing for your files. If there is anything else I could help you with do not hesitate to call.

Sincerely,
Lisa Brandt,
Red Book Data Analyst

290. The government's investigation has uncovered substantial evidence that Immunex's fraudulent practices are widespread. For example, in a report published by DHHS, the DOJ documented at least 7 instances where the published AWP for drugs manufactured by Immunex were substantially higher than the actual prices listed by wholesalers.

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

| Drug | 2001 <i>Red Book</i> AWP | DOJ Determined Actual AWP | Difference | Spread |
|------------------------|---|--|-------------------|---------------|
| Leucovorin Calcium | \$137.94 | \$14.58 | \$123.36 | 846% |
| Methotrexate Sodium | \$20.48 | \$7.10 | \$13.38 | 188% |

292. 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 mitoxane 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%.

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

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

294. The Johnson & Johnson Group has engaged in an ongoing deliberate scheme to inflate AWP and to market the spread to increase the sales of its products. For example, the federal investigations have documented fraudulently inflated AWP reported for epoetin alfa (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.⁸

295. 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 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.⁹

296. 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

⁸ 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.

⁹ 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.

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.

297. 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.

298. 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.

O. The Pharmacia Group (Pharmacia and P&U)

299. 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 . . . shows that Pharmacia & Upjohn has 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.

. . . .

These practices must stop and these companies must return the money that is owed to the public because of their abusive practices.

See Extension of Remarks of U.S. Representative Pete Stark in the House of Representatives, October 3, 2000.

300. During its investigation, the government uncovered specific instances of fraud by The Pharmacia Group. For example, by letter dated May 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 the HCFA Administrator.

301. 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® (vincristine sulfate) was \$370.75 in 1997, one physician group's (American Oncology Resources) price in 1997 was only \$4.15. 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).

302. In a letter dated October 3, 2000 to Pharmacia (with accompanying exhibits), Representative Stark addressed the Pharmacia Group's illegal practices:

- a. 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.
- b. 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.

- c. 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”).
- d. Pharmacia & Upjohn reported price increases in October of 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 . . .”

- e. 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 AWP’s 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).

303. 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.

304. 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.

305. The government’s investigation has uncovered substantial evidence that the Pharmacia Group’s fraudulent practices are widespread. For example, in a report published by the DHHS, the DOJ documented at least 43 instances where the published AWP for drugs manufactured by the Pharmacia Group were substantially higher than the actual prices listed by wholesalers.

306. The chart below sets forth 12 drugs for which the Pharmacia Group reported inflated AWP. These figures compare the DOJ’s determination of an accurate AWP, based upon wholesalers’ price lists, with the AWP reported by the Pharmacia Group.

| 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 ¹⁰ | \$158.67 | \$151.31 | 96% |
| Clindamycin Phosphate | \$93.60 | \$61.20 | \$32.40 | 53% |
| Cyclophosphamide | \$6.29 | \$3.92 | \$2.37 | 60% |

¹⁰ Calculation based on the AWP listed in the 2000 *Red Book*.

| | | | | |
|-------------------------------------|-----------|----------|----------|--------|
| Cytarabine | \$8.98 | \$4.06 | \$4.92 | 122% |
| Doxorubicin HCL | \$1104.13 | \$150.86 | \$953.27 | 632% |
| Etoposide | \$157.65 | \$9.47 | \$148.18 | 1,565% |
| <i>Fluorouracil</i> | \$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% |

307. 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%.

308. 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.

309. 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.

310. 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:

| | 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 |

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

P. The Schering-Plough Group (Schering-Plough and Warrick)

312. The Schering-Plough Group has engaged in an ongoing deliberate scheme to inflate AWP's. 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.

313. 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.

314. 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, MEDICARE:

Payments for Covered Outpatient Drugs Exceed Providers' Cost, Tables 1 and 2, pp. 7-8. The Schering-Plough Group is one of three companies noted by the DOJ as manufacturing albuterol. *See* Program Memorandum Intermediaries/Carriers, Sept. 8, 2000, Dept. of Health and Human Serv., Health Care Financing Admin.

315. 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.

316. 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.

317. The government's investigation has uncovered substantial evidence that the Schering-Plough Group's fraudulent practices are widespread. For example, in a report published by the DHHS, the DOJ documented at least one instance where the published AWP for a drug manufactured by the Schering-Plough Group was substantially higher than the actual price listed by wholesalers. 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.

318. 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 has resulted in excessive overpayments by Plaintiffs and the Class.

Q. The Sicor Group (Sicor, Gensia and Gensia-Sicor)

319. The Sicor Group has engaged in an ongoing deliberate scheme to inflate AWP. 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.

320. 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 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.

321. 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 |

322. The government's investigation has uncovered substantial evidence that the Sicor Group's fraudulent practices are widespread. For example, in a report published by the DHHS, the DOJ documented at least 17 instances where the published AWP for drugs manufactured by The Sicor Group were substantially higher than the actual prices listed by wholesalers.

323. The chart below sets forth three examples of the Sicor Group reporting inflated AWP. These figures compare the DOJ's determination of an accurate AWP, 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 ¹¹ | \$100.00 | \$25.00 | 25% |
| Amikacin Sulfate | \$87.50 | \$72.68 | \$14.82 | 20% |
| Tobramycin Sulfate | \$342.19 | \$6.98 | \$335.21 | 4,802% |

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

R. Watson

325. Watson has engaged in an ongoing deliberate scheme to inflate AWP's in order to increase the market share of its products. Although each of the Medicare Part B reimbursable drugs marketed by Watson is also available from other pharmaceutical manufacturers and are not brand name pharmaceuticals, the government's investigation has uncovered substantial evidence of Watson's fraudulent pricing practices with respect to certain generic pharmaceuticals.

326. Watson's AWP scheme is widespread, and the government investigation has documented substantially inflated AWP's associated with Watson. For example, in a report published by DHHS, the DOJ documented at least 12 instances where the published AWP's pharmaceuticals manufactured and marketed by Watson were substantially higher than the actual prices listed by wholesalers.

327. The chart below sets forth 7 examples of Watson reporting inflated AWP's. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the Watson in the 1999-2001 *Red Book*.

¹¹ Calculation based on the AWP listed in the 2000 *Red Book*.

| Drug | Watson's 1998-2001 Red Book AWP | 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% |

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

VI. DIRECT DAMAGE SUSTAINED BY PLAINTIFFS AND THE MEMBERS OF THE CLASS

329. Plaintiffs are directly damaged by Defendants' fraudulent AWP pricing schemes because Plaintiffs frequently are required to make a co-payment for a Covered Drug or a brand name drug, or because such Plaintiffs occasionally make payment in full, and their payments are based on inflated AWP.

330. For example, as alleged in this Complaint, Medicare Part B recipients must pay 20% of the total amount that is reimbursed by Medicare to the pharmaceutical manufacturer. Thus, if Medicare reimburses \$100 for a covered drug based upon the reported AWP, the Medicare beneficiary is responsible for 20%, or \$20 in the illustrated situation.

331. Many Medicare beneficiaries obtain supplemental insurance known, for example, as "Medigap" or "Medicare Plus" to cover the costs of pharmaceuticals as well as other costs not paid by Medicare. Such supplemental insurers are also Third-Party Payors who are damaged by the AWP Schemes.

332. Plaintiffs and other Third-Party Payors also typically make reimbursement to health care providers for pharmaceuticals based upon the AWP. Accordingly, Third-Party

Payors are directly damaged by fraudulent AWP pricing schemes for drugs covered by employee health and benefit plans or by private insurance because reimbursement is also typically based on the AWP, as in the case of Medicare and Medicaid reimbursement.

VII. CLASS ACTION ALLEGATIONS

333. The Plaintiffs bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of themselves and two Classes comprised of:

Class 1: The Medicare Part B Co-Pay Class:

All persons or entities who, for purposes other than resale and during the Class Period, paid for the purchase of a prescription drug manufactured by a Defendant Drug Manufacturer, which payment constituted a contribution toward the Medicare Part B co-payment.

Class 2: The Third-Party Payor Class:

All Third-Party Payors that, during the Class Period, contracted with a PBM or other intermediary to, based on a “discount” off of AWP, provide to its participants a brand name prescription drug manufactured by a Defendant Drug Manufacturer.

Excluded from the Class are (a) each Defendant and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors; (b) any co-conspirators; and (c) any governmental entities who purchased such drugs during the Class Period.

334. The Class Period is January 1, 1991 to the present.

335. The Class consists 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.

336. 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 Covered Drugs and/or brand name drugs at inflated

prices based on AWP. 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, in the case of co-payments, have had medical providers make pharmacy decisions based on economic factors as opposed to purely medical factors.

337. The Class representatives for Class 1, the Medicare Part B Co-Pay Class, are: Plaintiffs Geller, Townsend, Sicher, Lee, Bennett, Munic, Miles, Douglas, Aierstuck, Hudson, Robinson, and the non-profit associations identified in paragraphs 29-51 herein.

338. The Class representatives for Class 2, the Third-Party Payor Class, are: Plaintiffs CMHU, THWF, TCBW, and UFCW Care identified in paragraphs 24-27 herein.

339. 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.

