

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF IOWA, CENTRAL DIVISION**

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THE STATE OF IOWA,

Plaintiff,

v.

ABBOTT LABORATORIES, INC.,  
AGOURON PHARMACEUTICALS, INC.,  
ALPHARMA, INC.,  
ALZA CORPORATION,  
AMGEN, INC.,  
ASTRAZENECA L.P.,  
ASTRAZENECA PHARMACEUTICALS, LP.,  
AVENTIS BEHRING L.L.C.,  
BARR LABORATORIES, INC.,  
BAXTER INTERNATIONAL, INC.,  
BAXTER HEALTHCARE CORPORATION,  
BAYER CORPORATION,  
BAYER PHARMACEUTICALS CORPORATION,  
BEN VENUE LABORATORIES, INC.,  
BOEHRINGER INGELHEIM CORPORATION,  
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,  
BRISTOL-MYERS SQUIBB COMPANY,  
CENTOCOR, INC.,  
CHIRON CORPORATION,  
DERMIK LABORATORIES, INC.,  
DEY, INC.,  
DEY, L.P.,  
ELI LILLY AND COMPANY,  
EMD, INC.,  
ENDO PHARMACEUTICALS, INC.,  
ETHEX CORPORATION,  
ETHICON, INC.,  
FOREST LABORATORIES, INC.,  
FOREST PHARMACEUTICALS, INC.,  
GENEVA PHARMACEUTICALS,  
GLAXOSMITHKLINE, PLC,  
GLAXOWELLCOME, INC.,  
GREENSTONE, LTD.,  
HOECHST MARION ROIUSSSEL, INC.,  
HOFFMAN-LAROCHE, INC.,

JURY TRIAL REQUESTED

**COMPLAINT**

IMMUNEX CORPORATION,  
IVAX CORPORATION,  
IVAX PHARMACEUTICALS, INC.,  
JANSSEN PHARMACEUTICA PRODUCTS, LP,  
JOHNSON & JOHNSON,  
KING PHARMACEUTICALS, INC.,  
KING RESEARCH AND DEVELOPMENT,  
MCNEIL-PPC, INC.,  
MEDIMMUNE, INC.,  
MERCK & CO., INC.,  
MONARCH PHARMACEUTICALS, INC.,  
MYLAN LABORATORIES, INC.,  
MYLAN PHARMACEUTICALS, INC.,  
NOVARTIS PHARMACEUTICALS CORPORATION,  
NOVOPHARM USA, INC.,  
ONCOLOGY THERAPEUTICS NETWORK CORP.,  
ORTHO-MCNEIL PHARMACEUTICAL, INC.,  
ORTHO-BIOTECH PRODUCTS, LP,  
PAR PHARMACEUTICAL, INC.,  
PAR PHARMACEUTICAL COMPANIES, INC.,  
PFIZER, INC.,  
PHARMACIA CORPORATION,  
PURDUE PHARMA, LP,  
PUREPAC PHARMACEUTICAL CO.,  
ROCHE LABORATORIES, INC.,  
ROXANE LABORATORIES, INC.,  
SANDOZ, INC.,  
SANOFI-AVENTIS  
SCHERING CORPORATION,  
SCHERING-PLOUGH CORP.,  
SICOR, INC.,  
SMITHKLINEBEECHAM d/b/a GLAXOSMITHKLINE,  
TAP PHARMACEUTICAL PRODUCTS, INC.,  
TEVA PHARMACEUTICALS INDUSTRIES, LTD.,  
TEVA PHARMACEUTICAL USA,  
THE PURDUE FREDERICK COMPANY,  
THE PURDUE PHARMA COMPANY,  
UDL LABORATORIES, INC.,  
WARRICK PHARMACEUTICALS CORPORATION,  
WATSON PHARMA, INC.,  
WATSON PHARMACEUTICALS, INC.  
WYETH,  
WYETH PHARMACEUTICALS, INC., and  
DOES 1-100,

Defendants.

Plaintiff, the State of Iowa, by and through its Attorney General Tom Miller, alleges on information and belief, as follows:

## **I. INTRODUCTION**

1. Iowa brings this action to recover millions of dollars in damages suffered by the Iowa Medicaid Program (“Iowa Medicaid”) as a result of defendant drug manufacturers’ unlawful pricing practices, and to halt such practices.

2. The unlawful practices are straightforward. Defendants purposefully report false and inflated price information for certain prescription drugs covered by Iowa Medicaid.

3. Defendants submit this false and inflated pricing information in order to “create a spread” between Medicaid providers’ actual acquisition cost (“AAC”) for defendants’ products and the amount at which the drug is reimbursed by Medicaid and other third party payors.

4. Defendants know that by creating this spread they can incentivize pharmacists (both mail-order and traditional retail), Group Purchasing Organizations (“GPOs”), Hospital Out-Patient Pharmacies, Nursing Homes and various other Medicaid pharmacy providers who select among competing drugs and/or develop formularies to purchase or give preferential treatment to defendants’ products. In other words, defendants compete with each other based on spread and reimbursement, rather than actual cost or efficacy.

5. Thus, for example, a retail pharmacy that needs to stock its shelves with a version of a multi-source or generic drug will select the generic with the greatest spread between the pharmacy’s AAC for that drug and the reimbursement amount the pharmacy will receive from Medicaid or other third party payors. Likewise, a GPO that is providing purchase options

for its members and needs to select a preferred brand drug like a cholesterol reducing statin will choose among Lipitor, Zocor, Pravachol, Lescol, Mevacor or Crestor based on spread. The fact of this distorted competition is not speculative. GeriMmed, a GPO serving long term care pharmacies, makes clear in its marketing materials to its customers that one of the “Keys to Unlocking Profits” with respect to “Single Source Medications” (or brand-name patented drugs) is to “BUY THE PACKAGE SIZE WITH THE BEST AWP SPREAD,”

6. Defendants are able to perpetrate this deception because defendants operate in and purposefully manipulate a market that, by defendants’ own design, is extremely complicated and non-transparent. Defendants know that Medicaid has no practical alternative but to rely on the false pricing information, which defendants report to the publishing compendia and represent to be true. Defendants know that their pricing practices result in Medicaid paying more for prescription drugs than any other payor.

7. There are two relevant components of the price Iowa Medicaid pays for the prescription drugs at issue in this case. The first is the price initially paid by Medicaid to the pharmacy provider for the drug. The second is the federal Medicaid rebate Iowa receives for brand drugs.

8. As to the initial price paid, Iowa, like all states, is required by federal law to reimburse providers at their Estimated Acquisition Cost (“EAC”). To that end, Iowa, like all states, established a formula to calculate EAC based on wholesale price information provided by the manufacturers.

9. There are four pricing benchmarks relevant to this EAC formula: wholesale acquisition cost or “WAC”; “average wholesale price” or “AWP”; the federal maximum allowable cost or federal upper limit “MAC” or “FUL”; and, since 2001, the Iowa

State Maximum Allowable Cost or “SMAC.” Defendants’ unlawful price reporting activity infects all four benchmarks and renders each of them false and inflated. Thus, regardless which benchmark Iowa utilizes to calculate its Medicaid prescription reimbursements and EAC, the net result is that Iowa overpays.

10. The second relevant component is the rebate that brand drug manufacturers pay to the states pursuant to a federal statutory formula set forth in 42 U.S.C. § 1396r-8 (the “Medicaid Rebate Statute”), and the statutorily-mandated Medicaid rebate contract that each manufacturer executes with the Secretary of Health and Human Services “on behalf of the States.”<sup>1</sup>

11. The relevant benchmark with respect to the brand drug Medicaid Rebate is something called “Best Price.” “Best Price” is reported by brand drug manufacturers only and can serve as the basis for the brand manufacturer’s rebate payments to the States. As set forth more fully below, Iowa alleges that certain brand manufacturers named in this complaint do not accurately report the Best Prices for certain of their drugs with the effect being that the manufacturers underpay the rebates they owe to Iowa for those drugs.

12. Defendants’ unlawful pricing schemes involve both components described above. Their manipulation of the Medicaid program through the improper reporting of false and inflated pricing information that form the bases for each of these two components has resulted in overcharges of many millions of dollars to the Iowa Medicaid Program, as set forth in detail herein.

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<sup>1</sup> See Medicaid Rebate Agreement, 56 Fed. Reg. 7049 (1991); Payment for Drugs under Rebate Agreements, 60 Fed. Reg. 48442 (1995) (codified at 42 CFR 441). A copy of the current standard Model Rebate Agreement, available at <http://www.cms.hhs.gov/medicaid/drugs/drebate.asp>, and substantially similar to that executed by each defendant named herein, is Exhibit E hereto.

13. Defendants' wrongful practices are especially pernicious given their effect on the public fisc and in connection with a government-sponsored, taxpayer-funded means-based entitlement program that was created to provide a social safety net for those who are among the nation's most vulnerable citizens — the poor and infirm.

14. As voluntary participants in the Iowa Medicaid program, who seek to have their drugs paid for by the government, defendants are charged with the knowledge and requirements of State and Federal law.

15. It is well settled that those who seek to be paid from the public fisc must “turn square corners” in their dealings with the government.

This observation has its greatest force when a private party seeks to spend the Government's money. Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; [such an entity] could expect no less than to be held to the most demanding standard in its quest for public funds. This is consistent with the general rule that those who deal with the Government are expected to know the law.

*North Memorial Medical Ctr. v. Gomez*, 59 F.3d 735, 739 (8th Cir. 1995) (citing *Heckler v. Community Health Servs.*, 467 U.S. 51, 64-65 (1984)).

16. Defendants ignore this obligation entirely and knowingly, brazenly and intentionally report false prices to the government. Defendants are liable under federal and state law for these affirmative misrepresentations.

17. In all, halting defendants' fraudulent, unfair and deceptive practices and recovering the millions of dollars in damages suffered by Iowa Medicaid is a matter of supreme public importance and the fundamental goal of this litigation.

18. The specific prescription drugs at issue in this litigation are identified by their unique national drug codes, known as “NDCs” (hereinafter the “at issue NDCs”) and listed in Exhibit B-1 through B-33 hereto.

## II. PARTIES

19. This action is brought for and on behalf of the sovereign State of Iowa, by and through Tom Miller, the duly elected and current Attorney General of the State of Iowa pursuant to, *inter alia*, the Iowa Consumer Fraud Act, Iowa Code § 714.16, and the common law and statutory authority of the Attorney General to represent the State of Iowa.

20. Defendants are brand (single source) and generic (multi-source) manufacturers and sellers of prescription drugs who have voluntarily agreed to participate in the Iowa Medicaid program and whose unlawful, misleading and deceptive scheme, described in this Complaint, has resulted in drugs being paid for by Iowa Medicaid at false and inflated prices as detailed herein.

21. Each defendant conducts extensive business in the State of Iowa.

22. Defendant **ABBOTT LABORATORIES, INC.** (“Abbott”) is an Illinois corporation engaged in the business of manufacturing and selling pharmaceuticals. Abbott’s principal place of business is located at 100 Abbott Park Road, Abbott Park, IL.

23. The following two defendants are hereinafter referred to as the **ALPHARMA GROUP OR ALPHARMA:**

(a) Defendant Alharma, Inc. (“Alharma”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Alharma’s principal place of business is located at One Executive Drive, Fort Lee, NJ 07024.

(b) Defendant Purepac Pharmaceutical Co. (“Purepac”), a wholly owned subsidiary of Alharma, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Purepac was acquired by Alharma in December

2001. According to the SEC, Purepac's principal place of business is also located at One Executive Drive, Fort Lee, NJ 07024.

24. The following two defendants are hereinafter referred to as the **AMGEN GROUP OR AMGEN**:

(a) Defendant Amgen, Inc. ("Amgen, Inc.") is a Delaware corporation in the business of manufacturing and selling pharmaceuticals. Amgen, Inc.'s principal place of business is located at One Amgen Drive, Thousand Oaks, CA 91320-1799.

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

25. The following two defendants are hereinafter referred to as the **ASTRAZENECA GROUP OR ASTRAZENECA**:

(a) AstraZeneca Pharmaceuticals L.P. is a Delaware limited partnership engaged in the business of manufacturing and selling pharmaceuticals. AstraZeneca's principal place of business is located at 1800 Concord Pike, Wilmington, DE 19850-5437.

(b) Defendant, AstraZeneca LP ("AstraZeneca LP"), is a Delaware limited partnership engaged in the business of manufacturing and selling pharmaceuticals. AstraZeneca LP's principal place of business is located at 725 Chesterbrook Boulevard, Wayne, PA.

26. Defendant **BARR LABORATORIES, INC.** ("Barr") is a New York corporation engaged in the business of manufacturing and selling pharmaceuticals. Barr's

principal place of business is located at 2 Quaker Road, P.O. Box 2900, Pomona, NY 10970-0519.

27. The following two defendants are hereinafter referred to as the **BAXTER GROUP OR BAXTER:**

(a) Defendant Baxter International, Inc. (“Baxter”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Baxter’s principal place of business is located at One Baxter Parkway, Deerfield, Illinois. In 1997, Baxter acquired Immuno International AG, a Swiss corporation, and is therefore its successor in interest.

(b) Defendant Baxter Healthcare Corporation (“Baxter Healthcare”) is the principal domestic operating subsidiary of Baxter International, also engaged in the business of manufacturing and selling pharmaceuticals and is also located at One Baxter Parkway, Deerfield, Illinois.

28. The following two defendants are hereinafter referred to as the **BAYER GROUP OR BAYER:**

(a) Defendant **BAYER CORPORATION** (“Bayer Corp.”) is an Indiana corporation engaged in the business of manufacturing and selling pharmaceuticals. Bayer Corp. itself is a wholly owned United States subsidiary of a German corporation, Bayer AG. Bayer Corp.’s principal place of business is located at 100 Bayer Road, Crafton, PA 15205-9741.

(b) Defendant **BAYER PHARMACEUTICALS CORPORATION** (“Bayer Pharm”) is a wholly owned subsidiary of Bayer Corp. located at 400 Morgan Lane, West Haven, Connecticut.

29. The following two defendants are hereinafter referred to as the **BMS**

**GROUP:**

(a) Defendant Bristol-Myers Squibb Company (“Bristol-Myers”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Bristol-Myers’ principal place of business is located at 345 Park Avenue, New York, NY 10154-0037. Westwood-Squibb (“Westwood”) is a division of BMS.

(b) Defendant Oncology Therapeutics Network Corp. (“OTN”), a wholly owned subsidiary of Bristol-Myers, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. OTN’s principal place of business is located at 395 Oyster Point Boulevard, Suite 405, South San Francisco, CA 94080.

30. The following defendants are hereinafter referred to as the

**BOEHRINGER GROUP:**

(a) Defendant Boehringer Ingelheim Corporation (“Boehringer”) is a Nevada corporation engaged in the business of manufacturing and selling pharmaceuticals. Boehringer’s principal place of business is located at 900 Ridgebury Rd., Ridgefield, CT 06877. Boehringer is a United States subsidiary of Pharm Investment Limited of Burlington, Canada which, in turn, is a division of C.H. Boehringer Sonn Grundstücksverwaltung GmbH & Co. KG of Ingelheim, Germany, a German corporation with its principal offices in Ridgefield, CT.

(b) Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (“Boehringer Pharm”), a wholly owned subsidiary of Boehringer, is a Connecticut corporation engaged in the business of manufacturing and selling pharmaceuticals. Boehringer Pharm’s principal place of business is located at 900 Ridgebury Rd., Ridgefield, CT 06877. At all times

relevant and hereto, all acts committed by or on behalf of Boehringer Pharm. were also committed by or on behalf of Boehringer.

(c) Defendant Boehringer Ingelhiem Roxane, Inc. f/k/a Roxane Laboratories, Inc. (hereinafter “Roxane”), a wholly owned subsidiary of Boehringer, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Roxane’s principal place of business is located at 1809 Wilson Rd., Columbus, OH 43216-6532.

(d) Defendant Ben Venue Laboratories, Inc. (“Ben Venue”), a wholly owned subsidiary of Boehringer, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Ben Venue’s principal place of business is located at 300 Northfield Road, Bedford, OH 44146. In 1993, Ben Venue created a separate division called Bedford Laboratories (“Bedford”) to market and sell its own generic formulas. In December 1997, Ben Venue was acquired by Boehringer.

31. Defendant **CHIRON CORPORATION** is a Delaware Corporation engaged in the business of manufacturing and selling pharmaceuticals. Chiron Corporation’s principal place of business is located at 4560 Horton St., Emeryville, CA 94608-2916. Chiron Corporation is also being sued for the conduct of its subsidiaries, divisions and predecessor corporations, including but not limited to Cetus Oncology Corp. These entities are referred to herein as “Chiron”.

32. The following three defendants are hereinafter referred to as the **DEY GROUP OR DEY**:

(a) Defendant Dey, L.P. is a Delaware limited partnership engaged in the business of manufacturing and selling pharmaceuticals with its principal offices at 2751 Napa Valley Corporate Drive, Napa, CA 94558.

(b) Defendant Dey Inc. f/k/a Dey Laboratories, Inc., (“Dey Inc.”), is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals and the general partner of Dey L.P. Dey Inc.’s principal place of business is located at 2751 Napa Valley Corporate Drive, Napa, CA 94558.

(c) Defendant EMD, Inc. (“EMD”) is a corporation with headquarters in Durham, North Carolina and is the sole shareholder of Dey. In 1998, Dey became a subsidiary of Lipha, S.A., based in Lyon, France. In 1991, Merck KGaA acquired the majority share of Lipha, S.A. Defendant Merck KGaA is a German company based in Darmstadt, Germany. At all times relevant and hereto, all acts committed by or on behalf of Dey L.P., Dey Inc. were also committed by or on behalf of EMD.

33. Defendant **ELI LILLY AND COMPANY** (“Eli Lilly”) is an Indiana corporation engaged in the business of manufacturing and selling pharmaceuticals. Eli Lilly’s principal place of business is located at Lilly Corporate Center, Indianapolis, IN 46285.

34. Defendant **ENDO PHARMACEUTICALS INC.** (“Endo”), a subsidiary of Endo Pharmaceuticals Holding Inc., is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Endo’s principal place of business is located at 100 Painters Drive, Chadds Ford, PA 19317.

35. Defendant **ETHEX CORPORATION** (“Ethex”), a wholly owned subsidiary of KV Pharmaceutical Company (“KV”), is a Delaware corporation with its principal place of business at 10888 Metro Court, St. Louis, MO. KV is also a Delaware corporation with its principal place of business at 2503 South Hanley Road, St. Louis, MO. Ethex is in the business of manufacturing, marketing and selling prescription pharmaceuticals.

36. The following two defendants are hereinafter referred to as the **FOREST GROUP OR FOREST**:

(a) Defendant Forest Laboratories, Inc. (“Forest”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Forest’s principal place of business is located at 909 Third Ave, New York, NY 10022.

(b) Defendant Forest Pharmaceuticals, Inc. (“Forest Pharm”) is a corporation engaged in the business of manufacturing and selling pharmaceuticals. Forest Pharm is a wholly owned subsidiary of Forest Laboratories, Inc. Forest Pharm’s principal place of business is located at 13600 Shoreline Drive, St. Louis, MO 63045.

37. The following three defendants are hereinafter referred to as the **GSK GROUP**:

(a) Defendant GlaxoSmithKline P.L.C. (“GSK”), created through the merger of Glaxo Wellcome, P.L.C. and SmithKlineBeecham P.L.C., is a British corporation engaged in the business of manufacturing and selling pharmaceuticals. GSK’s principal place of business is located at 980 Great West Road, Brentford, Middlesex, EN, TW8 9, U.K. Cerenex Pharmaceuticals (“Cerenex”) is a division of GSK.

(b) Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline (“SmithKline”), a wholly owned subsidiary of the former SmithKlineBeecham P.L.C., is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals. SmithKline’s principal place of business is located at One Franklin Plaza, 16th and Race Streets, Philadelphia, PA 19102.

(c) 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, NC. Cerenex Pharmaceuticals (“Cerenex”), a division of Glaxo prior to the merger, was responsible for Glaxo’s central nervous system drugs, including Zofran.

38. The following two defendants are hereinafter referred to as the **HOFFMAN-LAROCHE GROUP**:

(a) Defendant Hoffman-LaRoche, Inc. (“Hoffman-LaRoche”) is a New Jersey corporation. Hoffman-LaRoche is the U.S. prescription drug unit of the Roche Group and is engaged in the business of manufacturing and selling pharmaceuticals. Roche’s principal place of business is located at 340 Kingsland Street, Nutley, NJ 07110-1199.

(b) Defendant Roche Laboratories, Inc. (“Roche”), a wholly owned subsidiary of Hoffman-LaRoche, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Roche principal place of business is located at 340 Kingsland Street, Nutley, NJ 07110-1199.

39. The following two defendants are hereinafter referred to as the **IVAX GROUP OR IVAX**:

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

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

40. The following eight defendants are hereinafter referred to as the **JOHNSON & JOHNSON GROUP**:

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

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

(c) Defendant Ortho-McNeil Pharmaceutical, Inc. (“Ortho McNeil”), a wholly owned subsidiary of J&J, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Ortho McNeil’s principal place of business is located at 1000 U.S. Route 202 South, Raritan, NJ 08869.

(d) Defendant Ortho Biotech Products, LP (“Ortho Biotech”), a wholly owned subsidiary of J&J, is a New Jersey limited partnership engaged in the business of manufacturing and selling pharmaceuticals. Ortho Biotech’s principal place of business is located at 700 U.S. Highway 202, Raritan, NJ 08869.

(e) Defendant McNeil-PPC, Inc. (“McNeil”), a wholly owned subsidiary of J&J, is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. McNeil’s principal place of business is located at 7050 Camp Hill Road, Fort Washington, PA 19034. McNeil Consumer & Specialty Pharmaceuticals (“McNeil Cons”) is a division of McNeil.

(f) Defendant Alza Corporation (“Alza”), is a Delaware Corporation engaged in the business of manufacturing and selling pharmaceuticals. Alza’s principal place of business located at 1900 Charleston Road, Mountain View, CA. J&J acquired Alza from defendant Abbott in 2000.

(g) Defendant Centocor, Inc. (“Centocor”), is a Pennsylvania Corporation engaged in the business of manufacturing and selling pharmaceuticals. Centocor’s principal place of business located at 244 Great Valley Parkway, Malvern, PA.

(h) Defendant Ethicon, Inc. (“Ethicon”), is a New Jersey Corporation, engaged in the business of manufacturing and selling pharmaceuticals. Ethicon’s principal place of business is located at Route 22 West, Somerville, NJ.

41. The following three defendants are hereinafter referred to as the **KING GROUP**:

(a) Defendant King Pharmaceuticals, Inc. (“King”) is a Tennessee corporation in the business of manufacturing and selling pharmaceuticals. King’s principal place of business is located at 501 Fifth St., Bristol, TN 37620.

(b) Defendant Monarch Pharmaceuticals, Inc. (“Monarch”), a wholly owned subsidiary of King, is a Tennessee corporation in the business of manufacturing and selling pharmaceuticals. Monarch’s principal place of business is located at 501 Fifth Street, Bristol, TN 37620.

(c) Defendant King Research and Development (“King R&D”), a wholly owned subsidiary and successor to Jones Pharma Incorporated, is a Tennessee corporation in the business of manufacturing and selling pharmaceuticals. King R&D’s principal place of business is located at 501 Fifth Street, Bristol, TN 37620.

42. Defendant **MEDIMMUNE, INC.** (“MedImmune”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. MedImmune’s principal place of business is located at One MedImmune Way, Gaithersburg, MD 20878. Since at least 1998, MedImmune has had a co-promotion and marketing agreement with the Ross Products Unit of defendant Abbott.

43. Defendant **MERCK & CO., INC.** (“Merck”) is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. Merck’s principal place of business is located at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

44. The following three defendants are hereinafter referred to as the **MYLAN GROUP**:

(a) Defendant Mylan Laboratories Inc. (“Mylan”) is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals, mainly through its subsidiaries. Mylan’s principal place of business is located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

(b) Defendant Mylan Pharmaceuticals Inc. (“Mylan Pharm”), a wholly owned subsidiary of Mylan, is a West Virginia corporation engaged in the business of manufacturing and selling pharmaceuticals. Mylan Pharm’s principal place of business is located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

(c) Defendant UDL Laboratories, Inc. (“UDL”), a wholly owned subsidiary of Mylan, is an Illinois corporation engaged in the business of manufacturing and selling pharmaceuticals. UDL’s principal place of business is located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

45. The following three defendants are hereinafter referred to as the **NOVARTIS GROUP**:

(a) Defendant Novartis Pharmaceuticals Corporation (“Novartis”) is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. Novartis’ principal place of business is located at One Health Plaza, East Hanover, NJ 07936.

(b) Defendant Sandoz, Inc. (“Sandoz”) is a wholly owned subsidiary of Novartis. Sandoz is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Sandoz’s principal place of business is located at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

(c) Defendant Geneva Pharmaceuticals (“Geneva”) was incorporated in 1991 under the laws of Colorado with its principal offices in Plainsboro, NJ. On December 1, 2003, Geneva was acquired by Sandoz.

46. The following two defendants are hereinafter referred to collectively as the **PAR GROUP OR PAR**:

(a) Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation in the business of manufacturing and distributing generic drugs in the United States and maintains its principal place of business located at One Ram Ridge Road, Spring Valley, NY 10977. Defendant Par Pharmaceutical Companies, Inc. is being sued for the conduct of its subsidiaries and/or divisions, including but not limited to, Par Pharmaceutical, Inc.

(b) Defendant Par Pharmaceutical, Inc., a wholly owned subsidiary of Par Pharmaceutical Companies, Inc., is in the business of manufacturing and distributing generic drugs in the United States and maintains its principal place of business at One Ram Ridge Road, Spring Valley, NY 10977.