340. 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)(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 AWP for the Covered Drugs and brand name drugs used by Plaintiffs and Class Members as the basis for reimbursement;
- b. Whether Defendants artificially inflated the AWP 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 AWP and the spreads available;

d. Whether Defendants provided free samples of the Covered Drugs 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 Covered Drugs and brand name drugs;

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 Defendants engaged in a pattern and practice that caused Plaintiffs and Class Members to make inflated payments for the Covered Drugs and brand name drugs;

i. Whether Defendants engaged in a pattern of deceptive and/or fraudulent activity intended to defraud Plaintiffs and the Class members;

j. Whether Defendants formed enterprises for the purpose of carrying out the AWP Scheme;

k. Whether Defendants used the U.S. mails and interstate wire facilities to carry out the AWP Scheme;

l. Whether Defendants' conduct violated RICO;

m. Whether AWPs are used as a benchmark for negotiating payments by Third-Party Payors for brand name drugs;

n. Whether Defendants are liable to Plaintiffs and the Class members for damages for conduct actionable under the various state consumer protection statutes.

341. 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.

342. 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

VIOLATIONS OF 18 U.S.C. § 1962(c)-(d)

(AGAINST DEFENDANT DRUG MANUFACTURERS FOR UNLAWFUL CONDUCT ASSOCIATED WITH MEDICARE PART B COVERED DRUGS)

343. 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.

344. This Count, which alleges violations of Sections 1962(c) and (d) of RICO, 18 U.S.C. § 1962(c)-(d), is asserted against the Defendant Drug Manufacturers and is brought on behalf of Class 1 by the Class 1 representatives.

345. Plaintiffs, the members of Class 1, the Defendant Drug Manufacturers and the providers are each “persons,” as that term is defined in 18 U.S.C. § 1961(3). At all relevant times, in violation of 18 U.S.C. § 1962(c), the Defendant Drug Manufacturers each 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 AWP Enterprises

346. In accordance with 18 U.S.C. § 1961(4), the RICO “enterprises” enumerated in ¶ 350(a)-(u) of this Complaint are associations-in-fact consisting of (a) various and independent medical providers who prescribed Covered Drugs for which a Defendant Drug Manufacturer reported an AWP, and (b) a Defendant Drug Manufacturer, including its directors, employees, and agents (“the AWP Enterprises”). The AWP Enterprises are ongoing and continuing business organizations consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to Plaintiffs and Class 1 members who are individual persons, and to participants in those Plaintiffs and Class 1 members who comprise health and welfare plans, and deriving profits from these activities.

347. The providers are alleged to be members of the AWP Enterprises because they were integral participants in the Defendant Drug Manufacturers’ AWP Scheme. Indeed, the providers were the parties who actually sought reimbursement from Plaintiffs and the members of Class 1.

348. The providers were aware of the Defendant Drug Manufacturers’ scheme, were knowing and willing participants in the AWP Scheme, and were aware of the involvement of other similarly-situated providers in that fraudulent and unlawful scheme.

349. The Defendant Drug Manufacturers and the providers operated collectively, pursuant to a conspiratorial agreement, a common purpose and as a continuing unit, to perpetrate the fraudulent AWP Scheme relating to the Covered Drugs alleged herein and their

collective knowledge, wrongful activity and willing involvement in the Defendant Drug Manufacturers' AWP Scheme is evidenced by:

(a) The mass market nature of the various promotional and sales material created and communicated by Defendant Drug Manufacturers to providers. Such pre-printed materials were obviously designed for a mass audience and not just for a single provider;

(b) The attendance by many providers at meetings of professional organizations, at which Defendant Drug Manufacturers established booths and exhibits discussing the wrongful practices alleged herein, including the "spread" and "return to practice;"

(c) The failure of any providers to advise U.S. Government regulators (including Medicare), private insurers and patients, including Plaintiffs and the members of Class 1, of the existence of the spreads;

(d) The fact that each provider was aware that he, she or it was making a profit from the spread, based on the nationally-published AWP; and

(e) The fact that various provider professional organizations aggressively lobbied against any change away from reimbursement for these Covered Drugs based upon AWP.

350. The AWP Enterprises are identified as follows:

(a) *The Abbott Provider Enterprise:* The Abbott Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Abbott reported an AWP, and Defendant Abbott, including its directors, employees and agents. The Abbott Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and

Class 1 members, and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Abbott Provider Enterprise affected interstate commerce.

(b) *The Amgen Provider Enterprise:* The Amgen Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Amgen reported an AWP, and Defendant Amgen, including its directors, employees and agents. The Amgen Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and the Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Amgen Provider Enterprise affected interstate commerce.

(c) *The AstraZeneca Provider Enterprise:* The AstraZeneca Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which AstraZeneca reported an AWP, and AstraZeneca, including its directors, employees and agents. The AstraZeneca Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the AstraZeneca Provider Enterprise affected interstate commerce.

(d) *The Aventis Group Provider Enterprise:* The Aventis Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the Aventis Group reported an AWP, and the Aventis Group, including its directors, employees and agents. The Aventis Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Aventis Group Provider Enterprise affected interstate commerce.

(e) *The Baxter Provider Enterprise:* The Baxter Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Baxter reported an AWP, and Baxter, including its directors, employees and agents. The Baxter Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Baxter Provider Enterprise affected interstate commerce.

(f) *The Bayer Provider Enterprise:* The Bayer Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Bayer reported an AWP on the one hand, and Bayer, including its directors, employees and agents. The Bayer Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and

individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Bayer Provider Enterprise affected interstate commerce.

(g) *The Boehringer Group Provider Enterprise:* The Boehringer Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the Boehringer Group reported an AWP, and the Boehringer Group, including its directors, employees and agents. The Boehringer Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Boehringer Group Provider Enterprise affected interstate commerce.

(h) *The Braun Provider Enterprise:* The Braun Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Braun reported an AWP, and Braun, including its directors, employees and agents. The Braun Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise

health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Braun Provider Enterprise affected interstate commerce.

(i) *The BMS Group Provider Enterprise:* The BMS Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the BMS Group reported an AWP, and the BMS Group, including its directors, employees and agents. The BMS Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the BMS Group Provider Enterprise affected interstate commerce.

(j) *The Dey Provider Enterprise:* The Dey Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Dey reported an AWP, and Dey, including its directors, employees and agents. The Dey Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Dey Provider Enterprise affected interstate commerce.

(k) *The Fujisawa Group Provider Enterprise:* The Fujisawa Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the Fujisawa Group reported an

AWP, and the Fujisawa Group, including its directors, employees and agents. The Fujisawa Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Fujisawa Group Provider Enterprise affected interstate commerce.

(l) *The GSK Group Provider Enterprise:* The GSK Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the GSK Group reported an AWP, and the GSK Group, including its directors, employees and agents. The GSK Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the GSK Group Provider Enterprise affected interstate commerce.

(m) *The Hoffman-La Roche Provider Enterprise:* The Hoffman-La Roche Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Hoffman-La Roche reported an AWP, and Hoffman-La Roche, including its directors, employees and agents. The Hoffman-La Roche Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and

administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Hoffman-La Roche Provider Enterprise affected interstate commerce.

(n) *The Immunex Provider Enterprise:* The Immunex Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Immunex reported an AWP, and Immunex, including its directors, employees and agents. The Immunex Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Immunex Provider Enterprise affected interstate commerce.

(o) *The Johnson & Johnson Group Provider Enterprise:* The Johnson & Johnson Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the Johnson & Johnson Group reported an AWP, and the Johnson & Johnson Group, including its directors, employees and agents. The Johnson & Johnson Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these

activities. At all relevant times hereto, the activities of the Johnson & Johnson Group Provider Enterprise affected interstate commerce.

(p) *The Merck Provider Enterprise:* The Merck Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Merck reported an AWP, and Merck, including its directors, employees and agents. The Merck Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Merck Provider Enterprise affected interstate commerce.

(q) *The Pfizer Provider Enterprise:* The Pfizer Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Pfizer reported an AWP, and Pfizer, including its directors, employees and agents. The Pfizer Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Pfizer Provider Enterprise affected interstate commerce.

(r) *The Pharmacia Group Provider Enterprise:* The Pharmacia Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the Pharmacia Group reported an AWP, and the Pharmacia Group, including its directors, employees and

agents. The Pharmacia Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Pharmacia Group Provider Enterprise affected interstate commerce.

(s) *The Schering-Plough Group Provider Enterprise:* The Schering-Plough Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the Schering-Plough Group reported an AWP, and the Schering-Plough Group, including its directors, employees and agents. The Schering-Plough Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Schering-Plough Group Provider Enterprise affected interstate commerce.

(t) *The Sicor Group Provider Enterprise:* The Sicor Group Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which the Sicor Group reported an AWP, and the Sicor Group, including its directors, employees and agents. The Sicor Group Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to

individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Sicor Group Provider Enterprise affected interstate commerce.

(u) *The Watson Provider Enterprise:* The Watson Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Watson reported an AWP, and Watson, including its directors, employees and agents. The Watson Provider Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Watson Provider Enterprise affected interstate commerce.

The Third-Party Payor AWP Enterprises

351. At all relevant times and in the alternative, in accordance with 18 U.S.C. § 1961(4), each of the Plaintiffs identified as Third-Party Payors in ¶¶ 23-26 of the Complaint constituted a separate RICO “enterprise.” As alleged herein, during the Class Period each of the Third-Party Payor AWP Enterprises was billed for and paid charges for Covered Drugs Manufactured by the Defendant Drug Manufacturers, and each of these Plaintiffs was victimized by the AWP Scheme. For purposes of this claim, such victim enterprises are referred to as the “Third-Party Payor AWP Enterprises.”