47. The following four defendants are hereinafter referred to as the **PFIZER**

**GROUP:**

a) Defendant Pfizer, Inc. (“Pfizer”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Pfizer’s principal place of business is located at 235 East 42nd Street, New York, NY 10017.

b) Defendant Pharmacia Corporation (“Pharmacia”) is a wholly-owned Pfizer subsidiary engaged in the business of manufacturing and selling pharmaceuticals. Pharmacia’s principal place of business is located at 100 Route 206 North, Peapack, NJ 07977.

c) Defendant Agouron Pharmaceuticals, Inc. (“Agouron”) is a California corporation engaged in the business of manufacturing and selling pharmaceuticals, and a wholly owned Pfizer subsidiary. Agouron’s principal place of business is located at 10777 Science Center Dr., San Diego, CA 92121.

d) Defendant Greenstone, LTD (“Greenstone”) is a Delaware corporation engaged in the business of manufacturing and or selling pharmaceuticals. Greenstone LTD is a wholly owned Pfizer subsidiary. Greenstone’s principal place of business is located at 100 Route 206 North, Peapack, NJ 07977.

48. The following three defendants are hereinafter referred to as the **PURDUE**

**GROUP OR PURDUE:**

(a) Defendant Purdue Pharma, L.P. (“Purdue L.P.”) is a Delaware limited partnership engaged in the business of manufacturing and selling pharmaceuticals. Purdue L.P.’s principal place of business is One Stamford Forum, 201 Tresser Boulevard, Stamford, CT.

(b) Defendant The Purdue Frederick Company (“Purdue Frederick”) is a New York corporation engaged in the business of manufacturing and selling pharmaceuticals. Purdue Frederick’s principal place of business is One Stamford Forum, 201 Tresser Boulevard, Stamford, CT.

(c) Defendant The Purdue Pharma Company (“Purdue Co.”) is a Delaware general partnership engaged in the business of manufacturing and selling pharmaceuticals. Purdue Co’s principal place of business is One Stamford Forum, 201 Tresser Boulevard, Stamford, CT. Defendants Purdue L.P. and Purdue Frederick are general partners of Purdue Co.

49. The following four defendants are hereinafter referred to as the **SANOFI-AVENTIS GROUP**:

(a) Defendant Sanofi-Aventis, f/k/a Aventis Pharmaceuticals, Inc., is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Sanofi-Aventis’s principal place of business is located at 55 Corporate Boulevard, Bridgewater, NJ 08807. Sanofi-Aventis was created as a result of a merger between Aventis Pharmaceuticals and Sanofi-Synthelabo in August 2004.

(b) Defendant Dermik Laboratories, Inc. (“Dermik”), a wholly owned subsidiary of Aventis Pharm, is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals. Dermik’s principal place of business is located at 1050 Westlakes Drive, Berwyn, PA 19312.

(c) Defendant Aventis Behring L.L.C. (“Aventis Behring”) is an Illinois limited liability corporation with its principal place of business located at 1020 First

Avenue, King of Prussia, PA. Aventis Behring LLC is the successor-in-interest to Centeon, LLC and Armour Pharmaceuticals.

(d) Defendant Hoechst Marion Roussel, Inc. (“Hoechst”), is a Delaware corporation with its principal place of business located at 10236 Marion Park Drive, Kansas City, MO.

50. The following three defendants are hereinafter referred to as the **SCHERING GROUP:**

(a) Defendant Schering-Plough Corp. (“Schering-Plough”) is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. Schering’s principal place of business is located at 2000 Galloping Hill Rd., Kenilworth, NJ 07033.

(b) Defendant Schering Corporation (“Schering”) is a corporation organized under the laws of New Jersey with its principal offices located at 1 Giralda Farms, P.O. Box 1000, Madison, New Jersey 07940. Schering-Plough and Schering are the actual manufacturers, marketers, sellers, and/or suppliers of the products involved in this litigation and are Warrick’s actual parent(s) or shareholder(s).

(c) Defendant Warrick Pharmaceuticals Corporation (“Warrick”), a wholly owned direct subsidiary of Schering-Plough and Schering, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Warrick’s principal place of business allegedly is located at 12125 Moya Boulevard, Reno, NV 89506. However discovery in the matter styled the *State ex rel. Ven-a-Care v. Warrick Pharmaceuticals Corp, et al.*, No GV002327 (D. Ct., Travis Co., Tex.), led the State of Texas to conclude that Warrick’s

principal offices and operations are actually in the State of New Jersey, where its direct parents Schering-Plough and Schering are located.

51. Defendant **TAP PHARMACEUTICAL PRODUCTS, INC.** (“TAP”), a joint venture between defendant Abbott and Takeda Chemical Industries, Ltd., of Osaka, Japan, is a corporation engaged in the business of manufacturing and selling pharmaceuticals. TAP’s principal place of business is located at 675 North Field Drive, Lake Forest, IL 60045.

52. The following four defendants are hereinafter referred to as the **TEVA GROUP OR TEVA**:

(a) Defendant Teva Pharmaceuticals Industries, Ltd. (“Teva Ltd.”) is an Israeli corporation engaged in the business of manufacturing and selling generic and proprietary branded pharmaceuticals and active pharmaceutical ingredients. Teva’s principal place of business is located at 5 Basel St., Petach Tikva 49131, Israel.

(b) Defendant Teva Pharmaceutical USA (“Teva USA”) is a Delaware corporation engaged in the business of manufacturing and selling of pharmaceuticals. Teva USA’s principal place of business is located at 1090 Horsham Rd., North Wales, PA 19454. Teva USA is a wholly-owned subsidiary of Teva Ltd.

(c) Sikor, Inc., f/k/a Gensia Sicor Pharmaceuticals, Inc. f/k/a Gensia Laboratories Ltd. (“Sicor”) is a Delaware corporation with its principal offices in Irvine, California. Gensia was founded in 1986 to manufacture and sell pharmaceutical products primarily related to cardiovascular diseases. In 1997 Gensia and Rakepoll Finance merged and the corporate name became Gensia Sicor. In 1999, Gensia Sicor changed its name to Sicor, Inc. In 2003, Teva Pharmaceuticals, Inc. acquired Sicor. Sicor’s principal place of business is located at 19 Hughes, Irvine, California 92618. Sicor is a wholly-owned subsidiary of Teva Ltd.

(d) Defendant Novopharm USA, Inc. (“Novopharm”) is a Delaware corporation engaged in the business of manufacturing and selling of pharmaceuticals. Novopharm’s principal place of business is located at 165 East Commerce Drive, Suite 100-201, Schaumburg, Illinois 60173. Novopharm is a wholly-owned subsidiary of Teva Ltd.

53. The following two defendants are hereinafter referred to as the **WATSON GROUP OR WATSON:**

(a) Defendant Watson Pharmaceuticals, Inc. (“Watson”) is a Nevada corporation engaged in the business of manufacturing and selling pharmaceuticals. Watson’s principal place of business is located at 311 Bonnie Circle, Corona, CA 92880.

(b) Defendant Watson Pharma, Inc., formerly known as Schein (“Watson Pharma”) is a wholly owned subsidiary of Watson since 2000 and a Delaware corporation. Watson Pharma is engaged in the business of manufacturing and selling pharmaceuticals. Watson Pharma’s principal place of business is located at 311 Bonnie Circle, Corona, CA 92880.

54. The following two defendants are hereinafter referred to as the **WYETH GROUP OR WYETH.**

(a) Defendant Wyeth formerly American Home Products Corp., is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Wyeth’s principal place of business is located at Five Giralda Farms, Madison, NJ 07940.

(b) Defendant Wyeth Pharmaceuticals, Inc., (“Wyeth Pharma”), a wholly owned subsidiary of Wyeth, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Wyeth Pharma’s principal place of business is located at 500 Arcola Road, Collegeville, Pennsylvania.

55. Various other individuals, partnerships, sole proprietors, business entities, companies, and corporations, currently unknown to Iowa and not named as defendants in this Complaint, participated in the violations alleged in this Complaint and performed acts and made statements in furtherance thereof. Such unknown persons or entities aided, abetted, or participated with defendants in the commission of the wrongful acts alleged herein or otherwise caused the damages suffered by Iowa.

56. Except as described herein, Iowa is, as yet, unaware of the true names, capacities, nature and extent of the participation in the course of conduct alleged herein of the persons sued as DOES 1-100 inclusive and, therefore, sue these defendants by such fictitious names. Iowa will amend this Complaint to allege the true names and capacities of the Doe defendants when ascertained.

57. Defendants unknown at this time may include independent pharmacies, dispensers, and other pharmacy providers who prescribed drugs and received inflated Medicaid reimbursements and engaged in fraudulent billing practices, as well as various other persons, wholesalers, publishers, partnerships, sole proprietors, firms, corporations and individuals that may have participated with defendants in the offenses alleged in this complaint and may have performed acts and made statements in furtherance of the alleged illegal conduct.

58. Each of the defendants designated herein as a Doe defendant is legally responsible in some manner for the unlawful acts referred to herein.

### **III. JURISDICTION AND VENUE**

59. Iowa asserts claims for violation of the Social Security Act, 42 U.S.C. § 1396 *et seq*, the Iowa Consumer Fraud Act, Iowa Code § 714.16, and for breach of contract, unjust enrichment, and common law fraud.

60. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because the action alleges violations of the Social Security Act, 42 U.S.C. § 1396 *et seq.* and breach of the federal Medicaid Rebate Agreement created pursuant to 42 U.S.C. §1396r-8. This Court has supplemental jurisdiction over Iowa’s state law claims pursuant to 28 U.S.C. § 1367.

61. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c). Defendants do business and are qualified to do business in this district; certain acts giving rise to the claims asserted in this complaint occurred within this district; and the illegal actions of defendants, as alleged in this complaint, caused damage to plaintiff within this district.

#### **IV. ALLEGATIONS APPLICABLE TO ALL DEFENDANTS**

##### **A. THE MEDICAID STATUTORY SCHEME**

62. Medicaid was established by Title XIX of the Federal Social Security Act (the “Act”), 42 U.S.C. § 1396 *et seq.* (the “Medicaid Program”). The Act mandates the establishment of minimum health and safety standards that must be met by providers and suppliers, such as defendants, participating in the Medicaid Program.

63. State participation in Medicaid is voluntary, but once a state agrees to participate, as Iowa has, the state must comply with all federal statutory requirements. The Medicaid plan proposed by each state must be approved by the federal government. *See* 42 U.S.C. §§ 1396a(a) and (b). Iowa’s Medicaid plan has been expressly approved by the federal government.

64. Federal Medicaid law requires states and localities to seek recovery of the full amount of any overcharge to the Medicaid program, including the federal and state shares of such overcharges. 42 U.S.C. § 1396a(a)(25)(A) & (B); 42 U.S.C. § 1396b(d)(3)(A).

65. Medicaid does not require states to cover prescription drugs, but all 50 states and the District of Columbia currently provide such coverage. 42 U.S.C. § 1396d(a)(2).

66. In Medicaid, drugs are identified and tracked by 11-digit national drug codes (NDCs). NDCs identify unique formulations of each drug, including the manufacturer, strength and package size. Currently there are over 65,000 NDCs.

67. Federal regulations require State Medicaid Programs to reimburse providers for Medicaid covered drugs at the “lower of the 1) estimated acquisition costs [“EAC”] plus reasonable dispensing fees established by the [Single State Medicaid Agency] or 2) providers’ usual and customary charges to the general public.” 42 C.F.R. § 447.331.

68. Typically, States base EAC on average wholesale price (AWP) minus a discount. According to a report issued by the United States Department of Health and Human Services Office of Inspector General (“OIG”) in September 2004, “Variation in State Medicaid Drug Prices, September 2004” (OEI-05-02-00681), the most common EAC formula in 2001 was AWP minus 10 percent.

69. Iowa’s EAC formula was AWP-10% until 2006, when it was changed to AWP-12%.

70. The OIG has recognized that the States must rely on EAC proxies (such as AWP) because of the difficulty in accessing pharmacies’ actual acquisition costs.

71. States have historically reimbursed at a discount off of AWP because States were aware that the AWP defendants caused to be reported for their products were somewhat higher than what pharmacies actually paid to obtain drugs. The discount rates were meant to re-capture this inflation and to approximate EAC, as Federal Regulations require. At no time did Iowa seek to reimburse at a rate higher than EAC.

72. The fact that most states discounted from AWP in the 10% range reveals what States believed the level of AWP inflation to be. Only recently has Iowa learned that the

true levels of AWP inflation were grotesquely higher than what was originally believed. Only recently has Iowa learned that the reported AWPs often bear no relationship whatsoever to defendants' true prices and can exceed 100%, 200% or even more of what those true prices are.

### **1. Iowa Medicaid's Reimbursement Formula for Prescription Drugs**

73. Iowa's 2006 Medicaid Provider Manual provides that the amount of payment for prescription drugs is based on several factors, in accordance with 42 C.F.R. § 447.331-447.332 and Iowa Admin. Code 441-79.1(8).

(a) "Estimated acquisition cost" (EAC) is defined as the average wholesale price ("AWP") as published by Medi-Span less 12%.

(b) "Maximum allowable cost" (MAC) is defined as the federal upper limit or "FUL" for multiple-source drugs, established in accordance with the methodology of the Centers for Medicare and Medicaid Services, as described in 42 C.F.R. § 447.332(a)(1)(i) and (ii).

(c) "State maximum allowable cost" (SMAC) reimbursement is price assigned by Iowa Medicaid to certain drug products meeting therapeutic equivalency, market availability, or other criteria determined appropriate by the Department. Since 2001, Iowa Medicaid established SMAC fees, *inter alia*, through a review of invoices which, in part, reflect or are based on published prices including WACs, AWPs and FULs. To the extent that defendants falsely report their prices, as described herein, defendants cause false and inflated SMACs to be set.

74. The 2006 Iowa Provider Manual provides further that reimbursement for covered **generic** prescription drugs *shall be the lowest of* the following, as of the date of dispensing:

- The estimated acquisition cost, defined as the average wholesale price as published by Medi-Span less 12 percent, plus the professional dispensing fee.
- The maximum allowable cost (MAC or FUL) plus the professional dispensing fee.
- The state maximum allowable cost (SMAC) plus the professional dispensing fee.
- The submitted charge, representing the provider's usual and customary charge for the drug.

75. Iowa's use of a SMAC began in 2001 when the Department of Human Services established it in response to 2001 Iowa Acts, Chapter 191, section 31. Prior to 2001, there was no Iowa SMAC.

76. Prior to Iowa's use of a SMAC, the Iowa Medicaid provider manual provided that generic drugs would be reimbursed at the lower of EAC, MAC/FUL or the submitted charge (representing the provider's usual and customary charge).

77. According to the Iowa 2006 Medicaid Provider Manual, reimbursement for covered **brand name** prescription drugs *shall be the lowest of* the following, as of the date of dispensing:

- The estimated acquisition cost (AWP-12%) plus the professional dispensing fee.
- The submitted charge, representing the provider's usual and customary charge for the drug.

78. From 1991 to 2005, Iowa defined EAC as AWP-10%. Throughout that period of time, Iowa's source for WACs, AWP, FULs and all other published wholesale price information was First Data Bank.

79. From 1991 to 2005, Iowa reimbursed for brand drugs based on the lower of EAC (AWP-10%) or the submitted charge (representing the provider's usual and customary charge).

80. The Medicaid reimbursements at issue in this litigation are those made on the basis of AWP, MAC/FUL or SMAC. Every drug listed in Exhibit B to this complaint has been reimbursed by Iowa Medicaid based on AWP, MAC/FUL or, since 2001, SMAC.

## **2. Iowa's Source for FULs and AWPs**

81. AWPs and FULs are published and reported by non-party publishing compendia such as First Data Bank ("FDB") and Medi-Span based on pricing information supplied by defendant drug manufacturers. Until 2006, Iowa used FDB as its source for FULs, WACs, AWPs and all published prices. Since 2006, Iowa has used Medi-Span for this data.

82. States use AWP and MAC/FUL as proxies for EAC in large part because defendants purposefully and fraudulently conceal their true prices claiming they are proprietary trade secrets.

## **B. DEFENDANTS' CORRUPTION OF ALL RELEVANT PRICING BENCHMARKS**

83. At all times, Iowa has intended to reimburse providers for Medicaid covered drugs at the providers' EAC.

84. Defendants have foiled Iowa's attempt to reimburse providers at EAC by fraudulently misrepresenting the true prices at which they sell their drugs and reporting false and inflated prices instead.

85. Thus, despite Iowa's good faith efforts to reimburse providers at EAC, because of defendants' unfair practices, deception and fraud, Iowa has reimbursed at amounts

that far exceed EAC. Iowa Medicaid's total expenditures for the years 1992 through 2005 for those of defendants' drugs for which Iowa asserts claims are set forth in Exhibit A hereto.

86. There are four pricing benchmarks relevant to the Iowa EAC formula and defendants' fraudulent practices have corrupted each.

### **1. Defendants' WACs Are False And Misleading**

87. The first pricing benchmark is wholesale acquisition cost or "WAC." WAC is supposed to represent the price a wholesaler pays a drug manufacturer for its products.

88. Iowa alleges that defendants report WACs or WAC equivalents (such as Direct Prices, Book Prices, Wholesale Net Prices, Catalog Prices or List Prices) for their products that are uniformly false and inflated.

89. The WACs are false and inflated because they do not, in fact, reflect the actual prices at which defendants sell their drugs to wholesalers. In fact, wholesalers routinely obtain drugs for prices well below WAC. One way in which the scheme works is as follows: Defendants enter into contracts with providers, such as large retail chain pharmacies like Walgreens, Walmart, or Costco, or group of providers or group purchasing organization comprised of retailers, to sell their products at certain prices ("contract prices"). The defendants then purport to sell the agreed upon drugs to wholesalers with whom they have a contractual arrangement, at a price defendants call WAC. In the overwhelming majority of cases, the WAC is higher than the contract price agreed upon by the provider and the drug manufacturer. The wholesaler then ships the product to the provider, charging the provider the lower contract price. When the wholesaler receives payment from the provider, it charges the manufacturer for the difference between the contract price agreed and the WAC. The wholesaler then sends a bill to the manufacturer, called a "charge back," for the difference between the WAC and the contract price actually paid by the provider. These charge backs, (or self adjustments, or other economic

inducements) are kept secret, so that it appears that the wholesaler actually purchased the drug at the higher WAC price. The effect of this practice is to create the impression that the “wholesale price” of the drug is higher than it really is.

90. Wholesalers also obtain routine discounts off WAC through volume purchases or other special deals with defendants. In all cases, the effect is that the wholesaler pays some price below WAC for the defendants’ products and the WACs (or WAC equivalents) defendants report are false and inflated.

91. Given that AWP’s are often set pursuant to a standard formula and based on the reported WAC, even a routine overstatement of WAC by a single digit percentage or some other relatively small number is significant given its ripple effect on the AWP. The inflated WAC triggers the publication of an inflated AWP on which all Iowa Medicaid reimbursements for that particular drug are based. Thus, even a mere one percent or two percent routine WAC inflation for a single drug can translate into millions of dollars in unlawful overcharges.

92. Given that FULs are often set based on a reported WAC, the inflated WAC likewise triggers the establishment of an inflated FUL.

## **2. Defendants’ AWP’s Are False And Misleading**

93. The second pricing benchmark is Average Wholesale Price or “AWP.” AWP is to be construed according to its plain meaning, *to wit*, it is supposed to represent an average of the actual prices charged by wholesalers and/or paid by providers to wholesalers. An accurate AWP must also take into account discounts and rebates.

94. Iowa alleges that defendants either report or cause to be reported false and inflated AWP’s that are not tethered in any way to defendants’ actual prices and that do not account for discounts and rebates.

95. Defendants cause these false and inflated AWP's to be reported in various ways. Some defendants report false WAC's or WAC equivalents, which defendants know will be marked up by FDB or other publishing compendia pursuant to a standard markup formula, to create a false AWP. That standard mark up formula has typically ranged from 20-25%. Iowa alleges that the standard mark up formula is itself deceptive and misleading. There is no justification whatsoever for a mark up between Wholesale Acquisition Cost and Average Wholesale Price of 20-25%. The mark up does not represent wholesaler profit or retailer cost or any other legitimate market activity.

96. Some defendants directly report false AWP's.

97. Regardless, in all cases defendants alone control the false and inflated AWP's that are published for their drugs. They do this by (a) directly supplying a false AWP to publishers, (b) supplying publishers with a false wholesale acquisition cost ("WAC") or WAC equivalent such as direct price or list price to which the publisher applies a standard 1.2 or 1.25 mark-up and/or (c) by supplying both false AWP and false WAC or false WAC equivalent.

98. The false AWP's appear in publishing compendia that are utilized by Medicaid and other payors. Iowa, like most other states, used the publisher First DataBank ("FDB") as its primary source for AWP's until 2006. Throughout the time period in which Iowa utilized FDB, FDB purported to supply Iowa with accurate AWP's, which FDB said that it received from the drug manufacturers themselves. First DataBank defined Average Wholesale Price for its customers in September 1991: "AWP represents an average price which a wholesaler would charge a pharmacy for a particular product."

99. At some point in 2001-2002, and while Iowa was utilizing its services, FDB increased the reported AWP's for hundreds of the brand drug NDC's for which Iowa

Medicaid reimburses. The AWP for those particular NDCs had previously been reported by FDB to be 20% higher than WAC. In late 2001 or early 2002, FDB increased the AWP for this group of NDCs so that the AWP would be 25% higher than WAC. Critically, this increase did not reflect an actual change in the true prices for the NDCs at issue.

100. Defendants herein were aware of the 5% AWP increase FDB reported for these NDCs and did nothing to stop or correct it. These Defendants did not inform Iowa Medicaid that the FDB AWP for their drugs were now even less accurate. These defendants did not inform Iowa Medicaid that it should cease to rely on these new AWP, which were even more inflated than the previous ones, to calculate its Medicaid reimbursements. In short, these defendants sat idly by in complete disregard of their duties to deal honestly with the government and with the knowledge that their silence would result in millions of dollars in further overcharges and damage to Iowa Medicaid.

101. The specific NDCs whose AWP were improperly increased by this additional 5% are set forth in Exhibit C hereto.

### **3. Defendants Cause Inflated FULs To Be Set**

102. The third relevant pricing benchmark is the federal maximum allowable cost (“MAC”) or Federal Upper Limit (“FUL”). FULs are established by the Center for Medicare and Medicaid Services (“CMS”) for multi-source and generic drugs that have three suppliers or more. At all times relevant hereto, FULs have been defined as 150% of the lowest published price for a therapeutic equivalent (using all national compendia) that can be purchased by pharmacies in quantities of 100 tablets or capsules or, in the case of liquids, the commonly listed unit. 42 C.F.R. § 447.332.

103. FUL is usually based on the reported WAC.

104. Iowa alleges that defendants' failure to submit accurate pricing data to the publishing compendia can cause false and inflated FULs to issue. It is clear that, in many instances, had defendants submitted accurate prices to pricing compendia, the FULs set by CMS would have been lower and the Iowa Medicaid Program would have paid less. This is because the FUL is set based on the lowest published price, whatever that price may be. Thus, when defendants intentionally report false and inflated WACs, AWP's and other wholesale prices to the publishing compendia, they cause the FUL to be set at a level higher than it would have been had defendants reported accurate prices in the first place.

105. Importantly, the FUL is a per-unit price that applies to all NDCs for a particular multi-source drug. In other words, if a FUL is in place for a particular multi-source drug, all NDCs for that drug will be reimbursed at that FUL.

106. As a result, each of the generic or multi-source drug manufacturer defendants are vigilantly aware of the reimbursement prices reported by their competitors, the actual price of their generic competitors' products, their own sale prices to Medicaid providers, and the FUL. Generic drug manufacturer defendants manipulate their own reported reimbursement prices and the secret deep discounts they offer in order to gain or maintain a competitive advantage in the market for their generic products. The larger the secret discount off the reimbursement price or the FUL, the greater the spread the generic manufacturer can create.

107. The natural and expected result is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP exceeding actual costs by over 50,000% or greater.

108. Exhibit B to this complaint details many examples where a specific defendant's failure to report an accurate price for its drug resulted in a false and inflated FUL being set. In each example of "FUL fraud" set forth in Exhibit B, Iowa alleges that defendant's true price (or the "actual acquisition cost" "ACC") for the NDC at issue *was more than 50% lower* than the established FUL. Had the defendant reported its true price for that NDC, the operative FUL would have been based on that defendant's true price and would have been lower than it was. In such case, and pursuant to Iowa's "lesser of" EAC formula, Iowa's reimbursement may have been less. Thus, in addition to its allegations of AWP fraud, Iowa alleges FUL fraud for every NDC listed in Exhibit B where the defendant's AAC is more than 50% below the established FUL.

#### **4. Defendants' False Prices Infect The Iowa SMAC**

109. The fourth relevant pricing benchmark is the Iowa State Maximum Allowable Cost or "SMAC" which has existed only since 2001 and, even then, only for certain drugs. Iowa sets SMACs for certain multi-source generic and other drugs in an effort to approximate providers' EAC for those drugs. In establishing a SMAC, Iowa, *inter alia*, reviews pharmacist invoices for each drug. These invoices often reflect or are based on defendants' published prices. Thus, to the extent an Iowa SMAC is based on an invoice that reflects or is based on a false published price, the Iowa SMAC is inflated as well.

#### **C. BRAND MANUFACTURERS' BEST PRICE FRAUD**

110. Federal law requires that any manufacturer of a drug that wishes to have its products paid for by Medicaid must enter into a rebate agreement with the Secretary of Health and Human Services ("HHS"), on behalf of the States pursuant to 42 U.S.C. § 1396r-8 and must pay rebates to the States on a quarterly basis. Congress passed the rebate provision expressly to help reduce state Medicaid drug expenditures.