Defendants’ Use of the U.S. Mails and Interstate Wire Facilities

352. At all relevant times, the AWP Enterprises and the Third-Party Payor AWP Enterprises identified in ¶¶ 350-51 engaged in and affected interstate commerce because they engage in the following activities across state boundaries: The sale and/or purchase of Covered

Drugs, and/or the transmission of sales and marketing literature, and/or the transmission and/or receipt of invoices and payments related to the use of Covered Drugs. During the Class Period, the AWP Enterprises prescribed and/or administered Covered Drugs to thousands of individuals located throughout the United States. Similarly, during the Class Period the Third-Party Payor AWP Enterprises purchased Covered Drugs manufactured and sold by the Defendant Drug Manufacturers.

353. The Defendant Drug Manufacturers' fraudulent and wrongful practices, illegal conduct and violations of RICO 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.

354. The nature and pervasiveness of the Defendant Drug Manufacturers' AWP Scheme, which was orchestrated out of the Defendant Drug Manufacturers' corporate headquarters, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and interstate wire facilities with various local district managers who oversee the sales forces and the numerous pharmaceutical sales representatives who, in turn, directly communicated with the providers.

355. Many of the precise dates of the 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 the Defendant Drug Manufacturers' 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 and wire fraud occurred, and how those acts were in furtherance of the AWP Scheme to defraud and do so below.

356. The Defendant Drug Manufacturers' use of the U.S. mails and interstate wire facilities to perpetrate their AWP Schemes involved thousands of communications throughout the Class Period including, *inter alia*:

- (a) Marketing materials about the AWP for Covered Drugs and the available spread, which were sent to providers located across the country;
- (b) Written representations of the AWP for Covered Drugs made to the *Red Book* and similar publications, which were made at least annually and in many cases several times during a single year;
- (c) Thousands of written and oral communications discussing, confirming and forwarding free samples of drugs, for which the Defendant Drug Manufacturers understood that the providers would unlawfully bill Plaintiffs and Class members;
- (d) Documents providing information or incentives designed to lessen the prices that providers paid for the drugs, and/or to conceal those prices or the AWP Scheme alleged here;
- (e) Written communications, including checks, documents discussing and relating to grants, payments of consulting fees, debt forgiveness and/or other financial inducements, as detailed herein;
- (f) Written and oral communications with U.S. Government agencies and private insurers that fraudulently misrepresented what the AWP for Covered Drugs were, or that were intended to deter investigations into the AWP for the Covered Drugs or to forestall changes to reimbursement based on something other than AWP;
- (g) Written and oral communications with health insurers and patients, including Plaintiffs and the members of the Class, inducing payments for Covered Drugs that were made in reliance on AWP; 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.

(i) In addition to the above-referenced RICO predicate acts, the Defendant Drug Manufacturers’ respective corporate headquarters have communicated by 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 Complaint.

Conduct of the RICO Enterprises’ Affairs and RICO Conspiracy

357. During the Class Period, the Defendant Drug Manufacturers have exerted control over their particular AWP Enterprise (as identified in ¶ 350(a)-(u)), and, in violation of Section 1962(c) of RICO, have conducted or participated in the conduct of the affairs of that particular RICO enterprise, directly or indirectly, in the following ways:

(a) Each Defendant Drug Manufacturer has directly controlled the price at which providers purchase its Covered Drugs;

(b) Each Defendant Drug Manufacturer has directly controlled the AWP’s that are reported in the *Red Book* and similar industry publications;

(c) Each Defendant Drug Manufacturer has directly controlled the price at which providers are reimbursed by the Medicare Program;

(d) Each Defendant Drug Manufacturer has directly controlled the creation and distribution of marketing, sales, and other materials used to inform providers located nationwide of the profit potential of its Covered Drugs;

(e) Each Defendant Drug Manufacturer has directly controlled the marketing and sales scheme to artificially and unlawfully inflate the Medicare reimbursement rate (and co-payment rate) to induce providers to prescribe Covered Drugs to their patients;

(f) Each Defendant Drug Manufacturer has directly controlled the use and distribution of free samples of its Covered Drugs to providers;

(g) Each Defendant Drug Manufacturer has directly or indirectly controlled the ability of providers to unlawfully seek reimbursement from the Medicare Program for free samples;

(h) Each Defendant Drug Manufacturer has relied upon its employees and agents to promote the AWP Schemes alleged herein through the U.S. mails, through interstate wire facilities, and through direct contacts with providers; and

(i) Each Defendant Drug Manufacturer has controlled and participated in the affairs of its respective AWP Enterprise by using a fraudulent scheme to manufacture, market and sell its Covered Drugs through the use of unlawful inducements to providers.

358. Each of the AWP Enterprises identified in ¶ 350(a)-(u) of this Complaint had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer. Each of the AWP Enterprises also had a consensual decision-making structure because, as described above, the providers played an active role in the affairs of the enterprise. In violation of Section 1962(d) of RICO, each of the Defendant Drug Manufacturers and each of the providers that were members of the AWP Enterprises conspired to conduct the affairs of such enterprises through the pattern of racketeering activity alleged herein. The conspiratorial agreement between the Defendant Drug Manufacturers and the providers and their overt acts are described in this Complaint.

359. In violation of Section 1962(c) of RICO, each of the Defendant Drug Manufacturers and the subject providers have conducted the affairs of each of the Third-Party Payor AWP Enterprises with which they dealt by reporting fraudulently inflated AWPs for Covered Drugs and by submitting false and misleading invoices to Plaintiffs, thereby inducing Plaintiffs to pay inflated amounts for Covered Drugs. In violation of Section 1962(d) of RICO,

each of the Defendant Drug Manufacturers and each of the subject providers conspired to conduct the affairs of each of the Third-Party Payor AWP Enterprises with which they dealt through the pattern of racketeering activity alleged herein. The conspiratorial agreement between the Defendant Drug Manufacturers and the providers and their overt acts that are described in this Complaint.

Pattern of Racketeering Activity

360. Each of the Defendant Drug Manufacturers has conducted and participated in the affairs of its respective AWP Enterprises and the Third-Party Payor AWP 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). 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 and other intended victims of the AWP Scheme.

361. The Defendant Drug Manufacturers' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWP's for their Covered Drugs, thereby creating a "spread" based on the inflated figure in order to induce providers to prescribe their Covered Drugs to their patients and causing the Medicare program to pay an artificially-inflated rate of reimbursement for the Covered Drugs. The Defendant Drug Manufacturers' AWP Scheme also consisted of providing free samples of the drugs to providers, instructing (or urging) such providers to bill the Medicare program for these free samples, and providing the providers with other unlawful financial incentives, including kickbacks and bribes, to induce use of the Covered Drugs.

362. The AWP Scheme was calculated and intentionally crafted so as to ensure that the Medicare Program would be over-billed for the Covered Drugs. In designing and implementing the AWP Scheme, the Defendant Drug Manufacturers were at all times cognizant of the fact that the entire Medicare Program and all patients for whom the Covered Drugs are prescribed rely upon the honesty of the Defendant Drug Manufacturers in setting the AWP as reported in the *Red Book* and similar publications. Thus, Plaintiffs and the members of Class 1 were intended targets of the Defendant Drug Manufacturers' AWP Scheme.

363. By intentionally and artificially inflating the AWP and by the providers with unlawful financial inducements to use the Covered Drugs, and by subsequently failing to disclose such practices to the patients from whom reimbursement was sought through the U.S. mails or interstate wire facilities, the Defendant Drug Manufacturers engaged in fraudulent, and unlawful conduct constituting a pattern of racketeering activity.

364. The Defendant Drug Manufacturers' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Plaintiffs and members of the Class. 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 Class 1. 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 AWP Enterprise and the Third-Party Payor AWP Enterprises.

The Defendant Drug Manufacturers' Motive

365. The Defendant Drug Manufacturers' motive in creating and operating the AWP Scheme and conducting the affairs of the RICO enterprises described herein was to fraudulently obtain sales of and profits from their Covered Drugs.

366. The Defendant Drug Manufacturers' AWP Scheme was designed to, and did, encourage providers to use their Covered Drugs. Thus, each of the Defendant Drug Manufacturers used the AWP Scheme in an effort to sell more of its Covered Drugs, thereby fraudulently gaining sales and market share and profits.

Damages Proximately Caused By The Defendant Drug Manufacturers' AWP Scheme

367. The Defendant Drug Manufacturers' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiff and members of Class 1 to be injured in their business or property because Plaintiffs and the members of the Class 1 have paid many millions, if not hundreds-of-millions, of dollars in inflated reimbursements or other payments for Covered Drugs.

368. Defendants sent billing statements through the U.S. mails or by interstate wire facilities and reported AWP and other information by the same methods in furtherance of their AWP Scheme. Plaintiffs and the members of Class 1 have made inflated payments for Covered Drugs based on and/or in reliance on reported and false AWP.

369. Under the provisions of Section 1962(c) of RICO, the Defendant Drug Manufacturers are jointly and severally liable to Plaintiffs and the members of Class 1 for three times the damages that Plaintiffs and the members of Class 1 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 FOR UNLAWFUL CONDUCT ASSOCIATED WITH MEDICARE PART B COVERED DRUGS)

370. 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.

371. This Count, which alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), is asserted alternatively against the Defendant Drug Manufacturers on behalf of Class 1 by the Class 1 representatives.

372. Plaintiffs, the members of Class 1 and the Defendant Drug Manufacturers are each “persons,” as that term is defined in 18 U.S.C. § 1961(3).

373. The following publishers of pharmaceutical industry compendia that periodically publish the AWP, 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 is a division of the 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*; (b) First DataBank, Inc., 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., 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 collectively referred to herein as “the Publishers.”