111. To that end, each defendant herein and the Secretary of HHS “on behalf of the Department of Health and all States” has executed a Rebate Agreement that is in all material respects identical to the Model Rebate Agreement attached hereto as Exhibit E.

112. State Medicaid Programs, including Iowa’s, are express third-party beneficiaries of the Medicaid Rebate Agreements.

113. The Federal Medicaid Rebate for brand-name drugs (defined as “single source drugs” or “innovator multiple source drugs”) is based on either (a) the difference between what is known as the AMP or “Average Manufacturers Price” and “Best Price”, or (b) 15% of the AMP, whichever is greater. 42 U.S.C. § 1396r-8(c)(1) – (2).

114. The Federal Medicaid Rebate for non-innovator multi-source drugs (generic drugs) is 11% of AMP. 42 U.S.C. § 1396r-8(c)(3).

115. Iowa’s Federal rebate claims concern only those rebates paid by brand manufacturers. Specifically, Iowa alleges that brand manufacturers routinely *overstate* the Best Price for certain of their products and, as a result, underpay the rebates owed.

116. “Best Price” is defined by statute as “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity in the United States,” with certain enumerated exceptions. 42 U.S.C. § 1396r-8(c)(1)(C)(i).

117. The Model Rebate Agreement defines Best Price as “the lowest price at which the manufacturer sells . . . to any purchaser in the United States in any pricing structure.” Model Rebate Agreement, Exhibit E at I(d).

118. “AMP” is defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. 42 U.S.C. § 1396r-8(k)(1).

119. To determine the amount of the rebate due, the states are required to report to the manufacturers, as well as to HHS, “information on the total number of units of each dosage strength and package size of each covered outpatient drug . . . for which payment was made under the plan during the period.” 42 U.S.C. § 1396r-8(b)(2).

120. HHS relies entirely on the manufacturers for Best Price and AMP data. Brand drug manufacturers are required to report their Best Prices and AMPs to the Secretary of HHS. The Secretary is required to keep this information confidential. 42 U.S.C. §§ 1396r-8(b)(3)(A), (D).

121. At all times, the manufacturers have ultimate responsibility to correctly calculate the rebate. As stated in the federal Model Rebate Agreement:

A State may, at its option, compute the total rebate anticipated, based on its own records, *but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.*

Model Rebate Agreement, annexed hereto and incorporated herein, at Exhibit E hereto, I(n).

122. Based on the information received from the states and the manufacturers, the Secretary reports to each state a Unit Rebate Amount (“URA”), which is “the amount calculated by the Health Care Financing Administration (now CMS) to which the Medicaid utilization information may be applied by states in invoicing the Manufacturer for the rebate payment due.” The rebate then is paid to the state Medicaid program by the defendant drug manufacturer.

123. States thus are provided with URAs, not AMPs or Best Prices. Like HHS, States are also required to keep confidential the rebate-related information that they receive. 42 U.S.C. § 1396r-8(b)(3)(D).

124. States have a direct and compelling interest in accurate Best Price reporting and the rebate program, which helps to reduce the costs the states themselves incurred for drugs purchased by Medicaid patients. It is within the state's statutory authority to investigate and prosecute Medicaid Best Price violations as alleged in this case.

125. Under the Medicaid rebate provision, any manufacturer that knowingly provides false information "is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information." "[S]uch civil money penalties are in addition to other penalties as may be prescribed by law." 42 U.S.C. § 1396r-8(b)(3)(C)(ii).

126. At all relevant times hereto, certain of the brand manufacturers named herein knowingly calculated and reported its Best Prices excluding factors that it was statutorily and/or contractually required to include, resulting in the payment of rebates that were less than required.

127. The same routine discounts, rebates, free samples and other inducements offered to providers but excluded in setting AWP are also excluded from defendants' calculations of Best Price. These include chargebacks, prompt pay discounts, free samples distributed by sales representatives, and other credits, up front and back end rebates off invoice transactions, and hidden discounts and financial incentives.

128. In addition, defendants routinely bundle deeply discounted or free drugs with other drugs. The Model Rebate Agreement executed by every defendant herein expressly provides that for bundled sales the discount must be allocated proportionately to the dollar value

of the units of each drug sold under the bundled arrangement. Defendants do not properly allocate bundled discounts when calculating Best Price.

129. Certain defendants also engage in re-labeling schemes to avoid reporting Best Price. Federal law expressly prohibits this practice. 42 U.S.C. § 1396r-8(b)(3)(C)(ii). For example, in 2003, two defendants herein, Bayer and GSK, agreed to pay \$344 million to resolve allegations that they engaged in health care fraud against state programs by failing to report their Best Price for certain drugs. In their wrongful scheme, known as “lick and stick,” they sold drugs to Kaiser Permanente Medical Care Program (the nation’s largest HMO) at deep discounts, but avoided including these discounts in their Best Price calculations by re-labeling the products with new NDC codes before sale.

130. As detailed below, a number of the brand manufacturer defendants herein, including Merck, Tap and Eli Lilly, recently were investigated by the Senate Finance Committee for abusing the Nominal Price Exception (“NPE”) to Best Price reporting. That investigation concluded that 12 of the 19 companies reviewed were misusing the NPE. A January 31, 2007 letter from the Senate Finance Committee to CMS summarizing the results of this investigation is attached hereto as Exhibit F. All 19 companies investigated are defendants herein. *Id.*

131. The NPE was created by Congress as a public policy exception to Best Price reporting and specifically to encourage drug manufacturers to continue to sell drugs at nominal prices to entities serving the public good, without the manufacturer having to pay increased rebates because of those sales. The exception allows drug companies to exclude from their Best Price calculations drugs with prices less than 10% of AMP, *unless* such prices are offered contingent on a purchase requirement or to commercial entities. 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III). If the nominally priced sales are offered contingent on a purchase

requirement or to commercial entities, those sales must be included in the Best Price calculation. The lower the Best Price, the higher the potential Medicaid rebate.

132. Iowa alleges that certain defendants herein routinely abuse the NPE. Defendants, including Merck for its drug Pepcid and TAP for its drug Prevacid (to select just two examples), make unlawful use of the so-called “nominal price” exception by omitting certain deeply discounted commercial sales and other sales from their Best Price calculation.

#### **V. DEFENDANTS CONCEAL THEIR TRUE PRICES**

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

134. Indeed, States rely on published AWP and WACs because defendants purposefully conceal their true prices. As George M. Reeb, Assistant Inspector General for CMS explained to the House Energy and Commerce Committee during its December 7, 2004 hearing, “one reason States continue to rely on AWP . . . is that states lack access to alternate, more accurate price information.” *Medicaid Prescription Drug Reimbursements: Why The Government Pays Too Much: Hearing before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce House of Representatives, 108th Cong., (2004).*

135. When the Medicaid rebate provision was enacted, the manufacturers made sure that pricing information reported to CMS would not be disclosed to the states.

136. Defendants consider their drug pricing information proprietary and restrict access to it. Defendants require providers to agree that the prices contained in their sales agreements with defendants are to be kept absolutely secret, terming them trade secrets to preclude providers from telling others the actual price they paid. These sales agreements

universally offer defendants' products at prices that are deeply discounted from the WACs, AWP's and other wholesale prices that defendants cause to appear in any publishing compendia.

137. Defendants further obscure the true prices for their drugs with their policy of treating different classes of trade differently. Thus, for the same drug, chain pharmacies are given one price, independent pharmacies another, group purchasing organizations another, hospitals another, clinics another, and doctors yet another.

138. Some defendants purposefully maintain two sets of pricing records: one with the inflated prices and another with the actual prices. Such industry practice was discussed by Patrick J. O'Connell, Chief of the Civil Medicaid Fraud Section of the Office of the Texas Attorney General, during his testimony before the Senate Finance Committee:

We also found that some manufacturers actually kept two sets of computer records with prices: one, with inflated prices that are reported to the price reporting services like First Data Bank or, in Texas' case, directly to the Medicaid program; and another with real contract prices that are used in every day business transactions with the manufacturers' customers.

*Medicaid Waste, Fraud and Abuse: Threatening the Health Care Safety Net: Hearings before the Senate Finance Comm., 109th Cong. (2005).*

139. The practice of keeping two sets of books was verified by Schering Plough whistleblower Beatrice Manning at the same hearing. Ms Manning testified that

"I want to stress that this scheme did not result from public corruption or inadequate Medicaid auditing. In essence, two sets of books were kept."

*Id.*

140. In addition, defendants hide their real drug prices by secretly providing free drugs and phony grants to providers as a further means of discounting the overall price of their drugs.

141. In addition to concealing their true prices, defendants have deliberately concealed why they cause false and inflated AWP's to be published. Defendants have concealed that they do this to create spreads between actual cost and reimbursement amounts that permit defendants to influence market share.

142. As recently as in 2003, for example, the CEO of defendant GlaxoSmithKline ("GSK") denied any benefit from spread manipulation. In a conversation with shareholders, GSK CEO J.P. Garnier stated that GSK "[has] never benefited from the spread becoming bigger or smaller." Garnier stated that the reimbursement system "has a big loophole and can create confusion. We don't like it one bit." GSK and its constituent predecessors Glaxo Wellcome and SmithKline Beecham long competed on spread and benefited from the increased market share permitted by the incentives the spread created.

143. While the government has been investigating some of defendants' practices since the late 1990s, it has only recently become clear that the OIG, Congressional and other estimates of the extent of defendants' AWP inflation were grossly understated — both as to generic and brand drug spreads — as the data set forth in the Exhibits B hereto demonstrate. Thus, it has only recently become clear that States' efforts to estimate EAC through a reimbursement formula that discounted 10, 12 or 15 percent off AWP were ineffective given the extent of defendants' fraud.

144. No government report has ever addressed the falsity of WAC. Indeed, the fact that State Medicaid reimbursement formulas have historically been either [WAC + a certain %] or [AWP- a certain %] reveals the traditional belief in the reliability of WAC. Under either a "WAC plus" or "AWP minus" formula, the States were endeavoring to approximate EAC. Defendants' unlawful and undisclosed manipulation of the price reporting system as a whole has

rendered States' efforts in this regard futile. And, as stated above, the publication of a false WAC leads to the publication of a false AWP and a false FUL.

145. No government report has ever addressed how defendants' false WAC pricing impacts the FUL.

## **VI. DEFENDANTS' MOTIVATION FOR FALSE PRICE REPORTING**

146. Defendants' motivation for causing false prices to be published is irrelevant in large part, if not entirely, given defendants' obligation to report truthful information to the government. Nevertheless, Iowa herein explains the "why" behind defendants' scheme because such context provides insight into the complexity of the prescription drug marketplace and underscores the difficulty any Medicaid payor encounters, given defendants' falsity, as it endeavors to calculate and reimburse at a true EAC.

147. Defendants submit false and inflated wholesale price information in order to create a spread between acquisition cost and reimbursement. They use this spread as an unlawful inducement to increase their market share and profits. Defendants' actual prices for drugs sold to providers, directly or through wholesalers, were much lower than the prices (AWP, direct price ("DP"), FUL, etc.) reported by defendants and used by Iowa Medicaid to calculate reimbursement. In so doing, defendants caused Iowa Medicaid to reimburse providers' claims for the covered drugs at inflated amounts. At the same time, providers were able to purchase defendants' drugs at materially lower prices than prices defendants reported, thus increasing the spread.

148. Defendants' unlawful scheme has completely corrupted the market for prescription drugs. Instead of competing on prices and efficacy alone, defendants have deliberately sought to create a powerful financial incentive for providers to prescribe drugs based

primarily on the spread between the true price of a drug and its published AWP or WAC, or for those with formulary power to give preferential treatment to defendants' drugs based on such spread. Creating incentives for providers to prescribe drugs based on spread or for those with formulary power to give preferential treatment for drugs based on spread is inconsistent with Iowa statutes and public policy.

149. Defendants' own marketing and sales materials show that defendants market their products based on the spread between reimbursement (based on AWP, WAC or a WAC equivalent) and actual acquisition cost. Defendants' own marketing documents make clear that they create spread and profitability based on reimbursement whether their products are single or multi-source. Defendants create spread for their drugs even when they are competing with over-the-counter alternatives. In short, the motivation to improperly inflate AWP exists whether a drug is brand name, single source, multi-source or generic.

150. With generic drugs, direct competition among bioequivalents provides an obvious motive to increase the spread. Defendants compete on reimbursement and profit rather than cost.

151. Brand name drugs protected by patent also face competition from other brand name drugs aimed at similar illnesses or in the same therapeutic class. For example, Altace, Aceon and Mavik (all ACE inhibitors) treat hypertension and all compete with each other for placement on drug formularies and preferred drug lists. Merck's Pepcid, GSK's Zantac, TAP's Prevacid and Wyeth's Protonix (all at-issue drugs) likewise compete with each other for placement on formularies. Such placement ensures access and utilization. Incentives, discounts, rebates and other forms of consideration — all based on the false and inflated AWPs — are offered to those who create and maintain such formularies and preferred drug lists.

152. As the following congressional testimony bears out, defendants claim they have no choice but to inflate their products AWP's and create spread. Mark Jones President of the Federal Qui Tam Whistleblower, Ven-a-Care of the Florida Keys, Inc., summarized:

Over the time period we've been investigating this, we've heard drug manufacturers first claim that they didn't know where AWP came from, it wasn't their number, and then that evolved into "Yes, we set the AWP's" and then we heard drug manufacturers say, "We don't know anything about marketing the spread. We're not interested in marketing the spread. We're only interested in the price we charge our customer." But we finally evolved into "Yes, there is a spread out there and yes we do market it." And now we're at the point with this industry where they're saying, "Look it's so messed up, everybody wants to buy drugs based solely on the spread value, and we can't stop it even if we want to."

*Medicaid Prescription Drug Reimbursements: Why The Government Pays Too Much: Hearings before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce House of Representatives, 108th Cong., 2nd Sess., (2004).*

153. All defendants have hidden their motives for reporting an inflated AWP from the public. One official, a high ranking employee of Dey, even went so far as to lie under oath about Dey's creation and marketing of its spread. Only with the disclosure of materials secured by litigants in recent discovery has it become apparent that one reason defendants were intentionally manipulating the nation's drug reimbursement system was to compete for market share on the basis of a phony price spread, instead of the true selling price of their drugs or the medicinal efficacy of these drugs to their users.

154. By secretly polluting the entire reimbursement system with false and inflated prices, defendants improperly and unlawfully have caused the Medicaid Program to subsidize these improper incentives for the purchase of defendants' products.

## **VII. THE FEDERAL GOVERNMENT HAS SPECIFICALLY DIRECTED DEFENDANTS TO REPORT ACCURATE PRICING DATA**

155. The federal government has emphasized the importance of accurate reported prices. In its April 2003 report, “Compliance Program Guidance for Pharmaceutical Manufacturers,” the HHS OIG reaffirmed that the “government sets reimbursement with the expectation that the data provided are complete and accurate.” The OIG made clear that the AWP, and other reported prices must be meaningful figures that are not artificially inflated:

Where appropriate, manufacturers’ reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

68 Fed. Reg. 23731 (2003).

156. Defendants routinely and consistently violate this obligation. They sell the vast majority of their drugs at prices that bear little or no relation to the reimbursement prices they report to the publishing compendia.

157. The OIG has also expressly rejected the notion that purposeful AWP manipulation was a lawful practice:

The “spread” is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the “spread,” it controls its customer’s profit.

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at “95 percent of average wholesale price.” 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers’ profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller’s immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. **In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the “spread” to induce customers to purchase its product.**

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. **The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.** Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

*Id.*

158. Defendants report wholesale price information that they know does not comply with the HHS OIG’s guidelines, in that they do not account for routine discounts off of WAC, bundled discounts, chargebacks, rebates, free samples, off invoice pricing and other discounts and inducements they routinely offer to wholesalers, chain pharmacies, group purchasing organizations, pharmacists and other distributors who are in a position to increase sales of defendants’ products.

## **VIII. DEFENDANTS' CONDUCT WAS INTENTIONALLY IN DISREGARD OF ESTABLISHED LAW**

159. Defendants want Iowa Medicaid to reimburse providers for defendants' drugs.

160. Defendants know that Iowa Medicaid is obligated to reimburse providers, and seeks to reimburse providers, based on providers' EAC.

161. Defendants know that Iowa Medicaid is dependent on the pricing benchmarks discussed herein as proxies for EAC.

162. Defendants know that the pricing benchmarks on which Iowa Medicaid relies are based on information that defendants provide.

163. Defendants know that when seeking to have their products paid for by the public fisc, they have a duty to "turn square corners" and submit honest pricing information. Defendants have ignored this duty by submitting false and inflated pricing information.

164. In addition, it has been the law for over 60 years that it is unlawful for a seller to cause to be circulated a price at which no, or few, sales are actually expected, whether it is called a list price, suggested price, or benchmark price. *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374 (1965); *FTC v. Crescent Publishing Group, Inc.*, 129 F. Supp. 2d 311 (S.D.N.Y. 2001). Defendants either know of this law or act in reckless and willful disregard of it.

165. Congress and the OIG have excoriated the pharmaceutical industry for causing untrue AWP's to be published and directed defendant drug manufacturers to report accurate prices.

166. Yet defendants have willfully ignored, and continue to ignore, 1) their duty to Iowa to behave with scrupulous honesty, 2) case law uniformly holding that their pricing

practices to be unlawful, and 3) reprimands of Congress and federal agencies overseeing the Medicaid programs.

## **IX. HARM TO IOWA AND ITS CITIZENS**

167. The Iowa Medicaid Program spent over \$1.6 billion for defendants' drugs between 1992 and 2005 alone. A substantial portion of this huge sum is the result of the inflation of prescription drug prices pursuant to the fraudulent scheme alleged herein.

168. Applying even the most conservative estimates, defendants' abuses result in millions of dollars in excessive payments by Iowa Medicaid for Medicaid-covered drugs.

169. At all times, each defendant knew of the reimbursement formula used in the Iowa Medicaid Program. Each defendant was aware that this formula sought to reimburse providers at EAC and that Iowa Medicaid relied on the defendants' reported prices as proxies for EAC.

170. By publishing false and inflated wholesale prices and by keeping their true wholesale prices secret, defendants have knowingly interfered with Iowa's ability to reimburse providers at EAC.

171. As a consequence, Iowa's Medicaid program has spent millions of dollars more for prescription drugs than it would have spent if defendants had published their true prices.

172. Exhibit B hereto lists the drugs and NDCs that are at issue in this litigation. Every drug listed in Exhibit B was paid for by Iowa Medicaid based on either AWP, MAC/FUL or, after 2001, SMAC. Exhibit B sets forth, for each drug: (a) the drug's NDC; (b) the drug Name; (c) the reported AWP; (d) the FUL, if one was in place; (e) what Iowa alleges based on actual invoice and transaction data obtained from the nations' largest wholesalers to be

the true AWP or “Actual Acquisition Cost” (“AAC”) of the drug; and (f) the spread between the AWP or FUL and the AAC.

173. The AACs in Exhibit B were either obtained from the McKesson Servall price database (which database is comprised of prices offered by the Servall Group Purchasing Organization to its constituent members who are independent retail pharmacies) or through the calculation of a weighted average based on actual invoice prices paid by members of the relevant classes of trade to the wholesalers AmeriSource Bergen or Cardinal. All three of these “AAC” sources have been blessed by the federal court with jurisdiction over the AWP MDL 1456.

174. Exhibit B also notes specifically when a defendants’ failure to report accurate prices resulted in a false and inflated FUL to be set.

175. Exhibit B demonstrates that the prices at which drugs were actually sold to Medicaid providers were much lower than the AWPs, WACs, or other wholesale prices reported or caused to be reported by defendants and used by Medicaid for reimbursement.

176. The spreads on Exhibit B make clear that even a 10%, 12% or 15% discount off AWP, or reimbursement at the FUL, does not eliminate the damage resulting from defendants’ purposeful submission of false and inflated reimbursement price information. The spreads make clear that, by submitting false and inflated data, defendants entirely undermined Iowa Medicaid’s effort to reimburse at EAC.

177. Exhibit B also demonstrates that defendants routinely submitted false prices for both brand and generic products.

#### **X. ALLEGATIONS PARTICULAR TO IOWA AND THE INDIVIDUAL DEFENDANTS**

178. The following examples are merely illustrative of each defendant’s unlawful activity, and are not intended to be an exact or exhaustive recitation of all of such

activity engaged in by each defendant. Instead, these allegations describe the wrongful conduct of each defendant in sufficient detail and particularity to support the liability allegations as to each. The particular pharmaceutical products identified below are similarly not intended to be an exhaustive list as to all products or NDCs for which each defendant engaged in misconduct. Additional detail is peculiarly within defendants' control pending discovery.

179. At all times relevant hereto, each of the following defendants entered into contracts with GPOs, hospitals, PBMs and other purchasers whereby such purchasers were guaranteed a price for defendants' drugs that was deeply discounted off the WACs, DPs, AWP's and/or other reimbursement price information defendants supplied to publishers. At times these reduced prices were in the form of upfront discounts. At times, the reduced prices were in the form of guaranteed rebates. The WACs, Direct Prices, AWP's and/or other reimbursement price information defendants supplied to publishers did not take into account these deeply discounted prices. Thus, the WACs, Direct Prices, AWP's and/or other reimbursement price information provided by defendants were false and inflated. The purpose of the inflation was to create the spread referred to herein, which defendants used to increase demand for their products at the expense of those who reimbursed for drugs based on AWP and FUL/MAC, such as Iowa Medicaid.

180. Exhibit A hereto presents a defendant-by-defendant summary of (a) the total expenditures at issue for that defendant; (b) the number of NDCs at issue for that defendant; (c) the number of NDCs at issue because of alleged AWP fraud; and (d) the number of NDCs at issue because of alleged FUL/MAC fraud.

**A. ABBOTT**

181. As summarized in Exhibit A, Iowa Medicaid spent over \$77 million on the 558 at-issue Abbott NDCs between 1992 and 2005 alone.<sup>2</sup> The specific Abbott NDCs for which Iowa seeks relief are set forth in Exhibit B-1 hereto. Iowa alleges both AWP and FUL fraud claims against Abbott.

182. At all times relevant hereto, Abbott has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-1 hereto, Abbott has routinely created such spreads.

183. Abbott has instructed its sales force to market the spread for its products. Abbott has specifically instructed sales staff to use the difference between AWP and actual acquisition cost as a selling point, and has prepared worksheets demonstrating the proper calculation of spread. These worksheets also described the AWPs of Abbott competitors to demonstrate the advantage of purchasing Abbott products with their inflated AWPs.

184. Abbott's upper level management, throughout the 1990s, engaged in a systematic and repeated pattern of conduct whereby they used the inflated reimbursement spread, resulting from Abbott's false reimbursement prices, as a marketing tool in order to persuade customers to purchase Abbott's products rather than its competitors.

185. Abbott touted the efficacy of one of its customers' proprietary software packages that allowed providers, when evaluating which drug to use, to see lowest unit cost, best spread difference, incentive-based contracts and preferred products under contract.

186. Abbott specifically promoted its injectibles as more profitable than competitors' because of the spread between AWP and acquisition cost. Abbott specifically

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<sup>2</sup> Iowa's claims are not confined to this time period.

developed a plan for its field representatives to promote its products based on reimbursement and spread.

187. Abbott deliberately tried to maximize the spread because it understood that its customers routinely engaged in “spread shopping” – comparing Abbott’s AWP’s with those of its competitors (including defendant Baxter), in order to determine the greatest spread. This practice dates back to late 1993 when Abbott compared its proposed contract price and published AWP’s with those of Baxter’s competing generic drugs.

188. The fact of the improper Abbott spread is well established. In a 2000 report published by HHS<sup>3</sup>, the DOJ documented at least 81 instances where the published AWP’s for various dosages of 16 subject multi-source drugs manufactured by Abbott were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 16 multi-source drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ’s determination of an accurate AWP for that particular dosage, based upon wholesalers’ price lists, with the AWP reported by Abbott in the 2001 *RedBook*.

<b>Drug</b>	<b>Abbott’s <i>RedBook</i> AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Acetylcysteine	\$ 35.87	\$ 21.90	\$ 13.97	64%
Acyclovir	\$ 1047.38	\$ 349.05	\$ 698.33	200%
Amikacin Sulfate	\$ 995.84	\$ 125.00	\$ 807.84	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%

<sup>3</sup> “An Additional Source of Average Wholesale Price Data In Pricing Drugs and Biologicals Covered by the Medicare Program,” (Sept. 8, 2000); <http://www.cms.hhs.gov/transmittals/downloads/ab0086.pdf>.

<b>Drug</b>	<b>Abbott's RedBook AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
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%

189. In a letter to Abbott dated October 31, 2000, Congressman Stark wrote:

You should by now be aware of Congressional investigations revealing that Abbott has for many years reported and published inflated and misleading data and has engaged in other deceptive business practices. This letter is a call for your company to immediately cease overcharging taxpayers and jeopardizing public health . . . .

The price manipulation scheme is executed through [your company'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 in your industry as "the spread." The evidence amassed by Congress clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or

inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims . . . .

Based on the evidence collected, Abbott should make arrangements to compensate taxpayers for the financial injury caused to federally funded programs. Any refusal to accept responsibility will most certainly be indicative of the need for Congress to control drug prices. If we cannot rely upon drug companies to make honest and truthful representations about their prices, then Congress will be left with no alternative but to take decisive action to protect the public.

146 Cong. Rec., E2037-38 (2000).

190. Abbott’s fraudulent pricing for the multi-source drug Vancomycin has been well documented by the DOJ in earlier years as well, as set forth below:

<b>1995</b>		<b>NDC</b>	<b>AWP</b>	<b>AVAIL. PRICE</b>	<b>SPREAD</b>
	Vancomycin Hydrochloride - Flip top vial 1gm/105 ea	00074-6533-01	60.44	8.40	620%
	Vancomycin - 500 mg	00074-4332-01	30.23	4.20	620%

<b>1996</b>		<b>NDC</b>	<b>AWP</b>	<b>AVAIL. PRICE</b>	<b>SPREAD</b>
	Vancomycin Hydrochloride - Flip top vial 1gm/105 ea	00074-6533-01	61.86	7.95	678%
	Vancomycin - 500 mg	00074-4332-01	31.44	3.95	696%

<b>1999</b>		<b>NDC</b>	<b>AWP</b>	<b>AVAIL. PRICE</b>	<b>SPREAD</b>
	Vancomycin - 1 gm	00074-6535-01	261.84	76.00	245%

191. Abbott also created spreads for the multi-source drug Amikacin. One report says “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.” 146 Cong. Rec. E2038 (2000).

192. Abbott also has engaged in substantial off-invoice pricing and distribution of free goods neither of which were taken into account by Abbott when it reported WACs or AWPs. Examples include Abbott billing one customer between April 2, 1998 through December 2, 1998 for sales in the gross amount of \$447,877 while simultaneously providing 10% free goods in the amount of \$44,788.

193. A 1996 year-end invoice to another customer shows gross annual sales of \$1,286,787 and a year end rebate of \$110,679 in connection with Abbott wishes the customer “Merry Christmas.” On information and belief, Abbott did not account for these free goods in its calculation of AWP or Best Price.

194. In connection with the wrongful conduct described herein, Abbott has been investigated by at least the United States Department of Justice, the United States Congress, Commonwealth of Massachusetts, the Office of Inspector General of the Department of Health and Human Services, the Attorneys General of California, Florida, Illinois, Ohio, Texas and Wisconsin, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse. The publicly available results of these investigations confirm Abbott’s routine practice of reporting false and inflated wholesale pricing information and non-compliance with rebate obligations.

195. Abbott has been sued by the Department of Justice and the States of Alabama, Alaska, California, Hawaii, Illinois, Idaho, Kentucky, Mississippi, Montana, Nevada, Pennsylvania, South Carolina, Texas, West Virginia and Wisconsin, and the City of New York and 42 New York Counties.

196. In July 2003, Abbott agreed to pay \$622 million in criminal and civil penalties to resolve allegations that its Ross Products Unit defrauded Medicare and Medicaid by failing to report Best Price. In that proceeding, the U.S. Attorney's Office in the Southern District of Illinois probed whether Ross Products Unit failed to include in calculating Best Price that it had used kickbacks to boost sales and defraud government insurers by discounting or giving away products. Providers thereafter would seek government reimbursements at higher prices.

197. Since at least 1998, Abbott's Ross Products Unit has had a joint marketing agreement with defendant MedImmune.

198. Abbott also was co-venturer with Japan's Takeda Chemical Industries, Ltd. in TAP Pharmaceuticals, which paid \$875 million in a 2001 settlement of allegations that TAP provided free and unreported samples of Lupron, a prostate cancer drug, to physicians with the understanding that they would bill Medicaid and Medicare for reimbursement based on the inflated AWP.

199. Abbott is among the pharmaceutical companies now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. The Committee has requested detailed reports on pricing practices, including records concerning the "spread" between actual market prices and payments by Medicaid. The basis of this investigation is "indicia from a number of sources, including utilization data, drug price/reimbursement spreads, and other relevant information."

200. Abbott also is the subject of the investigation led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is improperly using the nominal

price exception to the Best Price reporting requirements. *See* Exhibit F hereto. On information and belief, Abbott routinely offers certain of its branded products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price.

## **B. THE ALPHARMA GROUP**

201. As summarized in Exhibit A, Iowa Medicaid spent over \$21 million on the 439 at-issue Alharma Group NDCs between 1992 and 2005 alone.<sup>4</sup> The specific Alharma Group NDCs for which Iowa seeks relief are set forth in Exhibit B-2 hereto.

202. At all times relevant hereto, the Alharma Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. Exhibit B-2 demonstrates that the Alharma Group defendants routinely have created such spreads.

203. In addition to the examples set forth in Exhibit B-2, other examples of Alharma Group pricing fraud include Purepac's fraudulent pricing for the Alprazolam 0.5 mg tablet (a subject drug). From 2000 to 2002 Alharma caused an AWP of \$665.57 to be reported for Alprazolam 0.5 mg (NDC 00228-2029-96) while simultaneously making that identical drug available for \$43.94 (a spread of 1414%).

204. Alharma has also been sued by the State of Florida, which alleges the following fraudulent AWP for Purepac's Isosorbide (a subject drug) over the four-year period 2001-2005.

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<sup>4</sup> Iowa's claims are not confined to this time period.

PUREPAC ISOSORBIDE 30 MG NDC #00228-2713-11					
DATE	FIRST DATABANK AWP	FIRST DATABANK WAC	RELATOR'S COST CONTRACT PRICE	SPREAD \$	SPREAD % (SPREAD \$ ÷ RELATOR'S COST)
11-12-2001	\$129.13	\$77.48	\$72.56	\$39.46	54%
01-28-2002	\$129.13	\$77.48	\$72.56	\$39.46	54%
03-10-2002	\$129.13	\$77.48	\$72.56	\$39.46	54%
11-21-2002	\$144.81	\$77.48	\$10.06	\$72.84	724%
11-05-2004	\$144.81	\$77.48	\$10.06	\$12.00	119%
03-31-2005	\$144.81	\$77.48	\$10.06	\$12.00	119%

205. Alharma is among the companies now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Medicaid Best Price and rebate requirements. The Committee has requested detailed reports on pricing practices, including records concerning the “spread” between actual market prices and payments by Medicaid. The basis of this investigation is “indicia from a number of sources, including utilization date, drug price/reimbursement spreads, and other relevant information.”

### C. THE AMGEN GROUP

206. As summarized in Exhibit A, Iowa Medicaid spent over \$14 million on the 37 at-issue Amgen Group NDCs between 1992 –and 2005 alone.<sup>5</sup> The specific Amgen Group NDCs for which Iowa seeks relief are set forth in Exhibit B-3 hereto.

207. At all times relevant hereto, the Amgen Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time

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<sup>5</sup> Iowa’s claims are not confined to this time period.

maintaining a false and inflated reimbursement prices. As evidenced by Exhibit B-3, the Amgen Group has routinely created such spreads.

208. The Amgen Group actively manipulated and marketed the spread for its oncological drugs to influence customer choice. In 2005, Amgen's Vice-President Edward Morrow confirmed the importance of Amgen's ability to market the spread in prior years for its oncological sales, and the success of such marketing.

209. The Amgen Group revenues from oncology drug sales are the largest of any company "in the oncology market in the U.S. – based entirely on sales of supportive therapy products like the anemia agent Aransep (darbepoetin) and the febrile neutropenia therapies Neupogen (filgrastim) and Neulasta (pegfilgrastim)." *See Oncologists Embrace Part B Demo, Amgen Says; Big Test In Two Months*, 67 *The Pink Sheet*, 006, Feb. 7, 2005, at 13.

210. In 2005, Amgen V.P. Morrow described the Oncology field as moving from the "drug revenue model" to the "drug service model" as Amgen loses the ability to create whatever spread it likes by setting both the acquisition cost and the reimbursement rate for its oncology products. Amgen noted that its past practice of spread-creating discounting, (i.e. "contracting and rebating") will be "less important on a going forward basis." *Id.*

211. The Amgen Group has admitted marketing the spread for Aransep<sup>6</sup> and in 2005, called for a "ceasefire" in the spread war between Aransep and J&J competing product Procrit (both at issue here). Specifically, Amgen V.P. Morrow stated that "From October of last year through January of 2004, the Aranesp/Procrit market share was relatively stable. Since J&J rolled out their contract in February and we responded . . . we have gained five share points." *See*

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<sup>6</sup>In 2004, Amgen caused an AWP of \$3172.50 to be reported for Aransep 150/0.3 mcg. That same year, the Amgen Group sold this identical drug for \$1340.93 (a spread of 137%) (NDC 55513004304).

*EPO Ceasefire? Amgen Aranesp Price To Remain Stable Unless J&J Acts First*, 66 The Pink Sheet 018, May 03, 2004, at 10.

212. The Amgen Group's aggressive discounting strategy for Aranesp concerned J&J. "We've seen recently much more aggressive pricing on the part of our competitor" with "discounting quite commonly in the order of magnitude of 40% off list. So this has become a very significant concern for us." *See J&J Draws Line On Procrit Price; Will Not Meet Amgen Aranesp 40% Discount*, 66 The Pink Sheet 016, April 19, 2004, Volume at 11.

213. J&J maintained that the Amgen Group's pricing strategy for Aranesp includes bundled discounts on other key products. "Some of that price discounting that is occurring with the competitive product is not just on their competing product, but other products that they are bundling with that product," VP-Investor Relations Helen Short said. "That is also entered into the mix of how their pricing competition is working." *Id.* J&J CFO Robert Darretta concurred. "It's pricing that's coming about both directly by lowering their red blood cell product [Aranesp], as well as their giving preferred pricing on their white blood cell product," Neupogen/Neulasta (filgrastim/ pegfilgrastim), Darretta said. *Id.*

214. Notably, during this "discounting war" between the Amgen Group and J&J, the AWP's for Procrit and Aranesp did not decrease once.

215. In addition to the Neupogen examples, in Exhibit B-3, in 2003, the Amgen Group caused an AWP of \$330.60 to be reported for subject drug Neupogen 480 mcg. That same year, the Amgen Group sold this identical drug for \$218.96 (a spread of 51%).

216. Other evidence of Amgen Group defendants routinely selling at deep discounts from list price include that during 1997 the Amgen Group admonished a customer service employee for an unnecessary error in charging list price (at the time, \$110/vial) for

subject drug Leucovorin 350 mg. The Amgen Group reminded everyone in customer service that they should have been aware that no one ever pays list price for Leucovorin, and that the customer should at least get the benefit of distributor pricing, (at the time, ranging from \$11.88/vial to \$21/vial), a significant discount to the above-mentioned list price. In 1997, the AWP for Leucovorin was \$137.94. Thus, the widely available wholesaler prices represented spreads between 500% and 1060%.

217. In addition to the examples set forth in Exhibits B-3, the Amgen Group calculated 1995 Average Selling Prices net of chargebacks of \$2.65 for subject drug 50 mg Leucovorin, \$4.80 for 100 mg Leucovorin, and \$22.92 for 350 mg Leucovorin. These sale prices compare to AWP of \$21.53, \$39.41 and \$137.94. These AWP resulted in spreads of 712%, 721% and 501%, respectively.

218. Also in addition to the examples set forth in Exhibit B-3, in 1998, the Amgen Group caused AWP of \$4.75, \$8.50, \$16.72 and \$20.48 for subject multi-source drugs Methotrexate LP 50 mg (NDC 58406-0681-14), Methotrexate LP 100 mg (NDC 58406-0683-18), Methotrexate 200 mg (NDC 58406-0683-12) and Methotrexate LP 250 mg (NDC 58406-0683-16), respectively. That same year, the Amgen Group listed these identical drugs through wholesalers at \$3.00, \$5.00, \$6.00 and \$7.90. These prices created spreads of 58%, 70%, 179% and 159%, respectively.

219. Upon information and belief, at all times relevant hereto the Amgen Group has known that price adjustments are required to retain the Amgen Group's market share and *profitability*. Discounting alone may address market share, but not profitability.

220. At all times relevant hereto the Amgen Group has known that its purchasers' profits depend on reimbursement rates for drugs, and that the Amgen Group's own sales and profits in turn depend on its customers' reimbursement payments and profits:

Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement rate could result in decreased sales of our products.

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

Amgen 2002 Form 10-K at 43-44.

221. The Amgen Group admits that it reports AWP's for each of its drugs to the publishers. *See* Amgen's Answer to the AMCC's Second Amended Consolidated Complaint (filed by the private Third-Party Payor plaintiff class) in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, Civil Action 01-CV-12257-PBS (MDL No. 1456 D. Mass.) at p.10, ¶ 160.

222. The Amgen Group has admitted that "[s]everal of Immunex's current and former products are or were regularly sold at substantial discounts from list price." 10-K (Period Ending December 31, 2004) at 24 (Mar. 9, 2005).

223. The Amgen Group also is the subject of the investigation led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is improperly using the nominal price exception to the Best Price reporting requirements. *See* Exhibit F. On information and belief, Amgen routinely offers its brand products to commercial customers for

prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price.

#### **D. ASTRAZENECA**

224. As summarized in Exhibit A, Iowa Medicaid spent over \$97 million on the 146 at-issue AstraZeneca NDCs between 1992 and 2005 alone.<sup>7</sup> The specific AstraZeneca NDCs for which Iowa seeks relief are set forth in Exhibit B-4 hereto. Iowa alleges both AWP and FUL claims against AstraZeneca.

225. At all times relevant hereto, AstraZeneca has known that it can promote its drugs by creating a spread and selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-4 hereto, AstraZeneca has routinely created such spreads.

226. AstraZeneca has consistently offered its drugs at prices significantly below the WAC and/or AWP that AstraZeneca caused to be reported. For example, AstraZeneca offered a Performance Incentive Reimbursement contract to those of its customers who would commit to purchasing its drugs exclusively through the wholesaler Cardinal Health. On information and belief, AstraZeneca did not take the rebates paid through this program into account in setting its WAC or AWP. On information and belief the Cardinal Performance Incentive Reimbursement is but one of many AstraZeneca incentive programs that reduced the actual cost of its products and was not accounted for in the setting of WAC or AWP.

227. Another is the rebate program AstraZeneca offered through suppliers which existed “in lieu of upfront discounts” but had the same practical effect, i.e., “to earn additional savings on top of those resulting from direct contract pricing.”

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<sup>7</sup> Iowa’s claims are not confined to this time period.

228. AstraZeneca has instructed its sales force to market the spread for its products. AstraZeneca has specifically instructed sales staff to use the difference between AWP and actual acquisition cost as a selling point, and has prepared worksheets demonstrating the proper calculation of spread. These worksheets also described the AWPs of AstraZeneca competitors to demonstrate the advantage of purchasing AstraZeneca products with their inflated AWPs.

229. AstraZeneca specifically prepared reimbursement worksheets to demonstrate that greater profits could be earned from its Zoladex product as compared with TAP's Lupron.

230. AstraZeneca has expressly stated that it was at a "competitive disadvantage" with its customers when its increased reimbursement prices (or AWPs) were not promptly published.

231. AstraZeneca also provided substantial volumes of free samples and engaged in off invoice transactions to lower providers' costs.

232. In its agreements with PBMs, AstraZeneca guaranteed it would maintain a spread between AWP and actual cost for all products in order to ensure PBM profit.

233. In connection with the wrongful conduct described herein AstraZeneca has been sued by Alabama, Alaska, California, Idaho, Illinois, Kentucky, Mississippi, Montana, Nevada, Pennsylvania, Wisconsin, and the City of New York and 42 New York Counties.

234. AstraZeneca has been investigated by at least the United States Congress, the Department of Justice, the Office of the Inspector General of the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration.

235. 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, a drug paid for by Iowa, that an AstraZeneca sales representative had given the doctor. The indictment alleged 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.

236. In June 2003, AstraZeneca pled guilty and paid \$291 million to settle the Zoladex charges. The U.S. Food and Drug Administration said in its statement regarding the settlement, “AstraZeneca provided thousands of free samples of Zoladex to physicians knowing that they would charge their patients and insurance programs for the samples.”

237. On May 29, 2003, AstraZeneca entered into a Corporate Integrity Agreement (“CIA”) with the OIG of the United States Department of Health and Human Services “to promote compliance . . . with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))” (“Federal Health Care Program Requirements”). Contemporaneously, AstraZeneca entered into a Settlement Agreement with the United States and various states.

238. The CIA covers any individuals who sell or market government reimbursed products on behalf of AstraZeneca; calculate or report prices; and/or include, negotiate, implement or report information related to government contracts relating to federal health care programs, including Medicare and the Medicaid drug rebate program (codified at 42 U.S.C. § 1396r-8 et seq.) The CIA also covers any AstraZeneca employee or agent responsible for “(1) sales and marketing activities for Government Reimbursed Products; (2) the calculation

and reporting of prices for federal health care programs, including . . . Medicaid or (3) the negotiation, implementation, and any reporting of information related to government contracts.”

239. In addition to promising compliance with federal health care program requirements, the CIA requires AstraZeneca to establish a written code of conduct to be agreed to by each covered person that confirms AstraZeneca’s “commitment to full compliance with all federal health care program requirements, including its commitment to comply with all government contracting requirements and to market and sell its government reimbursed products in accordance with federal health care program requirements.”

240. The CIA requires further that AstraZeneca implement policies and procedures that address the code of conduct described above as well as:

(a) the calculation and reporting of accurate prices for government reimbursed products to certain entities, including CMS, the State Medicaid programs, and the drug price reporting services on which government agencies now rely (First DataBank Inc., the *RedBook*, etc.) or shall rely in the future;

(b) the proper calculation and reporting of all data and information reported to CMS and/or the State Medicaid programs in connection with the Medicaid drug rebate program, codified at 42 U.S.C. § 1396r-8;

(c) the proper uses and tracking of drug samples in accordance with all applicable requirements, including, but not limited to, the Prescription Drug Marketing Act, codified in 21 U.S.C. §§ 331, 333 and 352; and

(d) measures designed to promote marketing and sales practices that conform with all statutes, regulations and requirements applicable to government reimbursed products. The Policies and Procedures shall specify that AstraZeneca shall comply with the

Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b(1) & (2), and other applicable statutes, regulations or requirements.

241. The CIA contemplates monetary penalties for non-compliance, and the retention of an independent review organization, (“IRO”). The IRO shall perform two types of review: (1) a systems review of AstraZeneca’s systems, processes, policies and practices relating to the Medicaid drug rebate program (“Medicaid Rebate Systems Review”) and (2) a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with AstraZeneca’s policies and procedures and Medicaid drug rebate program requirements.

242. CIA notwithstanding, AstraZeneca now is the subject of an investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements. *See* Exhibit F. On information and belief, AstraZeneca routinely offers its brand products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price.

#### **E. BARR**

243. As summarized in Exhibit A, Iowa Medicaid spent \$17 million on the 270 at-issue Barr NDCs between 1992 and 2005 alone.<sup>8</sup> The specific Barr NDCs for which Iowa seeks relief are set forth in Exhibit B-5 hereto. Iowa alleges both AWP and FUL fraud claims against Barr.

244. At all times relevant hereto, Barr has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false

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<sup>8</sup> Iowa’s claims are not confined to this time period.

and inflated reimbursement prices. As evidenced by Exhibit B-5 hereto, Barr has routinely created such spreads.

245. Barr has instructed its sales force to market the spread for its products. Barr has specifically instructed sales staff to use the difference between AWP and actual acquisition cost as a selling point, and has prepared worksheets demonstrating the proper calculation of spread. These worksheets also described the AWP of Barr competitors to demonstrate the advantage of purchasing Barr products with their inflated AWP.

246. In connection with the wrongful conduct described herein, Barr also has been sued by the States of Alabama, Alaska, Hawaii, Idaho, Illinois, Kentucky, Massachusetts, Mississippi, the City of New York and 42 New York Counties.

247. Kentucky and Illinois each report that for Barr's Chlordiazepoxide (25 cap) (Dosage 100s) (NDC 000555-01569-02) (a subject drug) 2000 AWP was \$22.60 yet the available price was \$4.09. This represents a spread of \$18.59 or 452%.

248. In February 2001, the AWP for the same Barr's Chlordiazepoxide 25 mg Capsule increased 50% to \$34.02, however, the available price increased only 7% to \$4.36. These price changes resulted in a new increased AWP spread of 680%.

249. While there was a FUL in place during at least some of the time period referred to above, Barr's failure to account for its deeply discounted prices resulted in that FUL being false and inflated. For example, the FUL for Chlordiazepoxide 25 mg Capsule was \$.1090/unit in 2001. Given that the FUL is set at 150% of the lowest reported price for therapeutic bioequivalents, this means the lowest reported price for Chlordiazepoxide 25 mg Capsule was \$.0726/unit.

250. Barr sold Chlordiazepoxide 25 mg Capsule for \$.0436/unit in 2001, which is 67% less than the lowest reported price that generated the FUL. If Barr properly reported this price, the FUL would have been \$0.0654/unit instead of \$.1090/unit and Iowa Medicaid would have reimbursed based on this lower FUL. Thus, Barr's failure to report accurate prices resulted in a fraudulent FUL and damage to Iowa Medicaid Programs is directly attributable to Barr. Exhibit B-5 sets forth an additional example of FUL fraud for Chlordiazepoxide 25 mg Capsule.

251. Barr is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. The Committee has requested detailed reports on pricing practices, including records concerning the "spread" between actual market prices and payments by Medicaid. The basis of this investigation is "indicia from a number of sources, including utilization data, drug price/reimbursement spreads, and other relevant information."

## **F. BAXTER**

252. As summarized in Exhibit A, Iowa Medicaid spent over \$3.8 million for the 125 at-issue Baxter NDCs between 1992 and 2005 alone.<sup>9</sup> The specific Baxter NDCs for which Iowa seeks relief are set forth in Exhibit B-6 hereto.

253. At all times relevant hereto, Baxter has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-6, Baxter has routinely created such spreads.

254. Baxter has instructed its sales force to market the spread for its products. Baxter has specifically instructed sales staff to use the difference between AWP and actual

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<sup>9</sup> Iowa's claims are not confined to this time period.

acquisition cost as a selling point, and has prepared worksheets demonstrating the proper calculation of spread.

255. Baxter sales strategy has included monitoring the AWP of competitors' products and raising its own AWP in response, using a number of justifications unconnected to the market price of the product.

256. Baxter's marketing and sales documents that compared the costs of their respective drugs to those of their respective competitors were specifically intended to induce providers 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."

257. Baxter cautioned its sales representatives not to demonstrate to its customers reimbursement scenarios where purchasing a competitor's product might be more profitable.

258. On information and belief, in 1992 Baxter informed its employees how to respond to inquiries concerning AWP increases for Baxter products:

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

259. In a 2000 report published by the DHHS, the DOJ documented at least 41 instances where the published AWP's for various dosages of multi-source drugs manufactured by

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

<b>Drug in Lowest Dosage Form</b>	<b>Red Book AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Dextrose	\$928.51	\$2.25	\$926.26	41,167%
Dextrose Sodium Chloride	\$357.69	\$2.93	\$354.76	12,108%
Sodium Chloride	\$928.51	\$1.71	\$926.80	54,199%
Factor VIII	\$1.28	\$.92	\$.36	39%

260. The states of Alabama, Illinois, Kentucky, Montana, Pennsylvania, Texas, and Wisconsin have filed lawsuits against Baxter in connection with the same wrongdoing at issue here.

261. In a September 28, 2000 letter to Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America, Congressman Pete Stark made clear that Baxter inflated multi-source AWPs to increase government reimbursement to its customers and gave free drugs to customers in order that they could obtain government reimbursement for these free drugs.

262. Congressman Stark disclosed internal Baxter documents, which stated that “[i]ncreasing AWPs was a large part of our negotiations with the large homecare companies.” See 146 Cong. Rec. E1622 (2000).

## **G. BAYER**

263. As summarized in Exhibit A, Iowa Medicaid spent over \$5 million on the 35 at-issue Bayer NDCs between 1992 and 2005 alone.<sup>10</sup> The specific Bayer NDCs for which Iowa seeks relief are set forth in Exhibit B-7 hereto.

264. At all times relevant hereto, Bayer has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining a false and inflated reimbursement prices. As evidenced by Exhibit B-7 hereto, Bayer has routinely created such spreads.

265. Bayer has instructed its sales force to market the spread for its products. Bayer has specifically instructed sales staff to use the difference between AWP and actual acquisition cost as a selling point, and has prepared worksheets demonstrating the proper calculation of spread. These worksheets also described the AWP of the Bayer competitors to demonstrate the advantage of purchasing Bayer products with their inflated AWP.

266. Bayer tracked Baxter's AWP for subject drug Recombinate and contemplated raising its own AWP to match a price increase by Baxter. This was done out of concern that customers would receive a lower reimbursement under Bayer's AWP and hence not purchase Bayer's product.

267. Bayer's sales representatives stated that in 1996 and 1997 the best way to achieve Bayer's sales goals was to use off-invoice pricing. Bayer customers like Quantum and Caremark preferred off-invoice pricing because it eliminated Medicaid risks.

268. For instance, in a 1996 contract negotiation, Bayer planned on using an off-invoice pricing system, in which the hidden price reduction would come in the form of a

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<sup>10</sup> Iowa's claims are not confined to this time period.

marketing grant, special educational grant, or a data gathering fee paid to Quantum to make up for the falsely inflated invoiced charges.

269. Another example of how this false invoicing scheme functioned is contained in Bayer's 1994 pricing offer to Quantum Health for the subject drug Gamimmune-N 10%. Bayer offered to bill Quantum \$30.00 per gram for Gamimmune (the invoice price) then at a later date issue Quantum a credit memorandum for \$5.80 per gram thereby creating the true (off-invoice price) of \$24.20.

270. Another example of the false invoicing scheme can be found in Bayer's 1994 pricing offer to Texas Health Resources. Bayer offered to invoice Kogenate at \$0.82 per unit, and then provide free goods until the per-unit price reached \$0.55.

271. Bayer believed that off-invoice pricing enabled Bayer to quickly lower its prices and maximize sales.

272. In connection with the wrongdoing at issue, Bayer has been sued by the states of Alabama, Hawaii, Illinois, Kentucky, Mississippi, Montana, Pennsylvania, the City of New York and 42 New York Counties.

273. Bayer also has been investigated by at least the DOJ, the United States Congress, the Commonwealth of Massachusetts, and HHS OIG.