374. At all relevant times, in violation of 18 U.S.C. § 1962(c), the Defendant Drug Manufacturers and the Publishers each 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 Publisher Enterprises

375. For purposes of this claim, the RICO “enterprises” are associations-in-fact consisting of (a) the various Publishers that reported AWP for Covered Drugs, and (b) a

Defendant Drug Manufacturer, including its directors, employees and agents (“the Publisher Enterprises”). The Publisher Enterprises are ongoing and continuing business organizations consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities.

376. At all relevant times, each of the Publishers was aware of the Defendants Drug Manufacturers’ AWP Scheme, was a knowing and willing participant in that scheme, profited from that scheme and was aware of the involvement of other Publishers in that scheme.

377. The Publisher Enterprises are identified as follows:

(a) *The Abbott Publisher Enterprise:* The Abbott Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWPs that were provided to them by Abbott, and Abbott, including its directors, employees and agents. The Abbott Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Abbott Publisher Enterprise affected interstate commerce.

(b) *The Amgen Publisher Enterprise:* The Amgen Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWPs that were provided to them by Amgen, and Amgen, including its directors, employees and agents. The Amgen Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and

administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Amgen Publisher Enterprise affected interstate commerce.

(c) *The AstraZeneca Publisher Enterprise:* The AstraZeneca Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by AstraZeneca, and AstraZeneca, including its directors, employees and agents. The AstraZeneca Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the AstraZeneca Publisher Enterprise affected interstate commerce.

(d) *The Aventis Group Publisher Enterprise:* The Aventis Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by the Aventis Group, and the Aventis Group, including its directors, employees and agents. The Aventis Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Aventis Group Publisher Enterprise affected interstate commerce.

(e) *The Baxter Publisher Enterprise:* The Baxter Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by Baxter, and Baxter, including its directors, employees and agents. The Baxter Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Baxter Publisher Enterprise affected interstate commerce.

(f) *The Bayer Publisher Enterprise:* The Bayer Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by Bayer, and Bayer, including its directors, employees and agents. The Bayer Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Bayer Publisher Enterprise affected interstate commerce.

(g) *The Boehringer Group Publisher Enterprise:* The Boehringer Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by the Boehringer Group, and the Boehringer Group, including its directors, employees and agents. The Boehringer Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the

common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Boehringer Group Publisher Enterprise affected interstate commerce.

(h) *The Braun Publisher Enterprise:* The Braun Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by Braun, and Braun, including its directors, employees and agents. The Braun Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Braun Publisher Enterprise affected interstate commerce.

(i) *The BMS Group Publisher Enterprise:* The BMS Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by the BMS Group, and the BMS Group, including its directors, employees and agents. The BMS Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the BMS Group Publisher Enterprise affected interstate commerce.

(j) *The Dey Publisher Enterprise:* The Dey Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by Dey, and Dey, including its directors, employees and agents. The Dey Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Dey Publisher Enterprise affected interstate commerce.

(k) *The Fujisawa Group Publisher Enterprise:* The Fujisawa Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by the Fujisawa Group, and the Fujisawa Group, including its directors, employees and agents. The Fujisawa Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Fujisawa Group Publisher Enterprise affected interstate commerce.

(l) *The GSK Group Publisher Enterprise:* The GSK Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by the GSK Group, and the GSK Group, including its directors, employees and agents. The GSK Group Publisher Enterprise is an ongoing and continuing business organization consisting of both

corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the GSK Group Publisher Enterprise affected interstate commerce.

(m) *The Hoffman-La Roche Publisher Enterprise:* The Hoffman-La Roche Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them Hoffman-La Roche, and Hoffman-La Roche, including its directors, employees and agents. The Hoffman-La Roche Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Hoffman-La Roche Publisher Enterprise affected interstate commerce.

(n) *The Immunex Publisher Enterprise:* The Immunex Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by Immunex, and Immunex, including its directors, employees and agents. The Immunex Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise

health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Immunex Publisher Enterprise affected interstate commerce.

(o) *The Johnson & Johnson Group Publisher Enterprise:* The Johnson & Johnson Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by the Johnson & Johnson Group, and the Johnson & Johnson Group, including its directors, employees and agents. The Johnson & Johnson Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Johnson & Johnson Group Publisher Enterprise affected interstate commerce.

(p) *The Merck Publisher Enterprise:* The Merck Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by Merck, and Merck, including its directors, employees and agents. The Merck Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Merck Publisher Enterprise affected interstate commerce.

(q) *The Pfizer Publisher Enterprise:* The Pfizer Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP

that were provided to them by Pfizer, and Pfizer, including its directors, employees and agents. The Pfizer Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Pfizer Publisher Enterprise affected interstate commerce.

(r) *The Pharmacia Group Publisher Enterprise:* The Pharmacia Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by the Pharmacia Group, and the Pharmacia Group, including its directors, employees and agents. The Pharmacia Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Pharmacia Group Publisher Enterprise affected interstate commerce.

(s) *The Schering-Plough Group Publisher Enterprise:* The Schering-Plough Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by the Schering-Plough Group, and the Schering-Plough Group, including its directors, employees and agents. The Schering-Plough Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and

administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Schering-Plough Group Publisher Enterprise affected interstate commerce.

(t) *The Sicor Group Publisher Enterprise:* The Sicor Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by the Sicor Group, and the Sicor Group, including its directors, employees and agents. The Sicor Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Sicor Group Publisher Enterprise affected interstate commerce.

(u) *The Watson Publisher Enterprise:* The Watson Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the Covered Drug AWP that were provided to them by Watson, and Watson, including its directors, employees and agents. The Watson Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Watson Publisher Enterprise affected interstate commerce.

The Third-Party Payor Publisher Enterprises

378. At all relevant times and in the alternative, in accordance with 18 U.S.C. § 1961(4), each of the Plaintiffs identified as Third-Party Payors in ¶¶ 23-26 of the Complaint constituted an “enterprise.” As alleged herein, during the Class Period each of the Third-Party Payor Publisher Enterprises was billed for and paid charges for Covered Drugs manufactured by the Defendant Drug Manufacturers, and each of these Plaintiffs was victimized by the AWP Scheme. For purposes of this claim, such victim enterprises are referred to as the “Third-Party Payor Publisher Enterprises.”

Defendants’ Use of the U.S. Mails and Interstate Wire Facilities

379. The Publisher Enterprises and the Third-Party Payor Publisher Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: The sale, purchase and/or administration of Covered Drugs; 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 Covered Drugs. During the Class Period, the Publisher Enterprises participated in the administration of Covered Drugs to millions of individuals located throughout the United States. Similarly during the Class Period, the activities of the Third-Party Payor Publisher Enterprises engaged in and affected interstate commerce because they contracted for the administration of their brand name prescription drug benefits based on AWP.

380. 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.

381. 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, the numerous pharmaceutical sales representatives who, in turn, directly communicated with providers and employees who communicated with the Publishers.

382. Many of the precise dates of Defendant Drug Manufacturers' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts) 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 Defendants 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.

383. 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 AWP for Covered Drugs and the available spread, which were sent to providers located across the country;
- (b) Written representations of the AWP made 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 providers paid for Covered Drugs and/or to conceal those prices or the AWP Scheme alleged here;
- (d) Written communications, including checks, relating to rebates, kickbacks or other financial inducements as detailed herein;
- (e) Written and oral communications with U.S. Government agencies and private insurers that fraudulently misrepresented what the AWP were, or that were

intended to deter investigations into the true nature of the AWP or to forestall changes to reimbursement based on something other than AWP;

(f) Written and oral communications with health insurers and patients, including Plaintiffs and the members of Class 1, inducing payments for the drugs that were made in reliance on AWP; and

(g) 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.

(h) In addition to the above-referenced RICO predicate acts, the Publishers have distributed their publications containing false AWP through the U.S. mails and by interstate wire facilities. Further, 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 Complaint.

Conduct of the RICO Enterprises’ Affairs and RICO Conspiracy

384. During the Class Period, the Defendant Drug Manufacturers and the Publishers have exerted control over their particular Publisher Enterprise (as identified in ¶ 377(a)-(u)) and, in violation of Section 1962(c) of RICO, have conducted or participated in the conduct of the affairs of that RICO enterprise, directly or indirectly, in the following ways:

(a) Each Defendant Drug Manufacturer has directly controlled the price for its Covered Drugs;

(b) Each Defendant Drug Manufacturer has directly controlled the AWP that are reported by the Publishers;

(c) Each Defendant Drug Manufacturer has directly controlled the creation and distribution of marketing, sales, and other materials used to inform providers nationwide of the profit potential of its Covered Drugs;

(d) Each Defendant Drug Manufacturer 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 Publishers;

(e) Each Defendant Drug Manufacturer has controlled and participated in the affairs of its respective Publisher Enterprise by using a fraudulent scheme to manufacture, market and sell its Covered Drugs on the basis of AWPs that each Defendant Drug Manufacturer provides to the Publishers; and

(f) The Publishers distributed their publications containing false AWPs through the U.S. mails and by interstate wire facilities

385. Each of the Publisher Enterprises identified in ¶ 377(a)-(u) of this Complaint had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer.

386. In violation of Section 1962(c) of RICO, each of the Defendant Drug Manufacturers have conducted the affairs of each of the Publisher Enterprises with which they associated by reporting fraudulently inflated AWPs for Covered Drugs that were then published by the Publishers.

Pattern of Racketeering Activity

387. Each of the Defendant Drug Manufacturers have conducted and participated in the affairs of the particular 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. These Defendants' 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). 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, the members of Class 1 and other intended victims of the AWP Scheme.

388. The Defendants Drug Manufacturers' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWP for their Covered Drugs, thereby creating a "spread" based on the inflated figure in order to induce others to advocate and favor that manufacturer's Covered Drugs. Further, others would bill their clients for the Defendant Drug Manufacturers' Covered Drugs based on the inflated AWP, which did not reflect the true price paid for the Covered Drugs.