274. The DOJ concluded that the AWP's for Bayer's Immune Globulin (a subject drug) were false and inflated.

275. In January 2002, Bayer agreed to pay a total of \$14 million to the United States and 45 states to settle allegations under the federal False Claims Act that the company caused physicians and other health care providers to submit fraudulently inflated reimbursement claims to state and federally-funded Medicaid program. Bayer reached the agreement with the

Justice Department, the United States Attorney's Office for the Southern District of Florida in Miami, the Office of Inspector General for the Department of Health and Human Services, and a team of state negotiators from Maine, Nevada, New York and Washington representing the National Association of Medicaid Fraud Control Units.

276. The government's investigation of the allegations, contained in a *qui tam* or whistleblower lawsuit in which the government intervened against Bayer, revealed that, beginning in the early 1990's, Bayer falsely inflated the reported AWP, the Direct Price, and the WAC used by state governments to set the reimbursement rate for the Medicaid program. According to the DOJ's January 23, 2001 press release, 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 by the government. The Bayer AWPs at issue in this settlement were Kogenate, Koate-HP, Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases.

277. The Bayer investigation revealed "marketing the spread," had the effect of discouraging market competition from manufacturers that do not inflate AWPs as a way of inducing doctors to purchase their products. In addition to entering into the monetary settlement, Bayer reached a five-year agreement with the OIG of HHS that required government monitoring of the company's conduct under a corporate integrity agreement. Under the compliance agreement, Bayer will provide the state and federal governments with the average selling prices of its drugs in order to facilitate the government's setting of fair reimbursement rates for the company's products, and potentially, the products of any competitors attempting to take advantage of Bayer's cooperation.

278. This Bayer settlement also included settlement of allegations that Bayer knowingly underpaid the Medicaid program for rebates owed by it to the states.

279. In April 2003, Bayer settled certain charges in connection with its efforts to evade paying rebates to states' Medicaid programs which were based on the lowest drug prices they were paying to an HMO, Kaiser Permanente, for Cipro and another Bayer drug, Adalat CC. Bayer is to pay a total of \$275 million to resolve criminal charges and civil liabilities in connection with the fraudulent drug pricing of Cipro and Adalat. The criminal portion of the global agreement calls for Bayer to plead guilty to charges that it violated the Food, Drug and Cosmetic Act by failing to notify the FDA between August and December 1995, of its production of private label Cipro for Kaiser. Bayer has agreed to pay a criminal fine of \$5.6 million and will admit that it engaged in this conduct with the intent to defraud or mislead. In the civil portion of its global settlement, Bayer resolved its federal civil False Claims Act liabilities and pay the United States, 49 states, the District of Columbia, and Public Health Service Entities \$251 million in civil damages for losses suffered by the Medicaid program and the Public Health Service entities due to Bayer's failure to report its Kaiser private label price to the government as the true Best Price for its drugs.

280. The foregoing settlement implicates none of Iowa's AWP claims against Bayer. To the extent it concerned Bayer's Best Price failures, at most, it may have some impact on two years' worth of rebate related damages.

## **H. THE BMS GROUP**

281. As summarized in Exhibit A, Iowa Medicaid spent over \$92 million for the 445 at-issue BMS Group NDCs between 1992 and 2005 alone.<sup>11</sup> The specific BMS Group

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<sup>11</sup> Iowa's claims are not confined to this time period.

NDCs for which Iowa seeks relief are set forth in Exhibit B-8 hereto. Iowa alleges both AWP and FUL fraud claims against BMS.

282. At all times relevant hereto, the BMS Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-8, BMS Group has routinely created such spreads.

283. At all times relevant hereto, BMS has been aware that providers and other purchasers of its drugs were using the spread to determine whether to purchase its drugs and has marketed spread to its customers. BMS was aware of and tracked the AWP of its competitors in order to remain competitive. For example, an internal BMS memorandum identifies its competitors who sell etoposide (Gensia, Phamacia, Abbott, Chiron, Ben Venue, Immunex and Alpha – all defendants herein), and their corresponding list prices and AWP.

284. BMS created this AWP competitor analysis, tracked the AWP of its competitors' relevant drugs and used the data internally to prepare suggested AWP for gaining and maintaining market share. For example, BMS informed physicians that they could take advantage of the growing disparity between BMS's Vepesid's listed AWP and the actual acquisition cost. BMS knew if the acquisition cost approached its list prices, then the financial incentive to purchase BMS drugs diminished.

285. For all the BMS drugs at issue here, BMS provided "wholesale prices" and "direct prices" to publishers with the knowledge and intent that these false and inflated prices would be converted to a false and inflated AWP. Indeed, BMS specifically requested that its pricing information be so converted.

286. BMS at all times relevant hereto tracked the amount by which the publishers would increase its direct price (i.e., either 1.20 or 1.25) markup. On occasion, BMS instructed publishers to apply the 1.25 markup to the already false and inflated BMS direct price.

287. For example, by letter dated February 27, 2001 to Bristol-Myers, Representative Stark outlined numerous examples of specific illegal practices by Bristol-Myers. Referring to a letter from Denise Kaszuba, a senior pricing analyst at Bristol-Myers to Medispan dated August 10, 1992, Rep. Stark noted:

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

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

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

147 Cong. Rec. E244-02, \*E244 -E245 (2001).

289. Ms. Kaszuba likewise communicated the specific product information necessary to establish the BMS AWP to First Data Bank and other publishers.

290. In connection with the same wrongdoing described herein, BMS has been sued by the states of Alabama, Alaska, California, Hawaii, Idaho, Illinois, Kentucky, Mississippi,

Montana, Pennsylvania South Carolina, Wisconsin, the City of New York and 42 New York Counties.

291. In 2000, BMS caused an AWP of \$51.43 to be published for subject drug Cyclophosphamide (Cytosan Lyophilized) IV, 1gm (NDC Code 00015-0548-41) while the available price was \$23.19, resulting in a spread of 122%.

292. Similarly in 2001, BMS routinely sold Cytosan Lyophilized for deep discounts off “list price” or WAC.

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

294. In 1998, BMS sold subject drug Vepesid 5ml/100mg, 7.5ml/150mg, 25ml/500 mg and 50 ml/1gm (all dosages at issue here) at discounts of 71.5% to 75% off WAC/list price.

295. In 1996, BMS increased its reported AWP for subject drug Blenoxane to \$291.49, while continuing to sell the drug to oncologists at its 1995 price of \$224.27. In 1997, BMS reported that it had increased the AWP of Blenoxane to \$304.60, when in fact, BMS had lowered the price to oncologists to \$155.00. In 1998, BMS again reported a false AWP for Blenoxane of \$304.60 while further reducing the actual price to oncologists to \$140.00.

296. In 1998, BMS sold subject drug Amikin 500mg/2ml-10s and Amikin 1g/vial 4ml-10s at discounts of 66% and 66.8% off WAC or direct price. Iowa paid based on AWP.

297. BMS is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. The Committee has requested detailed reports on pricing practices, including records concerning the “spread” between actual market prices and payments by Medicaid. The basis of this investigation is “indicia from a number of sources, including utilization data, drug price/reimbursement spreads, and other relevant information.”

298. BMS also is the subject of the investigation led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements. *See* Exhibit F. On information and belief, BMS routinely offers its products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price.

## **I. BOEHRINGER GROUP**

299. As summarized in Exhibit A, Iowa Medicaid spent over \$30 million for the 376 at-issue Boehringer Group NDCs between 1992 and 2005 alone.<sup>12</sup> The specific Boehringer Group NDCs for which Iowa seeks relief are set forth in Exhibit B-9 hereto. Iowa alleges both AWP and FUL fraud against the Boehringer Group defendants.

300. At all times relevant hereto, the Boehringer Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time

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<sup>12</sup> Iowa’s claims are not confined to this time period.

maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-9, the Boehringer Group defendants have routinely created such spreads.

301. The Boehringer Group has instructed its sales force to market the spread for its products. The Boehringer Group has specifically instructed sales staff to use the difference between AWP and actual acquisition cost as a selling point, and has prepared worksheets demonstrating the proper calculation of spread. These worksheets also described the AWPs of the Boehringer Group competitors to demonstrate the advantage of purchasing Boehringer Group products with their inflated AWPs.

302. The Boehringer Group has consistently offered its drugs and other solutions to its customers at prices significantly below the published AWP. At all times relevant hereto, the Boehringer Group knew the spread was of great importance to its customers and it actively marketed and manipulated the spread.

303. For example, in a report published by HHS, the DOJ documented at least 32 instances where the published AWPs for various dosages of nine multi-source drugs manufactured by the Boehringer Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the nine subject multi-source drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by the Boehringer Group in the *RedBook*.

<b>Drug</b>	<b>The Boehringer Group's 2001 RedBook AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Acyclovir Sodium	\$ 528.00	\$ 207.00	\$ 321.00	155%
Amikacin Sulfate	\$ 437.50	\$ 65.53	\$ 372.17	570%
Mitomicyn	\$ 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%
Methotrexate Sodium	\$ 68.80	\$ 2.63	\$ 66.17	2,516%
Vinblastine Sulfate	\$ 212.50	\$ 8.19	\$ 204.31	2,495%

304. Another example is the rebate program Boehringer offered through suppliers. These rebates were offered “in lieu of upfront discounts” but had the same practical effect, i.e., to further reduce the actual price paid for Boehringer products.

305. In connection with the wrongful conduct described herein, the Boehringer Group has been investigated by the DOJ, the HHS OIG, the House Committee on Energy and Commerce, and the Attorneys General for the States of Nevada, Pennsylvania and Wisconsin.

306. In connection with the wrongful conduct described herein, Boehringer has been sued by the States of Alabama, Alaska, California, Hawaii, Idaho, Illinois, Kentucky, Massachusetts, Mississippi, Missouri, Montana, Ohio, Pennsylvania, South Carolina, Texas, Wisconsin, the City of New York and 42 New York Counties.

307. In 2000, the spread for ipratropium bromide increased to 328% due to a decrease in true wholesale price but a purposeful failure to adjust the published AWP.

308. From 1994 through 1996, Roxane and its affiliates disseminated an AWP for subject drug lithium carbonate of \$7.99 while the available market price was approximately \$2.30, resulting in a spread of \$5.69 or 247%.

309. Illinois alleges that in 2000, Roxane and its affiliates published an AWP for subject drug Furosemide 20 mg tablets of \$36.05, while the available market price was approximately \$8.30, resulting in a spread of \$27.75, or 334%.

310. In February 2001, the AWP for the same Boehringer Group's Furosemide 20 mg Tablet [NDC 00054429731] was \$139.90, an increase of 288%, from the prior year while the available price increased only 7% to \$8.84. These price changes resulted in a new increased AWP spread of 1483%.

311. While there was a FUL in place during at least some of the time period referred to above, the Boehringer Group's failure to account for its deeply discounted prices resulted in that FUL being false and inflated. As set forth in Exhibit B-9 hereto, in 2001 the FUL for the Boehringer Group's Furosemide 20 mg Tablet was \$4.20 or \$.0420/unit in 2001. Given that the FUL is set at 150% of the lowest reported price for therapeutic bioequivalents, this means the lowest reported price for Furosemide 20 mg Tablet was \$.0280/unit.

312. The Boehringer Group sold Furosemide 20 mg Tablet for \$.0088/unit in 2001, which is 218% less than the lowest reported price that generated the FUL. If the Boehringer Group properly reported this price, the FUL would have been \$0.0132/unit instead of \$.0420/unit and Iowa Medicaid Programs would have reimbursed based on this lower FUL. Thus, the Boehringer Group's failure to report accurate prices resulted in a fraudulent FUL and damage to Iowa Medicaid Programs directly attributable to Boehringer Group.

313. In 2000, Ben Venue and its affiliates published an AWP for subject drug Haloperidol Decanoate 100mg/ml (a subject drug) of \$576.00, while the available market price was approximately \$150.00, resulting in a spread of \$426.00, or 284%.

314. In 2000, Roxane and its affiliates published an AWP for subject drug Prednisone 20 mg tablets of \$57.72, while the available market price was approximately \$18.31, resulting in a spread of \$39.41, or 215%.

315. Boehringer's failure to report accurate prices for its drug Prednisone 20 mg also caused an inflated FUL to be set for that drug in the years 2000 and 2001. In addition to the examples given in Exhibit B-9 hereto, in 2000 the FUL for the Boehringer Group's Prednisone 20 mg Tablet was \$.0760/unit. Given that the FUL is set at 150% of the lowest reported price for therapeutic bioequivalents, this means the lowest reported price for Prednisone 20 mg Tablet was \$.0506/unit.

316. The Boehringer Group sold Prednisone 20 mg Tablet for \$.0329/unit in 2000, which is 54% less than the lowest reported price that generated the FUL. If the Boehringer Group properly reported this price, the FUL would have been \$0.0493/unit instead of \$.0760/unit and Iowa Medicaid Programs would have reimbursed based on this lower FUL. Thus, Boehringer Group's failure to report accurate prices resulted in a fraudulent FUL and damage to Iowa Medicaid directly attributable to Boehringer Group. Exhibit B-9 sets forth how Boehringer's pricing resulted in FUL fraud for Prednisone 20 mg in 2001.

317. The Boehringer Group's Roxane is among the pharmaceutical companies referred to above now under investigation by the House Committee on Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. The Committee has requested detailed reports on pricing practices, including records concerning the "spread" between actual market prices and payments by Medicaid. The basis of this investigation is "indicia from a number of sources, including utilization data, drug price/reimbursement spreads, and other relevant information."

318. Boehringer also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements. *See* Exhibit F hereto. On

information and belief, Boehringer routinely offers its brand products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price.

**J. CHIRON**

319. As summarized in Exhibit A, Iowa Medicaid spent over \$1.8 million for the 2 at-issue Chiron NDCs between 1992 and 2005 alone.<sup>13</sup> The specific Chiron NDCs for which Iowa seeks relief are set forth in Exhibit B-10 hereto.

320. At all times relevant hereto, Chiron has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-10, Chiron has created such spreads.

321. Chiron has instructed its sales force to market the spread for its products. Chiron has specifically instructed sales staff to use the difference between AWP and actual acquisition cost as a selling point, and has prepared worksheets demonstrating the proper calculation of spread. These worksheets also described the AWP of the Chiron competitors to demonstrate the advantage of purchasing Chiron products with their inflated AWP.

322. As set forth in the table below, Chiron aggressively sold its products at prices that were significantly lower than the spread.

<b>Defendant Chiron's Prices &amp; Spread From 1995 Contract</b>					
<b>Drug</b>	<b>NDC</b>	<b>Contract Price</b>	<b>AWP</b>	<b>Provider's Gross Profit or "Spread"</b>	<b>Spread as a % of Contract Price</b>
Cytarabine,	53905131-10	\$2.88/vial	\$62.50	\$59.62	2070%

<sup>13</sup> Iowa's claims not confined to this time period.

Lyoph					
Cytarabine, Lyoph	53905132-10	\$8.75/vial	\$250.00	\$241.25	2757%
Cytarabine, Lyoph	53905133-01	\$21.50/vial	\$508.00	\$486.50	2263%
Cytarabine, Lyoph	53905134-01	\$43.00/vial	\$98.90	\$55.90	130%
Doxorubicin, Solution	53905235-10	\$13.92/vial	\$47.37	\$33.45	240%
Doxorubicin, Solution	53905236-10	\$27.26/vial	\$94.70	\$67.44	247%
Doxorubicin, Solution	53905237-01	\$68.15/vial	\$236.74	\$168.59	247%
Doxorubicin, Solution	53905238-01	\$283.50/vial	\$945.98	\$662.48	234%
Leucovorin, Lyoph	53905051-10	\$2.30/vial	\$184.38	\$182.08	7917%
Leucovorin, Lyoph	53905052-10	\$3.75/vial	\$350.00	\$346.25	9233%
Leucovorin, Lyoph	53905053-01	\$9.51/vial	\$78.00	\$68.49	720%
Methotrexate, PFS	53905031-10	\$2.30/vial	\$6.88	\$4.58	199%
Methotrexate, PFS	53905032-10	\$3.22/vial	\$8.75	\$5.53	172%
Methotrexate, PFS	53905033-10	\$4.35/vial	\$17.50	\$13.15	302%
Methotrexate, PFS	53905034-10	\$4.60/vial	\$26.88	\$22.28	484%

323. In 1995, Chiron aggressively marketed the spread for subject drugs Leucovorin Injection 200 mg (NDC 53905-0053-01) and for Doxorubicin HCL, sol, 200 mg MDV (NDC 53905-0238-01). In an advertisement in 1995, Chiron offered both of these drugs at prices significantly discounted to AWP. Chiron caused per vial AWP of \$78.00 and \$945.98 to be reported for Leucovorin 200 mg and Doxorubicin, respectively, and highlighted this fact in their advertisement. The advertisement also highlighted acquisition costs of \$9.67 for 200 mg Leucovorin and \$259.00 for 200 mg Doxorubicin. These acquisition costs and AWP result in spreads of 706% for Chiron's 200 mg Leucovorin, and 265% for Chiron's 200 mg Doxorubicin.

324. This advertisement granted customers two free vials of Leucovorin 200 mg for every 10 ordered, and one free vial of Doxorubicin for every 10 ordered. In addition to this example, Chiron has utilized other impermissible off-invoice inducements to stimulate sales of its drugs without accounting for them in its WAC, AWP, or Best Prices. 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, Chiron provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

325. Chiron has routinely sold subject drugs Acetylcystine (NDC 53905-0211-03, 53905-0212-03), Doxorubicin (NDC 53905-0213-03, 53905-0214-03), Cytarabine (53905-0131-10, 53905-0131-20), and Doxorubicin HCL (NDC 53905-0231-10, 53905-0232-06) among others at spreads that ranged between 100 and 400 percent.

326. Between 1995 and 1998, Chiron kept its AWP for Mitomycin 20 mg, NDCs 53905-0252-01 and 55390-0252-01 at \$434.60, while its wholesale price decreased each year.

<b>PERCENTAGE OF “SPREAD “BETWEEN CHIRON’S REPORTED AWP AND THE TRUE COST FOR MITOMYCIN 20 MG, NDC#s 53905-0252-01 AND 55390-0252-01</b>			
<u>Year</u>	<u>AWP</u>	<u>TRUE COST</u>	<u>Percent “Spread”</u>
1995	\$434.60	\$338.00	28%
1996	\$434.60	\$260.00	67%
1997	\$434.60	190.00	129%
1998	\$434.60	152.95	184%

327. If the AWP stayed the same, but the price decreased as set forth below, the reported AWP cannot be an “average” wholesale price.

## **K. DEY**

328. As summarized in Exhibit A, Iowa Medicaid spent over \$17 million on the 54 at-issue Dey NDCs between 1992 and 2005 alone.<sup>14</sup> The specific Dey NDCs for which Iowa seeks relief are set forth in Exhibit B-11 hereto. Iowa alleges both AWP and FUL fraud claims against Dey.

329. At all times relevant hereto, Dey has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-11, Dey has routinely created such spreads.

330. For example, on May 30, 1995, Dey Marketing Director, Helen Burnham, issued a memo to Sales and Marketing that stated in part that WAC was not representative of Dey's published wholesale prices, but like AWP, was used for calculation of reimbursement. Helen Burnham has also stated that Dey's spread on the drug Metaproterenol (a subject drug) between pharmacy direct price and AWP remained very competitive even with the reduction in AWP.

331. Robert P. Mozak, Executive Vice President of Sales and Marketing at Dey, has stated in regard to Albuterol pricing strategy that Dey should increase the spread in order to provide incentive to retail and chain providers. Dey has admitted that increasing spread for retail will provide Dey with the highest profit.

332. Dey Sales Representative, Ross Uhl, has made reference to a pricing formula that spread equals AWP minus cost.

333. Dey has instructed its sales force to market the spread for its products. Dey has specifically instructed sales staff to use the difference between AWP and actual

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<sup>14</sup> Iowa's claims are not confined to this time period.

acquisition cost as a selling point, and has prepared worksheets demonstrating the proper calculation of spread.

334. On information and belief, in an internal worksheet filled out by Dey in preparation for a bid of potential sales to one of its customers, Dey listed the current contract price of various products as well as a recommended new contract price. In the notes next to these figures the worksheet states, “This account needs AWP-40% or better to see profit due to the employer groups they serve.”

335. In its suit against First DataBank and Medi-Span, Dey admitted to controlling its published AWP. Specifically, Dey has an agreement with First DataBank and Medi-Span to provide the reporting services with AWP pricing information. (¶¶ 26-32 of Dey Complaint filed in *Dey, L.P. v. First Databank, Inc., et al.*, No. 26-21019 (Cal. Super. Ct. - Napa.)

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

(¶ 32 of Dey Complaint; *see also* ¶ 36 of Dey Complaint for similar allegation against Medispan, filed in *Dey, L.P. v. First Databank, Inc., et al.*, No. 26-21019 (Cal. Super. Ct. - Napa).

336. Dey has been sued by the United States Department of Justice and the states of Alabama, Alaska, California, Connecticut, Hawaii, Idaho, Illinois, Kentucky, Massachusetts, Mississippi, Missouri, Montana, Pennsylvania, South Carolina, Texas, West Virginia, Wisconsin, the City of New York and 42 New York Counties.

337. Wisconsin alleges that in 2000 the Dey drug Metaproterenol Sulfate (.4% 2.5 ml 25s) (NDC 49502-0678-03) (a subject drug) had an AWP of \$30.75 yet was available at \$11.29, representing a spread of 172%.

338. In *State ex rel. Ven-a-Care, v. Dey, L.P.* No GV002327 (Tex Dist.), the State of Texas sued Dey for reporting false prices for two of the Dey drugs at issue here, albuterol sulfate and ipratropium bromide. Texas alleged that between 1995 and 1999 Dey defrauded the Texas State Medicaid program by reporting false wholesale pricing data for these drugs. In June 2003, Dey settled the Texas allegations for 2.5 times actual damages, or \$18 million.

339. The Connecticut Attorney General sued Dey for AWP manipulation. Connecticut documented the following spreads between Dey’s published AWP’s and actual wholesale prices for many of its drugs.

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

340. In a 2001 report published by HHS, the DOJ documented at least 15 instances where the published AWP’s for various dosages of four multi-source drugs manufactured by Dey were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the multi-source drugs identified by the DOJ and the spread associated with one particular dosage of each. These figures compare the DOJ’s determination of an accurate AWP for that particular dosage, based upon wholesalers’ price lists, with the AWP reported by Dey in the 2001 RedBook.

Drug in Lowest Dosage Form	2001 <i>RedBook</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%

341. Albuterol sulfate, a multisource drug at issue here and one of Dey’s top selling products, was a focus of the federal government’s investigation into AWP inflation. The OIG found that “Medicare’s reimbursement amount for albuterol was nearly six times higher than the median catalog price” See “Excessive Medicare Reimbursement for Albuterol,” OEI-03-01-00410, March 2002.

342. 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.

343. Similarly, between 1993 and 1998, Dey kept its AWP for Albuterol Sulfate 0.083% NDC 4950-20687, at \$32.25, while its wholesale price decreased each year.

<b>PERCENTAGE OF “SPREAD” BETWEEN DEY LAB’S REPORTED AWP AND THE ACTUAL WHOLESALE PRICE FOR ALBUTEROL SULFATE 0.083% NDC# 4950-20687-03, 3ML/25’s</b>			
Year	<i>Red Book</i> /First DataBank AWP	McKesson Wholesale Price	Percent “Spread”
1993	\$30.25	\$25.39	16.1%
1994	\$30.25	\$23.69	21.4%
1995	\$30.25	\$15.26	49.6%
1996	\$30.25	\$15.26	49.6%
1997	\$30.25	\$11.84	60.9%
1998	\$30.25	\$10.00	67.0%

344. Dey’s fraudulent pricing scheme took root in the early 1990s. In 1993, Dey’s *Red Book* AWP for albuterol sulfate (.083% concentration, 3 ml) was \$30.25, yet it was available from McKesson at the wholesale price of \$25.45 (a spread of 16.1%). By 1998, Dey’s

*Red Book* AWP for the same concentration/dose of albuterol sulfate was still \$30.25, yet the McKesson wholesale price had plummeted to \$10.00 (creating a spread of 202%). See September 25, 2000 letter from U.S. Rep. Bliley to Nancy-Ann Min DeParle.

345. At all times relevant hereto, Dey has also utilized “off-invoice” pricing practices whereby Dey provides free goods for products. On information and belief these free goods are not accounted for in Dey’s computation of WAC or AWP resulting in further inflation of both.

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

347. In an effort to conceal the existence of a spread, Dey misrepresented the true wholesale prices of its drugs. For instance, in a handwritten memorandum to Dey’s pricing committee records discussions regarding a potential pricing structure with a customer as follows:

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

348. Dey is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

349. Dey's Chief Financial Officer, Pamela Marrs, testified on December 7, 2004 that Dey did not lower its AWP's because to do so would cause it to lose customers. *Medicaid Prescription Drug Reimbursements: Why the Government Pays Too Much: Hearing before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce House of Representatives, 108th Cong., 2nd Sess. (2004).*

## **L. ELI LILLY**

350. As summarized in Exhibit A, Iowa Medicaid spent \$4.9 billion on the 13 at-issue Eli Lilly NDCs between 1992 and 2005 alone.<sup>15</sup> The specific Eli Lilly NDCs for which Iowa seeks relief are set forth in Exhibit B-12 hereto. Iowa alleges both AWP and FUL fraud claims against Eli Lilly.

351. At all times relevant hereto, Eli Lilly has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-12, Eli Lilly has routinely created such spreads.

352. At all times relevant hereto, Eli Lilly has negotiated prices with its providers, PBMs, GPOs and other large purchasers at deep discounts off of WAC. Thus, the WACs reported by Lilly are false and misleading. Lilly reports false and misleading WACs in order to inflate the published AWP's for its products and enable Lilly to market spread.

353. In 1999, King Group purchased from Lilly the U.S. and Puerto Rican marketing rights of Lorabid, an antibiotic used in the treatment of bacterial infections, for approximately \$67.8 million. Defendant Eli Lilly manufactures Lorabid for King Group and retains the right to receive additional payments if certain sales performance milestones are achieved.

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<sup>15</sup> Iowa's claims are not confined to this time period.

354. Based on pricing information provided to the House Committee of Energy and Commerce in July 2001, Lilly's 100 ml vial of Vancocin 10 gm (NDC 00002725501) had a reported AWP of \$156.01. The average of available prices for the same 100 ml vial was \$46.00 (a 182% discount from the reported WAC of \$130.00). The intentionally false and misleading AWP was 239% more than the available price.

355. In addition, in December 2000, Lilly's Humalog Mix 75/25 Vial (NDC 00002751101) had a reported AWP of \$47.70. The available price for the same dosage was \$6.70 (a 493% discount from the reported WAC of \$39.75). The false and misleading AWP was 612% more than the available price. Additional examples of Lilly's false price reporting for the Humalog Mix 75/25 Vial are set forth in Exhibit B-12.

356. In order to gain market share for its drugs, Lilly further perpetuated the false and misleading nature of its wholesale price information by offering or causing to be offered significant market share rebates and discounts as well as extended contracts with fixed pricing. On information and belief Lilly never took these discounts and rebates into account in its calculation of AWP or WAC.

357. For example, throughout 2004, Lilly had "Equal Access Upfront Discount Programs" for *all* doses of Zyprexa and Symbyax that it offered to members of certain group purchasing organizations ("GPOs"). Under these programs, Lilly provided an upfront discount of 8% off Lilly's Net Wholesale Price ("NWP") (Lilly's WAC equivalent) if in the previous six months the member had net purchases of antipsychotic medications exceeding \$100,000.00. In return for the discount, Lilly was guaranteed placement on the GPO's formulary. On information and belief, Lilly did not account for these sorts of GPO discounts in its calculation of AWP or WAC.

358. Contemporaneous with the above GPO discount, Zyprexa 15 mg Tablet [NDC 00002441560] had an AWP of \$935.19 and a NWP/WAC of \$748.15 resulting in a 25% AWP spread. The upfront 8% discount produces a true WAC of \$688.30 and an AWP spread of 35%, an effective 10% increase in AWP spread. Iowa Medicaid did not have the benefit of this discount. They paid for Zyprexa, one of their largest Medicaid expenditures, based on Lilly's false reported AWP.

359. Eli Lilly is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. The Committee has requested detailed reports on pricing practices, including records concerning the "spread" between actual market prices and payments by Medicaid. The basis of this investigation is "indicia from a number of sources, including utilization data, drug price/reimbursement spreads, and other relevant information."

360. Eli Lilly also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements. *See* Exhibit F. On information and belief, Eli Lilly routinely offers its brand products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price or report them as its Best Price.

## M. ENDO PHARMACEUTICALS

361. As summarized in Exhibit A, Iowa Medicaid spent over \$4.5 million on the 74 at-issue Endo NDCs between 1992 and 2005 alone.<sup>16</sup> The specific Endo NDCs for which Iowa seeks relief are set forth in Exhibit B-13 hereto. Iowa alleges both AWP and FUL fraud claims against Endo.

362. At all times relevant hereto, Endo has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-13, hereto Endo has routinely created such spreads.

363. At all times relevant hereto, Endo has negotiated prices with providers, PBMs, GPOs and other large purchasers at deep discounts off of WAC. Thus, the WACs reported by Endo are deliberately false and misleading. Endo reports false and misleading WACs in order to inflate the published AWP for its products and enable Endo to create a spread. Endo, like all drug manufacturers, competes on spread and reimbursement.

364. For example,

Endo Drug	Year	AWP	WP	Spread
Selegeline 5mg	2002	\$1015.25	\$82.62	1,128%
Catopril/Hetz 50/25	2002	\$123.90	\$13.01	852%
Oxycodone w/APAP 5/500	2002	\$81.30	\$12.14	569%
Cimetidine 400 mg	2001	\$146.88	\$12.81	1,046%
Glipizide 10mg	2001	\$63.77	\$6.58	869%

365. Additional actionable spreads for the above drugs are set forth in Exhibit B-13 hereto.

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<sup>16</sup> Iowa's claims are not confined to this time period.

366. In 2000, Endo caused an AWP of \$815.06 to be issued for Cyclobenzaprine 10 mg tablets, yet simultaneously made the drug available for \$56.25 (a spread of 1,349%).

367. While there were FULs in place for a number of Endo drugs during at least some of the relevant time period, Endo’s failure to report its deeply discounted prices resulted in some of those FUL being false and inflated. Given that the FUL is set at 150% of the lowest reported price per unit for therapeutic bioequivalents, a comparison of the unit price for Endo drugs to the applicable FUL reveals the false and misleading nature of Endo’s wholesale price information, as indicated by the following examples and those set forth in Exhibit B-13:

<b>Defendant ENDO</b>						
<b>Drug</b>	<b>Year</b>	<b>NDC Code</b>	<b>FUL price/unit</b>	<b>FUL Baseline Price (Lowest)</b>	<b>ENDO Contract Price</b>	<b>Spread % less than Baseline</b>
Selegiline 5 mg Tablets	2002	60951-0620-85	\$0.7658	\$0.5105	\$0.1652	209%
Captopril-HCTZ 50/25 Tablets	2002	60951-0731-70	\$0.3702	\$0.2468	\$0.1301	90%
Oxycodone W/APAP 5/500 Capsules	2002	60951-0660-70	\$0.2250	\$0.1500	\$0.1214	24%
Cyclobenzaprine 10 mg Tablets	2001	60951-0767-90	\$0.0910	\$0.0606	\$0.0562	8%
Carbidopa/Levo 25/100 Tablets	2001	60951-0605-68	\$0.3915	\$0.2610	\$0.1487	75%

368. Endo’s failure to report accurate prices for the above drugs and those set forth in Exhibit B-13 resulted in false and inflated FULs being issued, and overcharges to Iowa Medicaid directly attributable to Endo.

## N. ETHEX

369. As summarized in Exhibit A, Iowa Medicaid spent over \$9 million on the 122 at-issue Ethex NDCs between 1992 and 2005 alone.<sup>17</sup> The specific Ethex NDCs for which Iowa seeks relief are set forth in Exhibit B-14 hereto. Iowa alleges both AWP and FUL fraud claims against Ethex.

370. At all times relevant hereto, Ethex has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-14 hereto, Ethex has routinely created such spreads.

371. At all times relevant hereto, Ethex has negotiated prices with its providers, PBMs, GPOs and other large purchasers at deep discounts off of WAC. Thus, the WACs reported by Ethex are deliberately false and misleading. Ethex reports false and misleading WACs in order to inflate the published AWPs for its products and enable Ethex to create a spread. Ethex, like all drug manufacturers, competes on spread and reimbursement.

372. In 2002, Ethex's Nitroglycerin 9 mg caplets (NDC 51877-0006-04) (a subject drug) were available at a market price of \$4.08, while Ethex reported an AWP of \$24.90, creating a spread of over 510%. The spreads for Nitroglycerin were similarly inflated in 2000 and 2001.

373. In 2003, Ethex reported an AWP of \$69.61 for Hydromorphone HCL 4 mg tablets (NDC 51187-70299-04) (a subject drug) yet the drug was available for \$15.98. This translates into spread of 335% from AWP. The spreads for Hydromorphone were similarly inflated in 2000 and 2001.

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<sup>17</sup> Iowa's claims are not confined to this time period.

374. While there was a FUL in place during at least some of the relevant time period for some of Ethex's drugs, Ethex's failure to report for its deeply discounted prices resulted in that FUL being false and inflated. For example, the FUL for Ethex's Doxazosin Mesylate 4 Mg Tablet was \$.6210/unit in 2002. Given that the FUL is set at 150% of the lowest reported price for therapeutic bioequivalents, this means the lowest reported price for Doxazosin Mesylate 4 Mg Tablet was \$.4140/unit.

375. Ethex sold Doxazosin Mesylate 4 Mg Tablet for \$.1522/unit in 2002, which is 172% less than the lowest reported price that generated the FUL. If Ethex properly reported this price, the FUL would have been \$0.2283/unit instead of \$.6210/unit and Iowa Medicaid would have reimbursed based on this lower FUL. Thus, Ethex's failure to report accurate prices resulted in a fraudulent FUL and damage to Iowa Medicaid directly attributable to Ethex.

376. Ethex is among the pharmaceutical companies referred to above now under investigation by the House Committee on Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. The Committee has requested detailed reports on pricing practices, including records concerning the "spread" between actual market prices and payments by Medicaid. The Committee has requested detailed reports on pricing practices, including records concerning the "spread" between actual market prices and payments by Medicaid. The basis of this investigation is "indicia from a number of sources, including utilization data, drug price/reimbursement spreads, and other relevant information."

## O. THE FOREST GROUP

377. As summarized in Exhibit A, Iowa Medicaid spent over \$32 million on the 114 at-issue Forest NDCs between 1995 and 2005 alone.<sup>18</sup> The specific Forest NDCs for which Iowa seeks relief are set forth in Exhibit B-15 hereto. Iowa alleges both AWP and FUL fraud claims against the Forest Group defendants.

378. At all times relevant hereto, Forest Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-15, the Forest Group has routinely created such spreads.

379. An example is the rebate program the Forest Group offered through Linovatrix suppliers, which existed “in lieu of upfront discounts” but had the same practical effect, i.e., to further reduce the true price paid for Forest’s products.

380. The Forest Group’s fraudulent pricing of Levothroid is well documented. From July of 1997 through June of 1999 Forest caused an AWP of \$19.18 to be reported for Levothroid .15 mg (NDC 00456-0325-01). During that same period, the product was available from wholesalers for \$8.65. Forest specifically marketed the product based on spread, noting it would generate a profit per unit of \$8.23 (based on reimbursement at AWP-12%), versus the profit per unit of only \$0.08 for the competing product Synthroid.

381. Forest Pharm is the subject of the investigation led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements. *See* Exhibit F. On information and belief, the Forest Group routinely offers its brand products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b)

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<sup>18</sup> Iowa’s claims are not confined to this time period.

does not account for these deeply discounted sales in its calculation of Best Price or report them as its Best Price.

**P. THE GSK GROUP**

382. As summarized in Exhibit A, Iowa Medicaid spent over \$166 million on the 304 at-issue GSK Group NDCs between 1992 and 2005 alone.<sup>19</sup> The specific GSK Group NDCs for which Iowa seeks relief are set forth in Exhibit B-16 hereto. Iowa alleges AWP and FUL fraud claims against the GSK Group defendants.

383. At all times relevant hereto, the GSK Group has known that it can promote its drugs by selling them at substantial undisclosed discounts while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-16 hereto, the GSK Group has routinely created such spreads.

384. The GSK Group's misconduct has at all relevant times been pervasive throughout its product line, affecting single-source and multi-source products alike.

385. GSK's constituent corporations Glaxo Wellcome and SmithKline Beecham competed vigorously in the anti-emetic market with their respective products Zofran and Kytril. Each company caused false and inflated AWPs to be reported for these drugs, actively marketed the spread for them to their customers, tracked each others' AWP and acquisition costs, prepared reimbursement worksheets for use by its sales forces to demonstrate for its customers the greater profitability of their drugs. Each company knew that its customers' product selection for these drugs was driven by reimbursement and spread.

386. In an effort to build market share, in 1996 Glaxo increased Zofran's AWP while lowering the actual price paid by its customers, effectively increasing the profit per dose of Zofran.

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<sup>19</sup> Iowa's claims are not confined to this time period.

387. In evaluating whether to increase the AWP of Zofran, Glaxo considered the impact a price increase would have on the attention Glaxo received from the press and Congress. Glaxo was concerned that since it was raising the price of one of its most expensive drugs, for the second time in a single year, and after the entrance of competitor in the market, it may have to explain its true pricing strategy, which was to increase the costs payors like Medicaid pay to retain its market share.

388. Glaxo feared that an 8% increase in Zofran's AWP in just a nine month period would raise the suspicion of congressional watchdogs and that Glaxo would be unable to justify this cost-shifting at the expense of the government.

389. While Iowa Medicaid has settled its Zofran and Kytril AWP fraud claims with GSK, plaintiff describes GSK's unlawful conduct with regard to these drugs because (a) such misconduct was pervasive throughout GSK and infected all of its pricing activity and (b) such misconduct directly impacted GSK's unlawful marketing efforts regarding at-issue (unsettled) NDCs. For example, GSK used its ability to influence product selection for Zofran and Kytril to influence purchasers to buy other GSK drugs such as Zantac and Zovirax, both of which were coming off patent in the late 1990s, and both of which are subject drugs. Glaxo Wellcome directly advertised that it would consider paying higher Zantac rebates to customers who put Zofran tablets or injectibles on their formularies or made them freely available.

390. GSK competed based on spread and rebate for Zantac and other single source drugs. GSK offered specific additional rebates for Zantac in response to direct marketing of Pepcid.

391. GSK has deliberately concealed that it competes on spread or benefits from spread. GSK CEO J.P. Garnier stated to investors in early 2003 that GSK "[has] never

benefited from the spread becoming bigger or smaller.” Garnier stated that the reimbursement system “has a big loophole and can create confusion. We don’t like it one bit.” GSK in its current form and in years past as Glaxo Wellcome and SmithKline Beecham clearly has competed on spread and benefited from spread. GSK has at all times relevant hereto utilized spread to influence demand for its products.

392. GSK has been sued by Alabama, Alaska, California, Connecticut, Hawaii, Idaho, Illinois, Kentucky, Mississippi, Montana, Pennsylvania, Wisconsin, the City of New York and 42 New York Counties in connection with the same wrongdoing as is at issue here.

393. The GSK Group recently agreed to pay in excess of \$87 million to settle federal False Claims Act allegations that GSK Group repackaged and privately labeled Paxil, an antidepressant and Flonase, a nasal spray for Kaiser at discounted prices, but failed to report these lower prices as Best Prices to the government.

394. On April 13, 2003, SmithKline Beecham Corporation, d/b/a/ GlaxoSmithKline entered into a Corporate Integrity Agreement (“CIA”) with the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services “to promote compliance . . . with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))” (“Federal Health Care Program Requirements”). Contemporaneously GSK entered into a Settlement Agreement with the United States and various states.

395. Persons covered by the “CIA” include all employees of the U.S. pharmaceuticals division of GSK responsible for the, *inter alia*, “reporting of pricing information for any products that are reimbursed by federal health care programs, including under the Medicaid drug rebate program, codified at 42 U.S.C. § 1396r-8” and “obligations related to

government contracts, including the agreements entered with the Department of Health and Human Services under the Medicaid drug rebate program and the drug pricing program under the Public Health Service (PHS) Act, 42 U.S.C. § 256.”

396. In addition to promising compliance with federal health care program requirements, the CIA requires GSK to establish a written code of conduct to be agreed to by each covered person that confirms GSK’s “commitment to full compliance with all federal health care program requirements, including its commitment to comply with all government contracting requirements and to market and sell its Government Reimbursed Products in accordance with federal health care program requirements.”

397. The CIA requires further that GSK implement policies and procedures that address:

- (a) The code of conduct described above as well as;
- (b) The methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services (“CMS”) and/or the state Medicaid programs in connection with the Medicaid drug rebate program;
- (c) Promotional practices that conform with all applicable federal health care program requirements, including the Medicaid drug rebate program and the Federal anti-kickback statute, codified at 42 U.S.C. § 1302a-7b; and
- (d) The requirements of all government contracts, including those under the Medicaid drug pricing program.

398. The CIA contemplates monetary penalties for non-compliance, and the retention of an independent review organization (“IRO”). The IRO performs two types of review: (1) a systems review of GSK’s systems, processes, policies and practices relating to the

Medicaid drug rebate program (“Medicaid Rebate Systems Review”) and (2) a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with GSK’s policies and procedures and Medicaid drug rebate program requirements.

399. CIA notwithstanding, GSK’s wrongful price reporting continues. GSK is among the pharmaceutical companies now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

400. GSK Group also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements. *See* Exhibit F. On information and belief, GSK routinely offers its brand products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price or report them as its Best Price.

401. This investigation complements documents that reveal widespread discounting of GSK’s Zantac 150 mg tablet at prices that are a fraction of the reported AWP. Specifically in the year 2000 GSK sold 150 mg Zantac tablets to East Jefferson General Hospital for 14 cents per pill.<sup>20</sup> Yet, at the same time GSK’s per pill AWP for 150 mg Zantac (NDC 00173-0344-47) was reported as \$1.79 per pill. Iowa also alleges unlawful pricing activity and actionable spreads for Zantac 150 mg tablets in 1998 and 2002. *See* Exhibit B-16.

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<sup>20</sup> *See* Exhibit B to Relator’s Brief In Opposition To Motion To Dismiss, Filed July 16, 2003, *U.S. Ex. Rel. William St. John LaCorte, MD v. Merck and Company, Inc.*, CV 993807, (E.D.L.A.).

402. On information and belief these deep discounts were not accounted for by GSK in its calculation of Zantac's 2000 AWP of \$1.79 per pill. Nor was the 14-cent-per-pill price reported as GSK's Best Price for Zantac 2000.

403. Iowa reimbursed based on the false Zantac 150 mg AWP in 2000, paying \$1.61 per pill (AWP – 10%, excluding co-pays and dispensing fees). Iowa thus paid 1150% more for Zantac 150 mg than was charged to East Jefferson General Hospital.

404. On information and belief, at all times relevant hereto, 1) the deep discounting programs described here have been widely used by GSK; (2) the deeply discounted prices have not been included in GSK's Best Price reporting or calculations 3) these deeply discounted prices have not been included in the AWP and other wholesale price information GSK reports or causes to be reported to publishers.

## **Q. THE HOFFMAN-LAROCHE GROUP**

405. As summarized in Exhibit A, Iowa Medicaid spent over \$14 million on the 77 at-issue Hoffman-LaRoche NDCs between 1992 and 2005 alone.<sup>21</sup> The specific Hoffman-LaRoche NDCs for which Iowa seeks relief are set forth in Exhibit B-17 hereto.

406. At all times relevant hereto, the Hoffman-LaRoche Group has known that it can promote its drugs by selling them at substantial undisclosed discounts while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-17 hereto, the Hoffman LaRoche Group has routinely created such spreads.

407. In 2002, Hoffman-LaRoche's Klonopin 1 mg tablets (NDC 00004-0058-01) (a subject drug) were available at a market price of \$85.80 while Hoffman-LaRoche set an AWP of \$105.78, creating a spread of over 27%.

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<sup>21</sup> Iowa's claims are not confined to this time period.

408. In 2002, Hoffman-LaRoche's Kytril 1 mg/ml vial (NDC 00029-4152-01) (a subject drug) was available at a market price of \$379.14, while Hoffman-LaRoche reported an AWP of \$780.80, creating a spread of over 105%.

409. Hoffman-LaRoche is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. The Committee has requested detailed reports on pricing practices, including records concerning the "spread" between actual market prices and payments by Medicaid. The basis of this investigation is "indicia from a number of sources, including utilization data, drug price/reimbursement spreads, and other relevant information."

410. Hoffman-LaRoche also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements. *See* Exhibit F. On information and belief, Hoffman-LaRoche routinely offers its brand products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price or report them as its Best Price.

## **R. THE IVAX GROUP**

411. As summarized in Exhibit A, Iowa Medicaid spent over \$33 million on the 661 at-issue Ivax NDCs between 1992 and 2005 alone.<sup>22</sup> The specific Ivax NDCs for which Iowa seeks relief are set forth in Exhibit B-18 hereto. Iowa alleges both AWP and FUL claims against the Ivax Group defendants.

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<sup>22</sup> Iowa's claims are not confined to this time period.

412. At all times relevant hereto, the Ivax Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-18 hereto, the Ivax Group has routinely created such spreads.

413. For example, in February 2000, the Ivax Group's 1000-count package of Methyldopa 250 mg tablet had a reported AWP of \$330.00. The available price for the same 1000-count package was \$60.18 (a 35% discount from the reported WAC of \$92.59). The intentionally false and misleading AWP was 448% over the generally available market price and 256% over the reported WAC. Iowa reimbursed the Ivax Group's 1000-count package of Methyldopa 250 mg tablet based on this false and misleading wholesale price information.

414. Additionally, in March 2002, the Ivax Group's 100-count package of Buspirone 10 mg tablet had a reported AWP of \$136.25 and a reported WAC of \$29.15. The intentionally false and misleading AWP resulted in a 367% spread over WAC. Iowa reimbursed the Ivax Group's 100-count package of Buspirone 10 mg tablet based on this false and misleading wholesale price information

415. On April 1, 2003, the available price for Ivax Group's 100-count package of Buspirone 10 mg tablet was \$17.75 (a 39% discount from the reported WAC of 29.15) and resulted in a 668% spread from the intentionally false and misleading AWP of \$136.25.

416. There was not a FUL for Buspirone 10 mg tablet until December 2002. While there were FULs in place for the above drugs during at least some of the time period referred to above, Ivax Group's failure to account for its deeply discounted contract prices for these drugs resulted in such FUL being false and inflated.

417. For example, on December 1, 2002, the FUL for Buspirone 10 mg tablet was set at \$0.3942/unit (which FUL continued unchanged through 2004). Given that the FUL is set at 150% of the lowest reported price/unit for therapeutic bioequivalents, this meant the lowest reported price for Buspirone 10 mg tablet was \$0.2628/unit.

418. In April 2003 Ivax Group sold Buspirone 10 mg tablet for \$0.1775/unit, which is 48% less than the lowest reported price that generated the FUL. If Ivax Group properly reported this discounted price, the FUL would have been \$0.2663/unit (150% of \$0.1775/unit) instead of \$0.3942/unit. Iowa Medicaid would have reimbursed based on this lower FUL. Thus, Ivax Group's failure to report accurate price information resulted in a fraudulent FUL and damage to Iowa Medicaid directly attributable to Ivax Group.

419. The Ivax Group Ivax has been sued by Alabama, Alaska, Florida, Hawaii, Idaho, Illinois, Kentucky, Massachusetts, Mississippi, South Carolina, Texas, Wisconsin, the City of New York and 42 New York Counties in connection with the wrongdoing at issue here.

420. Illinois, Kentucky and Wisconsin allege inflated and false wholesale pricing information for Ivax's Verapamil (a subject drug) as follows:

<b>Defendants IVAX GROUP</b>						
<b>Drug</b>	<b>Size</b>	<b>NDC Code</b>	<b>2000 AWP</b>	<b>2000 Price</b>	<b>Spread \$</b>	<b>Spread %</b>
Verapamil HCL 240mg	100s	00172-4280-60	\$120.95	\$10.50	\$110.45	1052%

421. Florida alleges the following for Ivax's Clozapine 100 mg (a subject drug) in 2000-2002.

<b>Defendant IVAX/ZENITH-GOLDLINE Clozapine 100 mg 100's NDC# 00172-4360-60</b>					
Date	First Databank AWP	First Databank WAC	Relator's Cost ----- Contract Price	Spread \$	Spread % (Spread \$ / Relator's Cost)
10-23-2000	\$316.95	\$245.85	\$165.08	\$109.87	67%
12-12-2000	\$316.95	\$245.85	\$165.08	\$109.87	67%
02-22-2001	\$332.80	\$245.85	\$148.73	\$126.22	85%
04-20-2001	\$332.80	\$245.85	\$156.56	\$118.39	76%
06-19-2001	\$332.80	\$245.85	\$148.73	\$126.22	85%
08-09-2001	\$332.80	\$245.85	\$148.73	\$126.22	85%
11-12-2001	\$332.80	\$245.85	\$148.73	\$126.22	85%
01-28-2002	\$332.80	\$245.85	\$133.07	\$141.88	107%
03-10-2002	\$332.80	\$245.85	\$133.07	\$141.88	107%
05-08-2002	\$332.80	\$245.85	\$133.07	\$129.99	98%
06-25-2002	\$332.80	\$245.85	\$133.07	\$129.99	98%

422. The Ivax Group admits it has been the target of government investigations into its AWP and wholesale pricing practices. In its Form 10-K filed with the Securities and Exchange Commission on March 16, 2005, the Ivax Group acknowledged that they are among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce “in connection with the Committee’s investigation into certain industry and [Ivax Group] practices regarding AWP.” Ivax SEC Form 10-K (FY 2005, 3/16/05) at 36.

423. The Ivax Group also admits it is either being sued or is under investigation for improper pricing practices related to the average manufacturer price and best price calculations by the Office of Attorney General for at least 12 states. Ivax SEC Form 10-K (FY 2005, 3/16/05) at 36-37 including Massachusetts, Florida, Illinois, Wisconsin, Kentucky, Alabama and Nevada.

424. The Ivax Group further admits that the “outcome of these investigations could include the imposition of substantial fines, penalties and injunctive or administrative remedies.” Ivax SEC Form 10-K (FY 2005, 3/16/05) at 37.

## **S. JOHNSON & JOHNSON GROUP**

425. As summarized in Exhibit A, Iowa Medicaid spent over \$192 million on the 186 at-issue Johnson & Johnson Group NDCs between 1992 and 2005 alone.<sup>23</sup> The specific J&J Group NDCs for which Iowa seeks relief are set forth in Exhibit B-19 hereto. Iowa alleges both AWP and FUL fraud claims against the J&J defendants.

426. At all times relevant hereto, the J&J Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-19 hereto, the J&J Group routinely has created such spreads.

427. 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 to see in actual dollars how much additional revenue the use of Remicade would bring to their practice.