389. The AWP Scheme was calculated and intentionally crafted so as to ensure that Plaintiffs and the members of Class 1 would be over-billed for the drugs. In designing and implementing this scheme, at all times these Defendants were cognizant of the fact that Plaintiffs and the members of Class 1 rely upon the honesty of the Defendant Drug Manufacturers in setting the AWP as reported by the Publishers.

390. By intentionally and artificially inflating the AWP, and by subsequently failing to disclose such practices to the individual patients and their insurers, the Defendant Drug Manufacturers engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

391. Defendants' racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive Plaintiffs and members of Class 1. Each separate use of the U.S. mails and/or interstate wire facilities employed by the Defendants 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 the members of Class 1. Each of the Defendants has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its particular Publisher Enterprise.

The Defendants' Motive

392. The Defendant Drug Manufacturers' motive in creating and operating the AWP Scheme and conducting the affairs of the Publisher Enterprises described herein was to fraudulently obtain sales of and profits from their Covered Drugs.

393. The AWP Scheme was designed to, and did, encourage others, including providers, to advocate the use of the Defendant Drug Manufacturers' Covered Drugs. Thus, each Defendant Drug Manufacturer used the scheme to sell more of its drugs, thereby fraudulently gaining sales and market share and profits.

Damages Caused By Defendants' AWP Scheme

394. The Defendant Drug Manufacturers' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and the members of Class 1 to be injured in their business or property because Plaintiffs and the members of Class 1 have paid many millions of dollars in inflated reimbursements or other payments for Covered Drugs.

395. Defendants sent billing statements through the U.S. mails or by interstate wire facilities and reported AWP's and other information by the same methods in furtherance of their AWP Scheme. Plaintiffs and the members of Class 1 have made inflated payments for Covered Drugs based on and/or in reliance on reported and false AWP's.

396. Under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Plaintiffs and members of Class 1 for three times the damages that Plaintiffs and the Class 1 members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

COUNT III

VIOLATIONS OF 18 U.S.C. § 1962(c)

**(AGAINST DEFENDANT DRUG MANUFACTURERS – EXCLUDING THE
BOEHRINGER GROUP, BRAUN, DEY, FUJISAWA AND WATSON DEFENDANTS –**

FOR UNLAWFUL CONDUCT ASSOCIATED WITH BRAND NAME PRESCRIPTION DRUGS)

397. 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.

398. 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 Class 2 by the Class 2 representatives.

399. Plaintiffs, the members of Class 2 and the Defendant Drug Manufacturers are each “persons,” as that term is defined in 18 U.S.C. § 1961(3).

400. The following publishers of pharmaceutical industry compendia that periodically publish the AWP, 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 is a division of the 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*; (b) First DataBank, Inc., 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., 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 collectively referred to herein as “the Publishers.”

401. At all relevant times, in violation of 18 U.S.C. § 1962(c), the Defendant Drug Manufacturers and the Publishers each 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 Publisher Enterprises

402. For purposes of this claim, the RICO “enterprises” are associations-in-fact each consisting of (a) the various Publishers that reported AWP for brand name drugs, and (b) a Defendant Drug Manufacturer, including its directors, employees and agents (“the Publisher Enterprises”). The Publisher Enterprises are ongoing and continuing business organizations consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities.

403. At all relevant times, each of the Publishers was aware of the Defendants Drug Manufacturers’ AWP Scheme, was a knowing and willing participant in that scheme, profited from that scheme and was aware of the involvement of other Publishers in that scheme.

404. The Publisher Enterprises are identified as follows:

(a) *The Abbott Publisher Enterprise:* The Abbott Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by Abbott, and Abbott, including its directors, employees and agents. The Abbott Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Abbott Publisher Enterprise affected interstate commerce.

(b) *The Amgen Publisher Enterprise:* The Amgen Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by Amgen, and Amgen, including its directors, employees and agents. The Amgen Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Amgen Publisher Enterprise affected interstate commerce.

(c) *The AstraZeneca Publisher Enterprise:* The AstraZeneca Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by AstraZeneca, and AstraZeneca, including its directors, employees and agents. The AstraZeneca Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the AstraZeneca Publisher Enterprise affected interstate commerce.

(d) *The Aventis Group Publisher Enterprise:* The Aventis Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by the Aventis Group, and the Aventis Group, including its directors, employees and agents. The Aventis Group Publisher Enterprise is an ongoing and continuing business organization consisting of both

corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Aventis Group Publisher Enterprise affected interstate commerce.

(e) *The Baxter Publisher Enterprise:* The Baxter Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by Baxter, and Baxter, including its directors, employees and agents. The Baxter Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Baxter Publisher Enterprise affected interstate commerce.

(f) *The Bayer Publisher Enterprise:* The Bayer Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by Bayer, and Bayer, including its directors, employees and agents. The Bayer Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Bayer Publisher Enterprise affected interstate commerce.

(g) *The BMS Group Publisher Enterprise:* The BMS Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by the BMS Group, and the BMS Group, including its directors, employees and agents. The BMS Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the BMS Group Publisher Enterprise affected interstate commerce.

(h) *The GSK Group Publisher Enterprise:* The GSK Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by the GSK Group, and the GSK Group, including its directors, employees and agents. The GSK Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the GSK Group Publisher Enterprise affected interstate commerce.

(i) *The Hoffman-La Roche Publisher Enterprise:* The Hoffman-La Roche Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them Hoffman-La Roche, and Hoffman-La Roche, including its directors, employees and agents. The Hoffman-La

Roche Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Hoffman-La Roche Publisher Enterprise affected interstate commerce.

(j) *The Immunex Publisher Enterprise:* The Immunex Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by Immunex, and Immunex, including its directors, employees and agents. The Immunex Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Immunex Publisher Enterprise affected interstate commerce.

(k) *The Johnson & Johnson Group Publisher Enterprise:* The Johnson & Johnson Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by the Johnson & Johnson Group, and the Johnson & Johnson Group, including its directors, employees and agents. The Johnson & Johnson Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that

comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Johnson & Johnson Group Publisher Enterprise affected interstate commerce.

(l) *The Merck Publisher Enterprise:* The Merck Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by Merck, and Merck, including its directors, employees and agents. The Merck Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Merck Publisher Enterprise affected interstate commerce.

(m) *The Pfizer Publisher Enterprise:* The Pfizer Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by Pfizer, and Pfizer, including its directors, employees and agents. The Pfizer Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Pfizer Publisher Enterprise affected interstate commerce.

(n) *The Pharmacia Group Publisher Enterprise:* The Pharmacia Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by the Pharmacia Group, and

the Pharmacia Group, including its directors, employees and agents. The Pharmacia Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Pharmacia Group Publisher Enterprise affected interstate commerce.

(o) *The Schering-Plough Group Publisher Enterprise:* The Schering-Plough Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by the Schering-Plough Group, and the Schering-Plough Group, including its directors, employees and agents. The Schering-Plough Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Schering-Plough Group Publisher Enterprise affected interstate commerce.

(p) *The Sicor Group Publisher Enterprise:* The Sicor Group Publisher Enterprise is an association-in-fact consisting of the Publishers that reported the brand name drug AWP that were provided to them by the Sicor Group, and the Sicor Group, including its directors, employees and agents. The Sicor Group Publisher Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling,

purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Sicor Group Publisher Enterprise affected interstate commerce.

The Third-Party Payor Publisher Enterprises

405. At all relevant times and in the alternative, in accordance with 18 U.S.C. § 1961(4), each of the Plaintiffs identified as Third-Party Payors in ¶¶ 23-26 of the Complaint constituted an “enterprise.” As alleged herein, during the Class Period each of the Third-Party Payor Publisher Enterprises was billed for and paid charges for brand name drugs manufactured by the Defendant Drug Manufacturers, and each of these Plaintiffs was victimized by the AWP Scheme. For purposes of this claim, such victim enterprises are referred to as the “Third-Party Payor Publisher Enterprises.”

Defendants’ Use of the U.S. Mails and Interstate Wire Facilities

406. The Publisher Enterprises and the Third-Party Payor Publisher Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: The sale, purchase and/or administration of brand name drugs; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission to patients of individual prescriptions for brand name drugs by mail-order pharmacies; and/or the transmission and/or receipt of invoices, statements and payments related to the use or administration of brand name drugs. During the Class Period, the Publisher Enterprises participated in the administration of brand name drugs to millions of individuals located throughout the United States. Similarly during the Class Period, the activities of the Third-Party Payor Publisher Enterprises engaged in and affected interstate commerce because they contracted for the administration of their brand name prescription drug benefits based on AWPs.

407. 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.

408. 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, the numerous pharmaceutical sales representatives who, in turn, directly communicated with providers and employees who communicated with the Publishers.

409. Many of the precise dates of Defendant Drug Manufacturers' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts) 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 Defendants 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.

410. 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 AWP for brand name drugs and the available spread, which were sent to providers located across the country;
- (b) Written representations of the AWP made 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 providers paid for brand name drugs, and/or to conceal those prices or the AWP Scheme alleged here;

(d) Written communications, including checks, relating to rebates, kickbacks or other financial inducements as detailed herein;

(e) Written and oral communications with U.S. Government agencies and private insurers that fraudulently misrepresented what the AWP's were, or that were intended to deter investigations into the true nature of the AWP's or to forestall changes to reimbursement based on something other than AWP's;

(f) Written and oral communications with health insurers and patients, including Plaintiffs and the members of Class 2, inducing payments for the drugs that were made in reliance on AWP's; and

(g) 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.

(h) In addition to the above-referenced RICO predicate acts, the Publishers have distributed their publications containing false AWP's through the U.S. mails and by interstate wire facilities. Further, 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 Complaint.

Conduct of the RICO Enterprises' Affairs and RICO Conspiracy

411. During the Class Period, the Defendant Drug Manufacturers and the Publishers have exerted control over their particular Publisher Enterprise (as identified in ¶ 404(a)-(p)) and in violation of Section 1962(c) of RICO have conducted or participated in the conduct of the affairs of that RICO enterprise, directly or indirectly, in the following ways:

(a) Each Defendant Drug Manufacturer has directly controlled the price for its brand name drugs;

(b) Each Defendant Drug Manufacturer has directly controlled the AWP's that are reported by the Publishers;

(c) Each Defendant Drug Manufacturer has directly controlled the creation and distribution of marketing, sales, and other materials used to inform providers nationwide of the profit potential of its brand name drugs;

(d) Each Defendant Drug Manufacturer 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 Publishers;

(e) Each Defendant Drug Manufacturer has controlled and participated in the affairs of its respective Publisher Enterprise by using a fraudulent scheme to manufacture, market and sell its brand name drugs on the basis of AWP's that each Defendant Drug Manufacturer provides to the Publishers; and

(f) The Publishers distributed their publications containing false AWP's through the U.S. mails and by interstate wire facilities.

412. Each of the Publisher Enterprises identified in ¶ 404(a)-(p) of this Complaint had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer.

413. In violation of Section 1962(c) of RICO, each of the Defendant Drug Manufacturers have conducted the affairs of each of the Publisher Enterprises with which they dealt by reporting fraudulently inflated AWP's for brand name drugs that were then published by the Publishers.

Pattern of Racketeering Activity

414. Each of the Defendant Drug Manufacturers have conducted and participated in the affairs of the particular 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. These Defendants' 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). 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, the members of Class 2 and other intended victims of the AWP Scheme.

415. The Defendants Drug Manufacturers' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWP for their brand name drugs, thereby creating a "spread" based on the inflated figure in order to induce others to advocate and favor that manufacturer's brand name drugs. Further, others would bill their clients for the Defendant Drug Manufacturers' brand name drugs based on the inflated AWP, which did not reflect the true price paid for the brand name drugs.

416. The AWP Scheme was calculated and intentionally crafted so as to ensure that Plaintiffs and the members of Class 2 would be over-billed for the drugs. In designing and implementing this scheme, at all times these Defendants were cognizant of the fact that Plaintiffs and the members of Class 2 rely upon the honesty of the Defendant Drug Manufacturers in setting the AWP as reported by the Publishers.

417. By intentionally and artificially inflating the AWP, and by subsequently failing to disclose such practices to the individual patients and their insurers, the Defendant Drug Manufacturers engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

418. Defendants' racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive Plaintiffs and the members of Class 2.

Each separate use of the U.S. mails and/or interstate wire facilities employed by the Defendants 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 the members of Class 2. Each of the Defendants has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its particular Publisher Enterprise.

The Defendants' Motive

419. The Defendant Drug Manufacturers' motive in creating and operating the AWP Scheme and conducting the affairs of the Publisher Enterprises described herein was to fraudulently obtain sales of and profits from their brand name drugs.

420. The AWP Scheme was designed to, and did, encourage others, including providers, to advocate the use of the Defendant Drug Manufacturers' brand name drugs. Thus, each Defendant Drug Manufacturer used the scheme to sell more of its drugs, thereby fraudulently gaining sales and market share and profits.

Damages Caused By Defendants' AWP Scheme

421. The Defendant Drug Manufacturers' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and the members of Class 2 to be injured in their business or property because Plaintiffs and the members of Class 2 have paid many millions of dollars in inflated reimbursements or other payments for brand name drugs.

422. Defendants 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 the members of Class 2 have made inflated payments for Covered Drugs based on and/or in reliance on reported and false AWPs.

423. Under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Plaintiffs and members of Class 2 for three times the damages that Plaintiffs

and the Class 2 members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

COUNT IV

VIOLATIONS OF 18 U.S.C. § 1962(c)

(AGAINST DEFENDANT DRUG MANUFACTURERS – EXCLUDING THE BOEHRINGER GROUP, BRAUN, DEY, FUJISAWA AND WATSON DEFENDANTS – FOR UNLAWFUL CONDUCT ASSOCIATED WITH BRAND NAME PRESCRIPTION DRUGS)

424. 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.

425. This Count, which alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), is asserted in the alternative against the Defendant Drug Manufacturers on behalf of Class 2 by the Class 2 representatives.

426. Plaintiffs, the members of Class 2 and the Defendant Drug Manufacturers are each “persons,” as that term is defined in 18 U.S.C. § 1961(3).

427. In addition, unnamed pharmacy benefit managers (“PBMs”) are each “persons,” as that term is defined in 18 U.S.C. § 1961(3). 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 and third-party payors (collectively referred to as “health plans”). PBMs purportedly encourage the cost effective utilization of prescription drugs through, *inter alia*, the establishment of formularies. Formularies are lists of required, preferred or recommended medications compiled by the PBMs based on, among other things, negotiated pricing and rebates with drug manufacturers. Formularies are used to steer patients toward the listed or preferred drugs within each therapeutic class through financial or other incentives and penalties (for example, through the use of different levels of co-payments). PBMs administer the formularies for health plans by

contracting with a given health plan to manage the pharmacy benefits program for the plan's members and beneficiaries. PBMs also craft networks of participating pharmacies. In exchange for being included in the network, the participating pharmacies agree to fill pharmaceutical prescriptions at a discount to the PBM. Because PBMs administer the pharmacy benefits for a substantial percentage of health plans and their members within the United States, drug manufacturers are under competitive pressures to have their brand name drugs listed on the formularies established by the PBMs.

428. At all relevant times, in violation of 18 U.S.C. § 1962(c), the Defendant Drug Manufacturers and the PBMs each 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 PBM Enterprises

429. For purposes of this claim, the RICO "enterprises" are associations-in-fact consisting of (a) PBMs that administered purchases of Defendant Drug Manufacturers' brand name drugs and billed its members on the basis of the Defendant Drug Manufacturers' reported AWP, and (b) a Defendant Drug Manufacturer, including its directors, employees and agents ("the PBM Enterprises"). The PBM Enterprises are ongoing and continuing business organizations consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities.

430. At all relevant times, each of the PBMs was aware of the Defendants Drug Manufacturers' AWP Scheme, was a knowing and willing participant in that scheme, profited from that scheme and was aware of the involvement of other PBMs in that scheme.

431. The PBM Enterprises are identified as follows:

(a) *The Abbott PBM Enterprise:* The Abbott PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of Abbott's brand name drugs and billed their members on the basis of Abbott's reported AWP's, and Abbott, including its directors, employees and agents. The Abbott PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Abbott PBM Enterprise affected interstate commerce.

(b) *The Amgen PBM Enterprise:* The Amgen PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of Amgen's brand name drugs and billed their members on the basis of Amgen's reported AWP's, and Amgen, including its directors, employees and agents. The Amgen PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Amgen PBM Enterprise affected interstate commerce.

(c) *The AstraZeneca PBM Enterprise:* The AstraZeneca PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of AstraZeneca's brand name drugs and billed their members on the basis of AstraZeneca's reported AWP's, and AstraZeneca, including its directors, employees and

agents. The AstraZeneca PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the AstraZeneca PBM Enterprise affected interstate commerce.

(d) *The Aventis Group PBM Enterprise:* The Aventis Group PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of the Aventis Group's brand name drugs and billed their members on the basis of the Aventis Group's reported AWP's, and the Aventis Group, including its directors, employees and agents. The Aventis Group PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Aventis Group PBM Enterprise affected interstate commerce.

(e) *The Baxter PBM Enterprise:* The Baxter PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of Baxter's brand name drugs and billed their members on the basis of Baxter's reported AWP's, and Baxter, including its directors, employees and agents. The Baxter PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual

Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Baxter PBM Enterprise affected interstate commerce.

(f) *The Bayer PBM Enterprise:* The Bayer PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of Bayer's brand name drugs and billed their members on the basis of Bayer's reported AWP's, and Bayer, including its directors, employees and agents. The Bayer PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Bayer PBM Enterprise affected interstate commerce.

(g) *The BMS Group PBM Enterprise:* The BMS Group PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of BMS Group brand name drugs and billed their members on the basis of the BMS Group's reported AWP's, and the BMS Group, including its directors, employees and agents. The BMS Group PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the BMS Group PBM Enterprise affected interstate commerce.

(h) *The GSK Group PBM Enterprise:* The GSK Group PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of GSK Group brand name drugs and billed their members on the basis of the GSK Group's reported AWP, and the GSK Group, including its directors, employees and agents. The GSK Group PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the GSK Group PBM Enterprise affected interstate commerce.

(i) *The Hoffman-La Roche PBM Enterprise:* The Hoffman-La Roche PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of Hoffman-La Roche's brand name drugs and billed their members on the basis of Hoffman-La Roche's reported AWP, and Hoffman-La Roche, including its directors, employees and agents. The Hoffman-La Roche PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Hoffman-La Roche PBM Enterprise affected interstate commerce.

(j) *The Immunex PBM Enterprise:* The Immunex PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of Immunex' brand name drugs and billed their members on the basis of Immunex'

reported AWP, and Immunex, including its directors, employees and agents. The Immunex PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Immunex PBM Enterprise affected interstate commerce.