428. At the same time, J&J deliberately marketed and promoted the sale of Remicade to physicians based on the availability of inflated payments made by Medicare, assuring them that they would make a significant profit from the purchase of Remicade as a

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<sup>23</sup> Iowa’s claims are not confined to this time period.

result of the spread between the actual price to physicians and reimbursement based on the published AWP.

429. At all times relevant hereto, the J&J Group has marketed its drugs based on reimbursement and spread. For example, the J&J Group has been aggressively marketing Procrit in response to discounting by Amgen for its competing drug Aranesp. J&J Vice President of Investor Relations, Helen Short, said J&J has been “implementing actions to ensure that we are on a level playing field [with our competitors] with respect to customer economics. . . . The initial focus of our competition has been on capturing existing share from us through the implementation of discount . . . programs in both clinics and hospitals . . . the focus has shifted to market share acquisition and protection” *J&J Modifies Procrit Pricing Practices To Compete With Amgen’s Aranesp*, 65 The Pink Sheet 016, April 21, 2003, at 13.

430. International Oncology Network, an Amerisource Bergen Company, published a document dated January 2004 entitled “Access to Care 2005” that confirmed Johnson & Johnson’s statements that its discounting would increase in 2003. The 15% discount from AWP for Procrit documented by the GAO in 2001 had grown to 54%, according to the market prices listed by the International Oncology Network. Under Iowa State’s AWP – 10% reimbursement formula, the spread for Procrit was 39%.

431. Johnson and Johnson competed through reimbursement and spread on all drugs, not just Procrit. J&J has discounted Procrit to many of its retail customers generally.

432. In addition to admitting significant discounts off list price to certain managed care customers, J&J has given a discount on Procrit to retailers since its launch in 1991 because it competes with Amgen’s chemically equivalent Epogen. Cavanaugh said that because Epogen’s competition was chemically equivalent, “the retailer may have the ability to influence

sales”. On information and belief, J&J does not account for these retail discounts in its calculation of WAC and AWP.

433. J&J is among the pharmaceutical companies referred to above now under investigation by the House Committee on Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. The Committee’s request focuses on the drug REMICADE (infliximab), marketed by the Company’s Centocor, Inc. subsidiary. The Committee has requested detailed reports on pricing practices, including records concerning the “spread” between actual market prices and payments by Medicaid. The basis of this investigation is “indicia from a number of sources, including utilization data, drug price/reimbursement spreads, and other relevant information.”

434. J&J is one of the subjects of the investigation led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements. *See* Exhibit F hereto. On information and belief, J&J routinely offers its brand products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price or report them as its Best Price.

## **T. THE KING GROUP**

435. As summarized in Exhibit A, Iowa Medicaid spent over \$10 million for the 162 at-issue King Group NDCs between 1992 and 2005 alone.<sup>24</sup> The specific King Group NDCs for which Iowa seeks relief are set forth in Exhibit B-20 hereto. Iowa alleges both AWP and FUL fraud claims against the King Group defendants.

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<sup>24</sup> Iowa’s claims are not confined to this time period.

436. At all times relevant hereto, the King Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-20 hereto, the King Group has routinely created such spreads.

437. For example, in July 1999, the King Group (Monarch)'s 100-count package of Humantin 250 mg Capsules had a published AWP of \$262.44. The generally available market price for the same 100-count package was \$157.46 (a 25% discount from the reported WAC of \$209.95). The intentionally false and misleading AWP was 66% more than the generally available market price. Iowa reimbursed this 100-count package of Humantin 250 mg Capsules in 1999 based on this false and misleading wholesale price information that the King Group reported or caused to be reported.

438. In November 2000, the King Group (Monarch)'s 30-count package of Lorabid Pulv 400 mg Capsule had a published AWP of \$177.19. The generally available market price for the same 30-count package was \$113.22 (a 25% discount from the reported WAC of \$141.75). The intentionally false and misleading AWP was 57% more than the generally available market price. Iowa reimbursed this 30-count package of Lorabid Pulv 400 mg Capsule based on this false and misleading wholesale price information that the King Group reported or caused to be reported. *Id.* Additional actionable spreads for Lorabid Pulv 400 mg Capsule in 2001, 2002, 2004 are set forth in Exhibit B-20.

439. In 2001 alone, the Iowa Medicaid Program spent over \$ 3.5 million for the King Group's Altace. Iowa' most popular dosage of Altace was the 10 mg capsule. In December 2001, the King Group (Monarch)'s 100-count package of Altace 10 mg Capsule had a published AWP of \$141.96. The generally available market price for the same 100-count

package was \$46.93 (a 142% discount from the reported WAC of \$113.57). The intentionally false and misleading AWP was 202% more than the generally available market price. Iowa reimbursed this 100-count package of Altace 10 mg Capsule in 2001 based on this false and misleading wholesale price information that the King Group reported or caused to be reported. *See Exhibit B-20.* Additional actionable spreads for Altace in 2003 and 2004 are set forth in Exhibit B-20.

440. Defendant King Group enters into co-promotion agreements, marketing agreements, strategic alliances, joint ventures and other similar mutually beneficial arrangements with other pharmaceutical companies for the sale and marketing of its and others' pharmaceutical products.

441. Defendant King Group has a co-promotion agreement with defendant Wyeth to promote and sell Monarch's Altace throughout the United States, including Iowa.

442. In 1999, King Group purchased from defendant Eli Lilly the U.S. and Puerto Rican marketing rights of Lorabid, an antibiotic used in the treatment of bacterial infections, for approximately \$67.8 million. Defendant Eli Lilly manufactures Lorabid for King Group and retains the right to receive additional payments if certain sales performance milestones are achieved.

443. All participants, including defendant Wyeth and defendant Eli Lilly, market and sell or directly benefit from the marketing and sale of King Group drugs based on the false and inflated wholesale price information of King Group drugs.

444. These co-promotion agreements, marketing agreements, strategic alliances, joint ventures or other similar mutually beneficial arrangements with defendant King Group, including those with defendant Wyeth and defendant Eli Lilly, resulted in and continue to

result in the reimbursement of pharmaceuticals by Iowa Medicaid Programs based on intentionally false and misleading wholesale pricing information.

445. In connection with the wrongful conduct described herein, the King Group is being investigated by OIG-HHS, Department of Veterans Affairs, Department of Justice, Centers for Medicaid and Medicaid Services, the Public Health Service and the Securities and Exchange Commission.

446. In March 2003, the SEC initiated a formal investigation of King Group relating to, among other topics, sales to VitaRx and Prison Health Services, “best price” lists, the pricing of pharmaceutical products provided to governmental Medicaid agencies, the accrual and payment of rebates on Altace, Fluogen and Lorabid (all subject drugs), the King Benevolent Fund, Inc., calculations related to Medicaid rebates, and the King Group Audit Committee’s internal review of issues raised by the SEC investigation.

447. On November 13, 2003, King Group received a subpoena from the OIG-HHS requesting the production of documents relating to some of the matters being investigated by the SEC and to King Group sales, marketing and other business practices for Altace, Aplisol and Levoxyl (all subject drugs).

448. In its 2003 Annual Report, King disclosed that it owed Medicaid and other government health programs approximately \$46.5 million in unpaid rebates. King estimated that it underpaid Medicaid by \$0.9 million from 1994-1997. An internal audit found that an additional \$18.9 million was due.

449. In its SEC Form 10K filed on March 21, 2005, Defendant King Group disclosed that it underpaid amounts due under Medicaid and other governmental pricing programs during the period from 1998 to 2002. Defendant King Group further disclosed that it

previously accrued \$130.4 million in respect of its estimated underpayments to Medicaid and other government pricing programs and estimated settlement costs with all relevant governmental parties.

## **U. MEDIMMUNE**

450. As summarized in Exhibit A, Iowa Medicaid spent over \$13 million on the 3 at-issue MedImmune NDCs between 1992 and 2005 alone.<sup>25</sup> The specific MedImmune NDCs for which Iowa seeks relief are set forth in Exhibit B-21 hereto.

451. At all times relevant hereto, MedImmune has known that it can promote its drugs by selling them at substantial undisclosed discounts while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-21 hereto, MedImmune has routinely created such spreads.

452. MedImmune has conceded that it inflates its reported AWP for Synagis to compensate for administrative costs. Specifically, in the Suffolk County New York AWP matter MedImmune admitted that “a physician administering Synagis encounters costs of administration which Synagis AWP is used to cover.”

453. This admission confirms that competition is not the only unlawful reason defendants improperly inflate their AWPs.

454. Nevertheless, MedImmune’s Synagis faces competition from Immune Globulin and alternative preventive therapies.

455. Since at least 1998, MedImmune has had a joint marketing agreement with Abbott’s Ross Products Unit to promote Synagis. Expenditures on behalf of the Iowa Medicaid recipients have increased substantially in the years since this joint marketing agreement was signed. Abbott’s Ross Products unit is the unit that causes Abbott to pay \$622 million in

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<sup>25</sup> Iowa’s claims are not confined to this time period.

criminal and civil penalties in 2003 to resolve allegations that the Ross Products Unit defrauded Medicaid.

## V. MERCK

456. As summarized in Exhibit A, Iowa Medicaid spent over \$67 million on the 174 at-issue Merck NDCs between 1992 and 2005 alone.<sup>26</sup> The specific Merck NDCs for which Iowa seeks relief are set forth in Exhibit B-22 hereto. Iowa alleges both AWP and FUL fraud claims against Merck.

457. At all times relevant hereto, Merck has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-22 hereto, Merck has routinely created such spreads.

458. In connection with the wrongful conduct described herein, Merck has been investigated by the DOJ generally for its marketing and selling practices, and more recently for its activities related to sales of Pepcid. Additionally, Merck has been investigated by the Attorney General of Texas and the Inspector General of the District of Columbia.

459. Merck also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements. *See* Exhibit F. On information and belief, Merck routinely offers its brand products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price or report them as its Best Price.

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<sup>26</sup> The claims of the State are not confined to this time period.

460. This investigation uncovered Merck documents that reveal widespread discounting of Merck products at prices that are a fraction of the reported AWP.

461. Merck also has been named as a defendant in two Qui Tam actions in which the Attorney Generals of Louisiana and Nevada have elected to intervene. These actions allege that Merck made sales of three of its products, Vioxx, Zocor, and Pepcid, at discounts of over 90% off of AWP. The veracity of these allegations is confirmed by publicly filed exhibits, which Iowa has viewed, as well as a Wall Street Journal report that one of the products, Zocor, was being sold for less than 10% of the reported AWP. *See Deep Discounts By Drug Firms Draw Scrutiny*, Wall Street J., April 28, 2005, at B1. This was not only a significant discount to AWP but Zocor's sales price (around .28 cents per pill) was also significantly lower than Merck's reported best price of \$2.30 per pill. *Id.*

462. The Louisiana qui tam action, *US ex rel., St. John LaCorte, MD. v. Merck*, alleges that in the year 2000 Merck sold 20 mg Pepcid tablets to East Jefferson General Hospital for the nominal price of \$0.10 per pill<sup>27</sup> as part of the "Flexible Nominal Pricing (Flex-NP) Program" for Pepcid. Yet, at the same time Merck's per pill AWP for 20 mg Pepcid (NDC 00006096331) was reported as \$1.95.

463. On information and belief the deep discounts offered through Merck's nominal pricing program were not accounted for by Merck in its calculation of Pepcid's 2000 AWP of \$1.95 per pill, nor were they accounted for in Merck's calculation of Best Price. Exhibit B-22 contains examples of other actionable spreads for Pepcid 20 mg in 1996, 1999 and 2001.

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<sup>27</sup> Merck defined nominal pricing as "a greater than ninety percent discount on the quarterly Average Manufacturer's Price (AMP). AMP is the average unit price paid to a manufacturer for a drug by wholesalers for drugs distribute to the retail pharmacy class of trade... Merck reserves the right to provide additional rebates if, because of changes in the AMP, the nominal price offered does not meet this definition." *See Request for Enrollment into Merck's Flex NP program filled out by East Jefferson General Hospital, Exhibit P, Relator's Brief In Opposition To Motion To Dismiss*, Filed July 16, 2003, *U.S. ex. rel. St. John LaCorte, MD v. Merck and Co., Inc.*, CV 993807, (E.D.L.A.).

464. Iowa reimbursed based on the false Pepcid 20 mg AWP in 2000, paying \$1.76 per pill (AWP – 10%, excluding co-pays and dispensing fees). Iowa thus paid 1700% more for Pepcid 20 mg than was charged to participants in Merck’s nominal pricing program, such as East Jefferson General Hospital.

465. On information and belief, at all times relevant hereto, 1) the deep discounting programs as alleged in the Nevada and Louisiana actions have been widely used by Merck, (2) these deeply discounted prices have not been included in Merck’s AMP or Best Price calculations, and 3) these deeply discounted prices have not been included in the AWP and other wholesale price information Merck reports or causes to be reported to publishers.

466. The Nevada action alleges that Merck sold Vioxx and Zocor (both subject drugs) to hospitals in Nevada and across the country at prices that were at least 92% less than Merck’s list price. These pricing levels were alleged to be part of the Zocor “Save” (Simvastatin Advanced Care Value Enhancement) program and the Vioxx “VIP” (Vioxx Incentive Program) marketing programs. The Zocor Save program is alleged to have started in April 1998, and to continue to the present.

## **W. THE MYLAN GROUP**

467. As summarized in Exhibit A, Iowa Medicaid spent over \$54 million on the 764 at-issue Mylan Group NDCs between 1992 and 2005 alone.<sup>28</sup> The specific Mylan Group NDCs for which Iowa seeks relief are set forth in Exhibit B-23 hereto. Iowa alleges both AWP and FUL fraud claims against the Mylan Group defendants.

468. At all times relevant hereto, the Mylan Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time

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<sup>28</sup> Iowa’s claims are not confined to this time period.

maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-23 hereto, the Mylan Group has routinely created such spreads.

469. An analysis of the 2002 published wholesale price information for Mylan Group UDL's drugs indicates examples of spreads between AWP and WAC that exceed the 20-25% range as follows:

<b>MYLAN GROUP(UDL)</b>						
<b>Drug</b>	<b>Size</b>	<b>NDC Code</b>	<b>2002 First DataBank AWP</b>	<b>2002 First DataBank WHN/WAC</b>	<b>Spread \$</b>	<b>Spread %</b>
Hydrochlorothiazide 25 mg Tablet	pkg	51079004920	\$10.20	\$5.24	\$4.96	94%
Diphenhydramine 50 mg Caps	pkg	51079006620	\$13.45	\$7.38	\$6.07	82%
Dipyridamole 50mg Tablet	pkg	51079006920	\$29.75	\$17.71	\$12.04	67%
Furosemide 40mg Tablet	pkg	51079007320	\$16.79	\$4.68	\$12.11	259%
Hydroxyzine PAM 50 mg Cap	pkg	51079007820	\$62.72	\$12.31	\$50.41	410%
Amitriptyline HCL 100 mg Tablet	pkg	51079056320	\$111.24	\$12.05	\$99.19	823%
Albuterol Sulfate 4 mg Tablet	pkg	51079065820	\$47.13	\$8.76	\$38.37	438%

470. The fact that Mylan's AWP's have no connection to its true wholesale acquisition prices is reflected by the fact that at the beginning of 2002, Dipyridamole 25 mg Tablet (a subject drug) had a published WAC of \$8.02 and a published AWP of \$17.30, resulting in a spread of \$9.28 or 115%. On June 1, 2002, UDL increased its Dipyridamole WAC 105% or to \$16.52. Notably, its AWP increased only 20% or to \$20.00.

471. The fact that WAC and AWP for Mylan's drug did not increase proportionally reveals the false and misleading nature of the wholesale prices. If the pre-June 1,

2002 AWP accurately reflected the drug's price, then when the WAC increased 105% the AWP likewise should have increased 105%. It did not.

472. The foregoing illustrates that at the very least one element of the wholesale price information for Dipyridamole 25 mg Tablet was false and either before or after the June 1, 2002 price increase. Plaintiffs, however, contend that one or all elements of the wholesale pricing information for Mylan Group drugs complained of herein are intentionally false and misleading.

473. Mylan and its subsidiary UDL are among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

## **X. THE NOVARTIS/SANDOZ GROUP**

474. As summarized in Exhibit A, Iowa Medicaid spent over \$193 million on the 1033 at-issue Novartis/Sandoz Group NDCs between 1992 and 2005 alone.<sup>29</sup> The specific Novartis/Sandoz Group NDCs for which Iowa seeks relief are set forth in Exhibits B-24 hereto. Iowa alleges both AWP and FUL fraud claims against the Novartis/Sandoz Group defendants.

475. At all times relevant hereto, the Novartis/Sandoz Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibits B-24, hereto, the Novartis/Sandoz Group has routinely created such spreads.

476. The Novartis/Sandoz Group has instructed its sales force to market the spread for its products. The Novartis/Sandoz Group has specifically instructed sales staff to use the difference between AWP and actual acquisition cost as a selling point, and has prepared worksheets demonstrating the proper calculation of spread. These worksheets also described the

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<sup>29</sup> Iowa's claims are not confined to this time period.

AWPs of the Novartis/Sandoz Group competitors to demonstrate the advantage of purchasing Novartis/Sandoz Group products with their inflated AWP.

477. Novartis has been sued by Alabama, Alaska, California, Florida, Hawaii, Idaho, Illinois, Kentucky, Mississippi, Montana, Nevada, South Carolina, Wisconsin, the City of New York and 42 New York Counties in connection with the same wrongdoing as is at issue here.

478. Florida alleges the following spreads for another subject drug, Novartis/Sandoz Group's Ranitidine:

<b>Defendant SANDOZ/GENEVA RANITIDINE TAB 300mg NDC# 00781-1884-10</b>					
<b>Date</b>	<b>First Databank AWP</b>	<b>First Databank WAC</b>	<b>Relator's Cost ----- Contract Price</b>	<b>Spread \$</b>	<b>Spread % (Spread \$ / Relator's Cost)</b>
02-22-2001	\$2,687.00	\$712.50	\$97.88	\$585.12	598%
06-19-2001	\$2,687.00	\$712.50	\$97.88	\$585.12	598%
11-12-2001	\$2,687.00	\$712.50	\$97.88	\$585.12	598%
01-28-2002	\$2,687.00	\$712.50	\$126.81	\$191.19	150%
03-10-2002	\$2,687.00	\$712.50	\$126.81	\$191.19	150%
05-08-2002	\$2,687.00	\$712.50	\$126.81	\$191.19	150%
06-25-2002	\$2,687.00	\$712.50	\$126.81	\$191.19	150%

479. In connection with the wrongful conduct described herein, Novartis/Sandoz has been investigated by the Office of Inspector General of the Department of Health and Human Services. The Office of the Inspector General published a report for the Department of Health and Human Services in 2000 documenting Novartis' inflated AWP for Aredia, its version of the multi-source drug pamidronate disodium.

480. Novartis admits it has been the target of government investigation into its AWP and pharmaceutical pricing. In its Form 20-F filed with the Securities and Exchange Commission filed on January 30, 2004, Novartis acknowledged that it “participated in an ongoing Congressional inquiry on the subject of AWP and pharmaceutical pricing.” Novartis SEC Form 20-F (1/30/04) at p. 137.

481. Novartis’ Geneva (now Sandoz) is also among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. *See* Exhibit F. On information and belief, Abbott routinely offers certain of its branded products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price or report those prices as its Best Price.

## **Y. PAR**

482. As summarized in Exhibit A, Iowa Medicaid spent over \$19 million on the 313 at-issue Par NDCs between 1992 and 2005 alone.<sup>30</sup> The specific Par NDCs for which Iowa seeks relief are set forth in Exhibit B-25 hereto. Iowa alleges both AWP and FUL fraud claims against Par.

483. At all times relevant hereto, Par has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-25 hereto, Par has routinely created such spreads.

484. For Example, in February 2000, PAR’s 100-count package of PAR’s Dexamethasone 4 mg Tablet (a subject drug) had a reported AWP of \$182.00. The generally

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<sup>30</sup> Iowa’s claims are not confined to this time period.

available market price for the same 1000-count package was \$6.02 (a 28% discount from the reported WAC of \$7.72). The intentionally false and misleading AWP was a 2923% over the generally available market price and 2258% over the reported WAC. Additional fraudulent spreads for Dexamethasone 4 mg Tablet are set forth in Exhibit B-25.

485. In connection with the wrongful conduct described herein, PAR has also been sued by Alabama, Alaska, Hawaii, Idaho, Illinois, Kentucky, Massachusetts, Mississippi, South Carolina, the City of New York and 42 New York Counties.

486. PAR admits it has been the target of government investigations into its AWP and wholesale pharmaceutical pricing practices. In its Form 10-K filed with the Securities and Exchange Commission on March 15, 2004, PAR acknowledged that in June 2003, it was among the pharmaceutical companies targeted by the House Committee of Energy and Commerce “investigation into pharmaceutical reimbursements and rebates under Medicaid.” (Par Pharmaceutical Companies Inc. SEC Form 10-K (FY 2003, 3/15/04).

487. On June 26, 2003, as part of its investigations, the House Committee of Energy and Commerce requested information from the three largest pharmaceutical wholesalers (Cardinal Health, Inc., AmerisourceBergen Corporation and McKesson Drug Co.) about matters related to pricing, sales and marketing of several generic drugs, some of which are manufactured by PAR.

## **Z. THE PFIZER GROUP**

488. As summarized in Exhibit A, Iowa Medicaid spent over \$221 million on 491 at-issue Pfizer Group NDCs between 1992 and 2005 alone.<sup>31</sup> The specific Pfizer Group NDCs for which Iowa seeks relief are set forth in Exhibit B-26 hereto. Iowa alleges both AWP and FUL fraud claims against the Pfizer Group defendants.

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<sup>31</sup> Iowa’s claims are not confined to this time period.

489. At all times relevant hereto, the Pfizer Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-26 hereto, the Pfizer Group has routinely created such spreads.

490. The Pfizer Group has instructed its sales force to market the spread for its products. The Pfizer Group has specifically instructed sales staff to use the difference between AWP and actual acquisition cost as a selling point, and has prepared worksheets demonstrating the proper calculation of spread. These worksheets also described the AWP of the Pfizer Group competitors to demonstrate the advantage of purchasing Pfizer Group products with their inflated AWP.

491. Between 1996 and 1998, Pharmacia increased its AWP for Bleomycin 15u (NDC #00013-1616-78) from \$292.43 in 1996 to \$309.98, while its true price to retailers decreased each year.

<b>PERCENTAGE OF "SPREAD" BETWEEN PHARMACIA'S REPORTED AWP AND THE TRUE COST FOR BLEOMYCIN 15U, NDC# 00013-1616-78</b>			
<b>Year</b>	<b>AWP</b>	<b>TRUE COST</b>	<b>Percent "Spread"</b>
1996	\$292.43	\$198.00	48%
1997	\$292.43	\$175.00	67%
1998	\$309.98	\$158.00	96%
1998	\$309.98	\$154.85	101%

492. If the AWP stayed the same but the price decreased as set forth above, the reported AWP cannot be an "average wholesale price."

493. In addition to marketing the spread, Pharmacia has utilized other impermissible inducements to stimulate sales of its drugs without accounting for them in its WAC or AWP. These inducements were designed to result in a lower net cost to the provider

while concealing the actual wholesale price beneath a high invoice price. By utilizing “off-invoice” inducements, Pharmacia provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

494. In connection with the wrongful conduct described herein, members of the Pfizer Group have been investigated as follows:

(a) Pfizer has been investigated by the HHS OIG and has entered into a \$49 million settlement arising from illegal practices with respect to Lipitor. The OIG found that Pfizer had been providing unrestricted educational grants and rebates that were in fact discounts off the purchase price of Lipitor. Pfizer concealed these discounts from states who were entitled to receive the “Best Price” for Lipitor.

(b) On October 24, 2002, Pfizer entered into a CIA with the HHS OIG “to promote compliance...with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))” (“Federal Health Care Program Requirements”). Contemporaneously, Pfizer entered into a Settlement Agreement with the United States and various states.

(c) The CIA applies specifically, to, *inter alia*, “all employees of the Pfizer Pharmaceuticals Group whose job responsibilities directly relate to the gathering, calculation, verification or reporting of information for purposes of the Medicaid Drug Rebate program” (codified at 42 U.S.C. § 1396r-8 et seq.).

(d) In addition to promising compliance with federal health care program requirements, the CIA requires Pfizer to establish a written code of conduct to be agreed to by each covered person that confirms Pfizer’s “commitment to full compliance with all federal health care program requirements, including its commitment to comply with all government

contracting requirements and to market and sell its Government Reimbursed Products in accordance with federal health care program requirements.”

(e) The CIA requires further that Pfizer implement policies and procedures that address: The code of conduct described above as well as; The methods for gathering, calculating, verifying and reporting the data and information reported to the CMS and/or the state Medicaid programs in connection with the Medicaid Drug Rebate Program; and Promotional practices that conform with all applicable federal health care program requirements, including the Medicaid Drug Rebate Program and the Federal Anti-Kickback Statute, codified at 42 U.S.C. § 1302a-7b.

(f) The CIA contemplates monetary penalties for non-compliance, and the retention of an IRO. The IRO shall perform two types of review: (1) a systems review of Pfizer’s systems, processes, policies and practices relating to the Medicaid Drug Rebate program (“Medicaid Rebate Systems Review”) and (2) a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with Pfizer’s policies and procedures and Medicaid Drug Rebate program requirements.

495. Pfizer and Pharmacia are among the pharmaceutical companies referred to above now under investigation by the House Committee on Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

496. Pfizer also is the subject of the investigation led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is improperly using the Nominal Price Exception to the Best Price reporting requirements. *See* Exhibit F. On information and belief, the Pfizer Group routinely offers its brand products to commercial customers for prices

less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price or report them as its Best Price.