(k) *The Johnson & Johnson Group PBM Enterprise:* The Johnson & Johnson Group PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of Johnson & Johnson Group brand name drugs and billed their members on the basis of the Johnson & Johnson Group's reported AWP, and the Johnson & Johnson Group, including its directors, employees and agents. The Johnson & Johnson Group PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Johnson & Johnson Group PBM Enterprise affected interstate commerce.

(l) *The Merck Provider Enterprise:* The Merck PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of Hoffman-La Roche's brand name drugs and billed their members on the basis of Merck's reported AWP, and Merck, including its directors, employees and agents. The Merck PBM Enterprise is an ongoing and continuing business organization consisting

of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Merck PBM Enterprise affected interstate commerce.

(m) *The Pfizer Provider Enterprise:* The Pfizer PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of Pfizer's brand name drugs and billed their members on the basis of Pfizer's reported AWP's, and Pfizer, including its directors, employees and agents. The Pfizer PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Pfizer PBM Enterprise affected interstate commerce.

(n) *The Pharmacia Group PBM Enterprise:* The Pharmacia Group PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of Pharmacia Group brand name drugs and billed their members on the basis of the Pharmacia Group's reported AWP's, and the Pharmacia Group, including its directors, employees and agents. The Pharmacia Group PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise

health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Pharmacia Group PBM Enterprise affected interstate commerce.

(o) *The Schering-Plough Group PBM Enterprise:* The Schering-Plough Group PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of Schering-Plough Group brand name drugs and billed their members on the basis of the Schering-Plough Group's reported AWP, and the Schering-Plough Group, including its directors, employees and agents. The Schering-Plough Group PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Schering-Plough Group PBM Enterprise affected interstate commerce.

(p) *The Sicor Group PBM Enterprise:* The Sicor Group PBM Enterprise is an association-in-fact consisting of the PBM Defendants who administered purchases of Sicor Group brand name drugs and billed their members on the basis of the Sicor Group's reported AWP, and the Sicor Group, including its directors, employees and agents. The Sicor Group PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering brand name drugs to individual Plaintiffs and Class 2 members and to participants in those Plaintiffs and Class 2 members that comprise health and welfare plans, and deriving profits from these activities. At all relevant times hereto, the activities of the Sicor Group PBM Enterprise affected interstate commerce.

The Third-Party Payor PBM Enterprises

432. At all relevant times and in the alternative, in accordance with 18 U.S.C. § 1961(4), each of the Plaintiffs identified as Third-Party Payors in ¶¶ 23-26 of the Complaint constituted an “enterprise.” As alleged herein, during the Class Period each of the Third-Party Payor PBM Enterprises was billed for and paid charges for brand name drugs manufactured by the Defendant Drug Manufacturers, and each of these Plaintiffs was victimized by the AWP Scheme. For purposes of this claim, such victim enterprises are referred to as the “Third-Party Payor PBM Enterprises.”

Defendants’ Use of the U.S. Mails and Interstate Wire Facilities

433. The PBM Enterprises and the Third-Party Payor PBM Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: The sale, purchase and/or administration of brand name drugs; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission to patients of individual prescriptions for brand name drugs by mail-order pharmacies; and/or the transmission and/or receipt of invoices, statements and payments related to the use or administration of brand name drugs. During the Class Period, the PBM Enterprises participated in the administration of brand name prescription drugs to millions of individuals located throughout the United States. Similarly during the Class Period, the activities of the Third-Party Payor PBM Enterprises engaged in and affected interstate commerce because they contracted for the administration of their brand name prescription drug benefits based on AWPs.

434. 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.

435. 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, the numerous pharmaceutical sales representatives who, in turn, directly communicated with providers and employees who communicated with the PBMs.

436. Many of the precise dates of Defendant Drug Manufacturers' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts) 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 Defendants 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.

437. 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 AWP for brand name drugs and the available spread, which were sent to PBMs located across the country;
- (b) Written representations of the AWP made 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 brand name drugs on a PBM's formulary;

(d) Documents providing information or incentives designed to lessen the prices that PBMs paid for brand name drugs, and/or to conceal those prices or the AWP Scheme alleged here;

(e) Written communications, including checks, relating to rebates, kickbacks or other financial inducements paid to PBMs to persuade them to advocate one Defendant Drug Manufacturers' brand name 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, including Plaintiffs and the members of Class 2, 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.

(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 Complaint.

Conduct of the RICO Enterprises' Affairs and RICO Conspiracy

438. During the Class Period, the Defendant Drug Manufacturers and the PBMs have exerted control over their particular PBM Enterprise (as identified in ¶ 431(a)-(p)) and in

violation of Section 1962(c) of RICO have conducted or participated in the conduct of the affairs of that RICO enterprise, directly or indirectly, in the following ways:

(a) Each Defendant Drug Manufacturer has directly controlled the price for its brand name drugs, which determines the amount of the PBMs' compensation;

(b) Each Defendant Drug Manufacturer has directly controlled the AWP's that are reported by the Publishers;

(c) Each PBM has directly controlled the price at which pharmacies are reimbursed by the PBM;

(d) Each Defendant Drug Manufacturer has directly controlled the creation and distribution of marketing, sales, and other materials used to inform PBMs nationwide of the profit potential of its brand name drugs;

(e) Each Defendant Drug Manufacturer 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

(f) Each Defendant Drug Manufacturer and each PBM has controlled and participated in the affairs of its respective PBM Enterprise by providing or receiving rebates or other inducements to place a certain Defendant Drug Manufacturer's brand name drugs on a PBM formulary or advocate the use of a certain brand name drug.

439. Each of the PBM Enterprises identified in ¶ 431(a)-(p) of this Complaint had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer.

440. In violation of Section 1962(c) of RICO, each of the Defendant Drug Manufacturers and the PBMs have conducted the affairs of each of the Third-Party Payor PBM Enterprises with which they dealt by reporting fraudulently inflated AWP's for brand name drugs and by submitting false and misleading invoices to Plaintiffs, thereby inducing Plaintiffs and the Class 2 members to pay inflated amounts for brand name drugs.

Pattern of Racketeering Activity

441. Each of the Defendant Drug Manufacturers have conducted and participated in the affairs of the particular 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. These Defendants' 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). 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, the members of Class 2 and other intended victims of the AWP Scheme.

442. The Defendants Drug Manufacturers' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWP for their brand name drugs, thereby creating a "spread" based on the inflated figure in order to induce the PBMs to advocate and favor that manufacturer's brand name drugs to the members of that PBM's clients. Further, the PBMs would bill their clients for the Defendant Drug Manufacturers' brand name drugs based on the inflated AWP, which did not reflect the true price paid by the PBMs for the brand name drugs.

443. The AWP Scheme was calculated and intentionally crafted so as to ensure that Plaintiffs and the members of Class 2 would be over-billed for the drugs. In designing and implementing this scheme, at all times these Defendants were cognizant of the fact that Plaintiffs and the members of Class 2 rely upon the honesty of the Defendant Drug Manufacturers in setting the AWP as reported by the Publishers.

444. By intentionally and artificially inflating the AWP and by providing the PBMs with unlawful financial inducements to advocate their particular drugs, and by subsequently

failing to disclose such practices to the individual patients and their insurers, the Defendant Drug Manufacturers engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

445. Defendants' racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive Plaintiffs and the members of Class 2. Each separate use of the U.S. mails and/or interstate wire facilities employed by the Defendants 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 the members of Class 2. Each of the Defendants has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its particular PBM Enterprise.

The Defendants' Motive

446. The Defendant Drug Manufacturers' motive in creating and operating the AWP Scheme and conducting the affairs of the PBM Enterprises described herein was to fraudulently obtain sales of and profits from their brand name drugs.

447. The AWP Scheme was designed to, and did, encourage others, including providers, to advocate the use of the Defendant Drug Manufacturers' brand name drugs. Thus, each Defendant Drug Manufacturer used the scheme to sell more of its drugs, thereby fraudulently gaining sales and market share and profits.

Damages Caused By Defendants' AWP Scheme

448. The Defendant Drug Manufacturers' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and the members of Class 2 to be injured in their business or property because Plaintiffs and the members of Class 2 have paid many millions of dollars in inflated reimbursements or other payments for brand name drugs.

449. Defendants 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 the members of Class 2 have made inflated payments for Covered Drugs based on and/or in reliance on reported and false AWP.

450. Under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Plaintiffs and members of Class 2 for three times the damages that Plaintiffs and the Class 2 members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

COUNT V

VIOLATIONS OF CONSUMER PROTECTION STATUTES

451. 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.

452. 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:

| | |
|--------------------|---|
| <i>California:</i> | Cal. Civ. Code §§ 1750, Bus. & Prof. Code § 17200, <i>et seq.</i> and 17500, <i>et seq.</i> |
| <i>Delaware:</i> | 6 Del. Code §§ 2511-2537 |
| <i>Florida:</i> | Fla. Stat. Stat. §§ 501.201-501.213 |
| <i>Illinois:</i> | 815 ILCS § 505/1, <i>et seq.</i> |
| <i>Louisiana:</i> | La. Rev. Stat. Ann. § 51:1405 |
| <i>Minnesota:</i> | Minn. Stat. Ann. §§ 325D.09 - 325D.16, § 325F.67 - 69 |
| <i>New Jersey:</i> | N.J. Stat. Ann. §§ 56:8-1 - 56:8-24 |

| | |
|----------------------|--|
| <i>New York:</i> | N.Y. Gen. Bus. L. §§ 349-350 |
| <i>Pennsylvania:</i> | 73 Pa. Stat. § 201-1 <i>et seq.</i> |
| <i>Texas:</i> | Tex. Bus. & Com. Code §§ 17.41 B 17.63 |
| <i>Washington:</i> | RCW 19.86.010, <i>et seq.</i> |

These statutes do not require a showing of either scienter or individual reliance.

453. 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 AWP's 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 AWP's in the *Red Book* and other publications; and

(e) Encouraging Medicare Part B providers to use drugs based upon the "spread" as opposed to medicines being prescribed based on medical reasons.

454. Defendants willfully engaged in such practices knowing them to be deceptive and with the intent that Plaintiffs and the Class would rely thereon.

455. 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.

456. Defendants have injured the public interest, and Defendants' actions continue to pose a threat to the public.

457. As a direct and legal result of Defendants' misleading, deceptive, unfair, false and fraudulent trade practices, Plaintiffs and the Class have sustained damages.

COUNT VI

DECLARATORY AND OTHER RELIEF PURSUANT TO 28 U.S.C. §§ 2201, 2002 (AGAINST DEFENDANT DRUG MANUFACTURERS FOR UNLAWFUL CONDUCT ASSOCIATED WITH MEDICARE PART B COVERED DRUGS)

458. 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.

459. 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 drugs covered under Medicare Part B. The Plaintiffs contend that setting stated reimbursement prices above the actual average wholesale price for Covered Drugs is unlawful, and that each Defendant Drug Manufacturer does so in violation of applicable law, knowing that Medicare beneficiaries and their insurers will incur similarly inflated substantial co-payments for drugs under Medicare Part B.

460. 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.

461. 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 drugs covered under Medicare Part B is unlawful, and are entitled to further relief pursuant to 28 U.S.C. § 2202.

COUNT VII

DECLARATORY AND OTHER RELIEF PURSUANT TO 28 U.S.C. §§ 2201, 2002

(AGAINST DEFENDANT DRUG MANUFACTURERS (EXCLUDING THE BOEHRINGER GROUP, BRAUN, DEY, FUJISAWA AND WATSON DEFENDANTS) FOR UNLAWFUL CONDUCT ASSOCIATED WITH BRAND NAME PRESCRIPTION DRUGS ADMINISTERED OUTSIDE OF THE MEDICARE PART B CONTEXT)

462. 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.

463. An actual case and controversy exists between the Plaintiffs and each of the Defendant Drug Manufacturers with respect to the Defendant Drug Manufacturer's conduct of deliberately overstating the AWP's for their brand name drugs, thereby creating a "spread" based on the inflated figure to induce intermediaries to advocate and favor that manufacturer's brand name drugs. Plaintiffs contend that this conduct is unlawful, and that each Defendant engages in this conduct in violation of applicable law, knowing that Plaintiffs and the members of the Class will incur inflated payments for brand name drugs.

464. Each Defendant contends to the contrary. Each Defendant, either by itself or through groups or its trade association, contends that it may exploit the drug pricing system without limit, and regardless of its effect on Plaintiffs and the Class.

465. The Plaintiffs, on behalf of themselves, their constituent members and all others similarly situated, are entitled to a judgment declaring that these practices are unlawful, and are entitled to further relief pursuant to 28 U.S.C. § 2202.

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 Class and their counsel as counsel for the Class;

B. The conduct alleged herein be declared, adjudged and decreed to be unlawful in violation of RICO and the unfair and deceptive trade practices acts set forth above;

C. Plaintiffs and the Class be granted an award of damages in such amount to be determined at trial, with trebling under Counts III and IV;

D. Plaintiffs and the Class 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 Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and

G. Plaintiffs and the Class 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.

By / Thomas M. Sobol /

DATED: September 6, 2002.

Thomas M. Sobol
Edward Notargiacomo
Hagens Berman LLP
225 Franklin Street, 26th Floor
Boston, MA 02110
Telephone: (617) 482-3700
Facsimile: (617) 482-3003

LIAISON COUNSEL

Steve W. Berman
Sean R. Matt
Kevin P. Roddy
Hagens Berman LLP
1301 Fifth Avenue, Suite 2900
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

Samuel Heins
Heins, Mills & Olson, P.C.
700 Northstar East
608 Second Avenue South
Minneapolis, MN 55402
Telephone: (612) 338-4605
Facsimile: (612) 338-4692

Eugene A. Spector
Spector, Roseman & Kodroff, P.C.
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Telephone: (215) 496-0300
Facsimile: (215) 496-6611

CHAIRS OF LEAD COUNSEL COMMITTEE

Michael M. Buchman
Milberg Weiss Bershad Hynes & Lerach, LLP
One Pennsylvania Plaza
New York, NY 10119
Telephone: (212) 594-5300
Facsimile: (212) 868-1229

Marc H. Edelson
Hoffman & Edelson
45 West Court Street
Doylestown, PA 18901
Telephone: (215) 230-8043
Facsimile: (215) 230-8735

Linda P. Nussbaum
Cohen, Milstein, Hausfeld & Toll, P.L.L.C.
825 Third Avenue, 30th Floor
New York, NY 10022
Telephone: (212) 838-7797
Facsimile: (212) 838-7745

Kenneth A. Wexler
Elizabeth Fegan Hartweg
Kenneth A. Wexler & Associates
One North LaSalle Street, Suite 2000
Chicago, IL 60602
Telephone: (312) 346-2222
Facsimile: (312) 346-0022

MEMBERS OF LEAD COUNSEL COMMITTEE AND EXECUTIVE COMMITTEE

Michael McShane
Alexander, Hawes & Audet, LLP
300 Montgomery Street, Suite 400
San Francisco, CA 94104
Telephone: (415) 982-1886
Facsimile: (415) 576-1776

Robert E. Piper, Jr.
Piper & Associates
624 Pierre Avenue
Shreveport, LA 71103
Telephone: (318) 226-0826
Facsimile: (318) 424-9900

MEMBERS OF EXECUTIVE COMMITTEE

Anthony Bolognese
Bolognese & Associates
One Penn Center
1617 JFK Boulevard
Suite 650
Philadelphia, PA 19103
Tel: (215) 814-6750
Fax: (215) 814-6764

Michael J. Flannery
Carey & Danis, LLC
676 North Michigan Ave.
Suite 3110
Chicago, IL 60611
Tel: (312) 649-0100
Fax: (312) 664-7731

Jonathan W. Cuneo
The Cuneo Law Group
317 Massachusetts Avenue, N.E.
Suite 300
Washington, D.C. 20002
Tel: (202) 789-3960
Fax: (202) 789-1813

Neal Goldstein (Of Counsel)
Freedman & Lorry, PC
400 Market Street, Suit 900
Philadelphia, PA 19106
Tel: (215) 925-8400
Fax: (215) 925-7516

Michael E. Criden
Hanzman & Criden, PA
Commerce Bank Center, Suite 400
220 Alhambra Circle
Coral Gables, FL 33134
Tel: (305) 357-9000
Fax: (305) 357-9050

Blake M. Harper
Kirk B. Hulett
Hulett Harper LLP
550 West C Street
Suite 1700
San Diego, CA 92101
Tel: (619) 338-1133
Fax: (619) 338-1139

Jonathan D. Karmel
Karmel & Gilden
221 N. LaSalle Street
Suite 1414
Chicago, IL 60601
Tel: (312) 641-2910
Fax: (312) 641-0781

T. David Copley
Lynn Lincoln Sarko
Mark A. Griffin
Keller Rohrback L.L.P.
1201 3rd Avenue
Suite 3200
Seattle, WA 98101
Tel: (206) 623-1900
Fax: (206) 623-3384

G. Mark Albright
Albright, Stoddard, Warnick & Albright
Quail Park 1, Building D-4
801 South Rancho Drive
Las Vegas, NV 89106

Dianne M. Nast
Roda & Nast, PC
801 Estelle Drive
Lancaster, PA 17601
Tel: 717-892-3000
Fax: 717-892-1200

Henry H. Rossbacher
Rossbacher & Associates
811 Wilshire Boulevard,
Suite 1650
Los Angeles, CA 90017-2666
Tel: (213) 895-6500
Fax: (213) 895-6161

Jonathan Shub
Sheller, Ludwig & Badey, P.C.
1528 Walnut Street, 3rd fl
Philadelphia, PA 19102
Tel: (215) 790-7300
Fax: (215) 546-0942

Scott R. Shepherd
Shepherd & Finkleman, LLC
117 Gayley Street,
Suite 200
Media, PA 19063
Tel: (610) 891-9880
Fax: (610) 891-9883

Lee Squitieri
Squitieri & Fearon
521 Fifth Avenue, 26th floor
New York, NY 10175
Tel: (646) 487-3049
Fax: (646) 487-3095

Lisa J. Rodriguez
Ira Neil Richards
Trujillo Rodriguez & Richards, LLC
The Penthouse
226 West Rittenhouse Square
Philadelphia, PA 19103
Tel: (215) 731-9004
Fax: (215) 731-9044

Mitchell A. Toups
Weller, Green, Toups & Terrell, L.L.P.
2615 Calder Street, Suite 400
P.O. Box 350
Beaumont, TX 77704
Tel: (409) 838-0101
Fax: 409-838-6780

Damon Young
Lance Lee
Young, Pickett & Lee
4122 Texas Boulevard
P.O. Box 1897
Texarkana, AR/TX 75504
Tel: (903) 794-1303
Fax: 903-792-5098; 903-794-5098

ADDITIONAL ATTORNEYS FOR PLAINTIFFS