497. Pharmacia and its subsidiaries have been investigated by the DOJ, the Texas Attorney General, the California Attorney General, the Massachusetts Attorney General, the Attorney General of the State of Connecticut, the Attorney General of the State of New York, the HHS OIG and the U.S. Congress.

498. Pharmacia was among the drug companies to which Congressman Stark sent the following September 28, 2000 letter. “The manipulated disparities between your company’s reported AWP and DPs [Direct Prices] are staggering. For example, in 1997, Pharmacia & Upjohn reported an AWP for its Chemotherapy drug Vincasar of \$741.50 when in truth its list price was \$593.20.” *See* 146 Cong. Rec. E1622 (2000).

499. This manipulation was not limited to brand name oncology drugs. Pharmacia aggressively marketed the spread on generic drugs by informing one of its customers as follows:

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 multisource products offered on the contract give AOR a wide margin for profit.

*Id.*

500. Pharmacia’s marketing of Adriamycin was not limited to this customer. Documents describing Pharmacia’s pricing strategy note that because Adriamycin’s AWP exceeds that of its generic competitors, a higher reimbursement is available. This same document advocates that the catalog price be maintained for reimbursement purposes.

501. These spreads were not aberrations. AWP's routinely exceeded Pharmacia contract prices by more than 100%.

<b>PHARMACIA 1995 Toposar Marketing</b>			
<b>Toposar</b>	<b>NDC</b>	<b>AWP</b>	<b>DP</b>
100 mg	0013-7336-91	\$ 136.49	\$ 109.91
200 mg	0013-7346-94	\$ 272.98	\$ 218.38
500 mg	0013-7356-88	\$ 665.38	\$ 532.30

502. In fact, Pharmacia sold the 100, 200, and 500 mg vials of subject drug Toposar to Texas Oncology Pharmacy Services in 1995 at deeply discounted prices of \$35.00/vial, \$70.00/vial, and \$175/vial. These prices resulted in spreads of over 280%.

503. Pharmacia tried to induce potential customers to purchase these 100, 200, and 500 mg vials of Toposar to other customers at prices of \$65, \$130, and \$325 per vial. When offering these higher prices, Pharmacia made sure that it prominently displayed the AWP next to the contract price, making the spreads, all of which exceeded 100%, hard to miss.

504. Also in 1995, Pharmacia sold its 10, 20, 50, and 150 mg vials of Pharmacia's Adriamycin RDF at prices of \$10.20/vial, \$20.40/vial, \$51.00/vial, and \$153.00/vial (NDCs 00013-1086-91, 00013-1096-91, 00013-1106-79, and 00013-1116-83). At the time, Pharmacia caused AWP's of \$46.00, \$92.00, \$230.00 and \$676.19 to be reported for these products. These AWP's resulted in spreads of 350.98%, 350.98%, 350.98% and 341.95%.

<b>PHARMACIA 1995 Adriamycin RDF Marketing</b>				
<b>Adriamycin RDF</b>	<b>NDC</b>	<b>LP</b>	<b>AWP</b>	<b>SPREAD</b>
10 mg	0013-1086-91	\$ 10.20	\$ 46.00	350.98%
20 mg	0013-1096-91	\$ 20.40	\$ 92.00	350.98%
50 mg	0013-1106-79	\$ 51.00	\$ 230.00	350.98%
150 mg	0013-1116-83	\$ 153.00	\$ 676.19	341.95%

505. In addition to these large spreads, Pharmacia also provided the purchaser with an unrestricted educational grant of \$35,000, in addition to \$12,000 worth of free goods.

On information and belief, these items were never accounted for in Pharmacia's Best Price Calculations.

506. Because of Pharmacia's use of free goods as a means of discounting, even these contract prices are not necessarily indicative of the true prices paid for Pharmacia drugs.

#### **AA. THE PURDUE GROUP**

507. As summarized in Exhibit A, Iowa Medicaid spent over \$21 million for the 32 at-issue Purdue Group NDCs between 1992 and 2005 alone.<sup>32</sup> The specific Purdue Group NDCs for which Iowa seeks relief are set forth in Exhibit B-27 hereto.

508. At all times relevant hereto, the Purdue Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-27, hereto, the Purdue Group has routinely created such spreads.

509. For example, in October 2000, the Purdue Group's (Purdue Frederick) 100-count package of MS Contin 100 mg Tablet SA had a published AWP of \$546.99. The generally available market price for the same 100-count package was \$355.07 (a 23% discount from the reported WAC of \$437.59). The intentionally false and misleading AWP was 54% more than the generally available market price. Iowa reimbursed this 100-count package of MS Contin 100 mg Tablet SA in 2000 based on this false and misleading wholesale price information that The Purdue Group reported or caused to be reported. Additional fraudulent spreads for MS Contin 100 mg Tablet are set forth in Exhibit B-27.

510. Also, in October 2000, the Purdue Group's (Purdue Pharma) 100-count package of OxyContin 80 mg Tablet SA had a published AWP of \$793.34. The generally available market price for the same 100-count package was \$551.23 (a 15% discount from the

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<sup>32</sup> Iowa's claims are not confined to this time period.

reported WAC of \$634.67). The intentionally false and misleading AWP was 44% more than the generally available market price. Iowa reimbursed this package of OxyContin 40 mg Tablet SA in 2000 based on this false and misleading wholesale price information that The Purdue Group reported or caused to be reported. Additional fraudulent spreads for Oxycontin 80 mg Tablet are set forth in Exhibit B-27.

511. Defendant Purdue Group collectively designed, manufactured, patented, developed, marketed, distributed and sold OxyContin throughout the United States, including Iowa.

512. Defendant Purdue Group has a co-promotion agreement with defendant Abbott Group (doing business as Abbott Sales Marketing and Distribution Company) to promote and sell OxyContin to hospitals, acute care and free-standing ambulatory care facilities throughout the United States, including Iowa.

513. Defendant Purdue Group enters into co-promotion agreements, strategic alliances, joint ventures and other similar mutually beneficial arrangements with other pharmaceutical companies, including defendant Abbott Group, for the sale and marketing of its pharmaceutical products. As such, all participants, including defendant Abbott Group, market and sell Purdue Group drugs with knowledge of or reckless disregard of the false and misleading nature of the wholesale price information of Purdue Group Drugs.

514. These co-promotion agreements, strategic alliances, joint ventures or other similar mutually beneficial arrangements with defendant Purdue Group, including that with defendant Abbott Group, resulted in and continue to result in the reimbursement of Purdue Group pharmaceuticals by Iowa Medicaid based on intentionally false and misleading wholesale pricing information.

515. Defendant Purdue Group acknowledges the false and misleading nature of the wholesale price information of its pharmaceutical products in responding to an AARP survey noting a 10.7% increase in AWP for Purdue Group products. Purdue Group spokesman Robert Hogen responded that Oxycontin had been sold for an average price increase of 4.3 percent per year since it was introduced in 1996. Mr. Hogen specifically pointed out that the AARP survey based on AWP was “quite deceptive” because no one pays AWP for pharmaceutical products because of rebates and discounts. *Drug Prices Rose Average 7.1 in '04: AARP Survey Says Increase was Twice the Inflation Rate*, Boston Globe, April 13, 2005.

516. Defendant Purdue Group is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

## **BB. SANOFI-AVENTIS GROUP**

517. As summarized in Exhibit A, Iowa Medicaid spent over \$38 million for the 128 at-issue Sanofi-Aventis Group NDCs between 1992 and 2005 alone.<sup>33</sup> The specific Sanofi-Aventis NDCs for which the Counties seek relief are set forth in Exhibit B-28 hereto. Iowa allege both AWP and FUL fraud claims against the Sanofi-Aventis Group defendants.

518. At all times relevant hereto, the Sanofi-Aventis Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining a false and inflated reimbursement prices. As evidenced by Exhibit B-28 hereto, the Sanofi-Aventis Group has routinely created such spreads.

519. Aventis was marketing the spread of Anzemet at least since 1997. In 1997, Aventis (then Hoescht Marion Roussel) caused an AWP of \$149.88 to be reported for Anzemet 100 mg IV in 5 ml vial. That same year, Amgen sold this identical drug for \$70 (a

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<sup>33</sup> The claims of the State are not confined to this time period.

spread of 114%). Iowa Medicaid reimbursed in 1997 based on this false AWP. Additional fraudulent spreads for Anzemet are set forth in Exhibit B-28.

520. The Sanofi-Aventis Group (at the time Hoechst Marion Roussel), aggressively marketed this spread. First, the Sanofi-Aventis Group highlighted the spread in advertisements in trade publications for Anzemet in which it displayed the price per unit next to the AWP, making the spread obvious.

521. Further, the Sanofi-Aventis Group intentionally and routinely marketed the spread to its customers. Sanofi-Aventis Group instructed its sales representatives to market the spread by comparing the spreads of Sanofi-Aventis Group drugs to the spreads of competitors. The Sanofi-Aventis Group instructed sales staff to use the difference between AWP and actual acquisition cost as a selling point, and prepared worksheets demonstrating the proper calculation of spread. These worksheets also described the AWPs of the Sanofi-Aventis Group competitors to demonstrate the advantage of purchasing Sanofi-Aventis Group products with their inflated AWPs.

522. Specifically, Sanofi-Aventis Group sales representatives were instructed to 1) understand the similarities and differences between Sanofi-Aventis Group drugs and competing products, 2) compute the reimbursement amounts for all the competing products, 3) discern whether the sales target was sensitive to reimbursement-based incentives and if so, 4) induce the sales target to purchase the Sanofi-Aventis Group product over its competitors' product based on the benefits of Sanofi-Aventis Group reimbursement.

523. When Sanofi-Aventis Group products had the largest spread, sales representatives were provided spread comparisons of all competing drugs, and informed that reimbursement would likely determine drug selection.

524. Sanofi-Aventis Group marketed their spread, even when it was equal to its competitors. Under such circumstances, Aventis sales representatives were instructed to explain that Aventis' lower AWP meant that drug purchasers had to "invest" less money to get the same spread, granting the providers a greater return on investment ("ROI"). Specifically, Aventis representatives were instructed to highlight that where two products have the same spread (e.g. \$50) the greater ROI is associated with the lower priced product. For example,

<b><u>Product 1</u></b>		<b><u>Product 2</u></b>	
<b>AWP =</b>	<b>\$100</b>	<b>AWP =</b>	<b>\$90</b>
<b>Acquisition Cost =</b>	<b>\$50</b>	<b>Acquisition Cost =</b>	<b>\$40</b>
<b>Spread=</b>	<b>\$50</b>	<b>Spread =</b>	<b>\$50</b>

525. With product 1, the provider has to pay \$50 to make \$50, or a 100% ROI. With Product 2, the provider has to pay only \$40 to make \$50, or to get 125% ROI. In addition, Aventis' sales representatives were instructed to highlight the lower opportunity cost of purchasing Aventis drugs.

526. In a 2000 report published by the DHHS, the DOJ documented at least 15 instances where the published AWPs for various dosages of four drugs manufactured by the Sanofi-Aventis Group (each drug is at issue in this litigation) were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 4 subject drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Aventis in the 2001 *RedBook*.

<b>Drug</b>	<b>2001 <i>RedBook</i> AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Anzemet Injectable (dolasetron Mesylate)	\$ 166.50	\$ 74.08	\$ 92.42	125%
Factor VIII/ Bioclate	\$ 1.25	\$ 0.91	\$ 0.34	37%

<b>Drug</b>	<b>2001 <i>RedBook</i> AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Factor VIII/ Helixate	\$ 1.18	\$ 0.78	\$ 0.40	51%
Gammar (immune globulin)	\$ 400.00	\$ 296.67	\$ 103.33	35%

527. A 2001 OIG report (See “Medicare Reimbursement of Prescription Drugs,” OEL-03-00-00310, Jan. 2001) further revealed that: (i) that AWP for all immune globulin 5 mg doses listed in the 1997 *RedBook* 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%; 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%.

528. In connection with the wrongful conduct described herein the Aventis Group has been investigated by at least the United States Department of Justice, the United States Congress, the Office of Inspector General of the Department of Health and Human Services, the Attorneys General for the States of California, Florida, Illinois, Montana, Pennsylvania, Texas and Wisconsin, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

529. Aventis Pharm is among the pharmaceutical companies now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. The Committee has requested detailed reports on pricing practices, including records concerning the “spread” between actual market prices and payments by Medicaid. The basis of this investigation is “indicia from a number of source, including utilization date, drug price/reimbursement spreads, and other relevant information.”

530. Sanofi-Aventis Group also is the subject of the investigation led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements. *See* Exhibit F. On information and belief, Sanofi-Aventis Group routinely offers its products to commercial customers for prices less than 10% AWP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price.

531. Various details of these investigations have been disclosed in Sanofi's-Aventis' Group recent SEC filings.

532. Sanofi's form 20-F for the year 2004 discloses that the U.S. Attorney's office in Boston recently expanded its investigation to the topic of whether Aventis "directly or indirectly made payments to customers or to those in a position to influence sales of [Aventis] pharmaceuticals in order to obtain or keep drug business and to evade Medicaid best price reporting requirements." The U.S. Attorney served Sanofi-Aventis with a subpoena demanding "documents related to [Sanofi's-Aventis's] interactions with and payments to managed care customers, formulary placement, sales and marketing of specific products to those managed care customers, as well as contracts with wholesalers and distributors and payments to non-Aventis employees."

533. The U.S. Attorney is also conducting a civil and criminal investigation of Sanofi-Aventis Group misconduct similar to that which was involved in the Bayer and GSK repackaging "lick and stick" settlements described herein. Boston's U.S. Attorney is examining "whether sales by Aventis ... of certain products to managed care organizations for resale under

those organizations' own private labels should have been included in the 'best price' calculations that are used to compute the Medicaid rebates for API products." *Id.*

534. The U.S. Attorney's Office in Chicago is conducting a civil and criminal investigation with regard to Aventis' Lovenox sales and marketing practices from January 1, 1999 to the present. *Id.* (Lovenox is among the drugs at issue in this complaint.)

535. There are several ongoing investigations into the Aventis Group's reporting of AWP for certain products. Sanofi's 2004 20-F stated that:

The Department of Justice is reviewing the merits of a qui tam action filed in 1995 in federal court in Florida, which alleges that the Average Wholesale Prices ("AWP") of certain pharmaceutical products, which are used to set Medicare reimbursement levels, were improperly established and used by API, Aventis Behring, and Armour Pharmaceutical Company in the marketing of their products. API and Aventis Behring also received subpoenas from the states of California and Texas with respect to such issues in 2000. API received a similar subpoena from the state of Massachusetts in April 2001.

536. In 2002, Aventis disclosed that "U.S. Centers for Medicare & Medicaid Services ("CMS") has indicated that it will seek repayment of amounts it alleges should have been included in rebates paid by [Aventis] to the various states as part of the Medicaid program. CMS claims that sales of certain products to managed care organizations for distribution by such organizations should have been included in [Aventis]'s "best price" calculations, which are used to compute the rebates." Aventis 20-F (For the fiscal year ended December 31, 2002).

## **CC. THE SCHERING GROUP**

537. As summarized in Exhibit A, Iowa Medicaid spent over \$39 million on the 164 at-issue Schering Group NDCs between 1992 and 2005 alone.<sup>34</sup> The specific Schering Group NDCs for which Iowa seeks relief are set forth in Exhibit B-29 hereto. Iowa alleges both AWP and FUL fraud claims against the Schering Group defendants.

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<sup>34</sup> Iowa's claims are not confined to this time period.

538. At all times relevant hereto, the Schering Group defendants have known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-29 hereto, the Schering Group defendants have routinely created such spreads.

539. Warrick and Schering should be treated as a single entity for liability purposes. Warrick could not exist without Schering/Schering-Plough. Warrick has only a handful of employees, yet Warrick generates annual sales of over \$150M. Warrick depends upon Schering/Schering-Plough's manufacturing, distribution, accounting and administrative departments for all of these internal functions. Warrick apparently does not even employ persons with those traditional business responsibilities. The only personnel Warrick allegedly employs are those who market and sell Schering/Schering-Plough's generic products. Warrick's business offices are within the offices of Schering/Schering-Plough. Warrick does not conduct its corporate business in Reno, Nevada as its letterhead represents. Instead, Schering/Schering-Plough and Warrick operate from the same office space in New Jersey, use the same computer systems, telephone systems, employees, and centralized departments, and apparently use each other's letterhead interchangeably.

540. The State of Texas when conducting depositions in the Texas action against Schering/Warrick discovered that the founder of Warrick did not know whether his "Warrick" consulting contract is with Warrick or Schering/Schering-Plough. These companies are not operated as separate entities, but rather integrate their resources to achieve a common business purpose to sell Schering/Schering-Plough's generic products.

541. Schering/Schering-Plough's brand version of Albuterol Sulfate, Proventil, was sold in conjunction with Warrick's generic Albuterol Sulfate. When Warrick's customers

purchased enough Warrick generic Albuterol Sulfate, Warrick would then give that customer a credit to obtain Proventil. These companies acted as one rather than as two independent drug manufacturers.

542. Schering/Schering-Plough sells Warrick products to large market segments with full knowledge of the false price representations, and, therefore, benefits from them.

543. In 1994 and 1995, Schering formulated a plan to avoid Medicaid Best Price requirements through the creation of a generics subsidiary, which would sell a generic line of products that mirrored Schering's branded line. The plan specified that these generics would only be sold in markets where Schering branded line would have to be discounted. The role of the generics subsidiary is currently being filled by Warrick.

544. Schering's plan was designed to segment the Medicaid and contract markets, thereby reducing rebates without having to lower contract pricing.

545. On July 16, 2004, Schering agreed to pay \$350 million in fines and plead guilty to criminal charges that it cheated Medicaid. The settlement stems from a six-year probe prompted by three whistleblowers who accused Schering of selling its products to private health-care providers for far less than it sold them to Medicaid. As part of the settlement, Schering is expected to admit it gave grants to private providers to conduct patient education and marketing programs as part of a scheme to induce them to buy the company's drugs at relatively high prices. Schering-Plough then billed Medicaid at these high prices without accounting for the offsetting grants.

546. In April 2004, Schering announced that it was paying \$27 million to settle charges brought in 2000 by the Texas Attorney General, which revealed that Schering-Plough,

with its subsidiary Warrick, had defrauded the State of Texas. Investigators determined that Schering-Plough provided the greatest “spread” amongst the drug companies selling Albuterol (one of the drugs paid for by the Iowa Medicaid Programs) in Texas, and thereby obtained the largest market share for Albuterol. Schering-Plough 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*, September 7, 2000, available in Attorney General Press Release Archive 2001-2002, <http://www.oag.state.tx.us/newspubs/newsarchive/>.

547. This follows a 2003 announcement by Schering that it was the subject of a federal grand jury investigation and criminal investigation led by the U.S. Attorney for the District of Massachusetts. The investigation concerned (i) providing remuneration, such as drug samples, to providers to induce the purchase of Schering products for which payment was made through federal health care programs; (ii) selling misbranded or unapproved drugs; (iii) submitting false wholesale pricing information for its pharmaceutical products to the government; and (iv) destroying evidence and obstructing justice relating to the government’s investigation. *See Schering-Plough Press Release* dated May 30, 2003, “Schering Plough Provides Update on Previously Reported Investigation by U.S. Attorney for District of Massachusetts.” Schering’s Form 10-K for the year 2000 stated that this investigation focused on “whether the AWP set by pharmaceutical companies for certain drugs improperly exceeds the average prices paid by dispensers . . . and other pricing and/or marketing practices.”

548. Schering took a charge of \$150 million for the fourth quarter of 2002 to reflect its estimate of the likely legal liability from the above government probe. The primary basis for the government investigation was the federal anti-kickback statute, which prohibits pharmaceutical companies from giving money or other items of value to doctors in exchange for

prescribing particular products to Medicaid patients. Schering's bundled discount practices for seven drugs at issue in this litigation are the subject of an investigation by the Boston U.S. Attorney. Those drugs are Proventil, Vanceril, Vancenase, Notro-Dur, Imdur, K-Dur and Claritin.

549. Both Schering and Warrick are among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. The Committee has requested reports on pricing practices, including records concerning the "spread" between actual market prices and payments by Medicaid. The basis of this investigation is "indicia from a number of sources, including utilization data, drug price/reimbursement spreads, and other relevant information."

550. Schering also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements. *See* Exhibit F. On information and belief, Schering routinely offers its brand products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price or report those prices as its Best Price.

551. Schering is being sued by the States of Alabama, Connecticut, Florida, Illinois, Massachusetts, Missouri, Montana, Nevada, Pennsylvania, Texas, West Virginia, Wisconsin, the City of New York and 42 New York Counties in connection with the wrongdoing alleged herein.

552. Schering was among the drug companies Congressman Stark investigated for improper Medicare/Medicaid pricing practices.

553. Warrick is being sued by the States of Alabama, Alaska, California, Connecticut, Hawaii, Idaho, Illinois, Kentucky, Massachusetts, Mississippi, Missouri, Montana, Nevada, Pennsylvania, South Carolina, Texas, West Virginia, Wisconsin, the City of New York and 42 New York Counties in connection with the wrongdoing alleged herein.

#### **DD. TAP PHARMACEUTICAL**

554. As summarized in Exhibit A, Iowa Medicaid spent over \$29 million on the 20 at-issue TAP NDCs between 1992 and 2005 alone.<sup>35</sup> The specific TAP NDCs for which Iowa seeks relief are set forth in Exhibit B-30 hereto.

555. At all times relevant hereto, TAP has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-30 hereto, TAP has routinely created such spreads.

556. In connection with the wrongful conduct described herein, TAP has been investigated by the Department of Justice. In addition, on October 13, 2001, the United States Attorney in Boston, Massachusetts announced that TAP, a corporation that arose from a partnership between Takeda Chemical Industries Ltd. and Abbott Laboratories, a defendant herein, 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

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<sup>35</sup> Iowa's claims are not confined to this time period.

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 federal 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;

557. Abbott and Takeda (the TAP co-venturers) 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.

558. 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.

559. 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 Pharm. Prods., Inc.*, No. CR-01-10354-WGY (D. Mass. Dec. 6, 2001).

560. The TAP defendants also have been sued in connection with their fraudulent pricing and marketing practices for Lupron, one of the drugs at issue here. *Russano v. Abbott Laboratories*, No. 01-6982 (N.D. Ill., filed Sept. 7, 2001).

561. TAP also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements. *See* Exhibit F.

562. This investigation complements documents from the Specialty Hospital of New Orleans that reveal widespread discounting of TAP products Prevacid 15 and 30 mg tablets at prices that are a fraction of the reported AWP. TAP has been named as a defendant in a Louisiana Qui Tam action<sup>36</sup> alleging that TAP made sales of these two products at discounts of over 90% off of AWP. The veracity of these allegations is confirmed by publicly filed exhibits that Iowa has viewed.

563. The Louisiana qui tam action alleges that in the year 2002, Tap sold 15 and 30 mg Prevacid tablets to the Specialty Hospital of New Orleans for \$0.24 per dose.<sup>37</sup> Yet, at the same time TAP's per pill AWPs for 15 and 30 mg Prevacid (NDCs 00300730930 and

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<sup>36</sup> *U.S. Ex. Rel. William St. John LaCorte, MD v. TAP Pharmaceuticals, Inc.*, CV 03-1483, (E.D.L.A.).

<sup>37</sup> *See* Oral Proton Pump Inhibitors Cost Analysis, Exhibit L, Complaint For Money Damages and Civil Penalties under the False Claims Act, Filed May 23, 2003, *U.S. Ex. Rel. William St. John LaCorte, MD v. TAP Pharmaceuticals, Inc.*, CV 03-1483, (E.D.L.A.).

00300304613) were reported or caused to be reported as \$4.20 and \$4.28 per pill. Additional fraudulent spreads for Prevacid 15 and 30 mg Tablets are set forth in Exhibit B-30.

564. On information and belief these deep discounts offered by TAP were not accounted for by TAP in its calculation of the 2002 AWP of \$4.20 per pill AWP. Nor were these deeply discounted prices reported as TAP's Best Prices for these products.

565. Iowa reimbursed based on the false Prevacid 15 and 30 mg AWP's in 2002, paying \$3.78 and \$3.85 per pill (AWP – 10%, excluding co-pays and dispensing fees). Iowa thus paid over 1500% more for Prevacid 15 and 30 mg than what was charged to the Specialty Hospital of New Orleans.

566. On information and belief, at all times relevant hereto, 1) the deep discounting programs as alleged here have been widely used by TAP, (2) these deeply discounted prices have not been included in TAP's Best Price reporting or calculations, and 3) these deeply discounted prices have not been included in the AWP's and other wholesale price information TAP reports or causes to be reported to publishers.

567. In connection with the wrongful conduct described herein, the Attorneys General of the States of Alabama, Illinois, Kentucky, Mississippi, Montana, Pennsylvania, Wisconsin, the City of New York and 42 New York Counties have sued TAP.

## **EE. TEVA GROUP**

568. As summarized in Exhibit A, Iowa Medicaid spent over \$48 million on the 748 at-issue Teva NDCs between 1992 and 2005 alone.<sup>38</sup> The specific Teva NDCs for which Iowa seeks relief are set forth in Exhibit B-31 hereto. Iowa alleges both AWP and FUL fraud claims against the Teva Group defendants.

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<sup>38</sup> Iowa's claims are not confined to this time period.

569. At all times relevant hereto, the Teva Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-31 hereto, the Teva Group has routinely created such spreads.

570. The Teva Group has instructed its sales force to market the spread for its products. The Teva Group has specifically instructed sales staff to use the difference between AWP and actual acquisition cost as a selling point and has prepared worksheets demonstrating the proper calculation of spread. These worksheets also described the AWP's of the Teva Group competitors to demonstrate the advantage of purchasing Teva Group products with their inflated AWP's.

571. In addition to the examples in Exhibit B-31, in April 2003, Teva Group's 1000-count package of Glyburide 5 mg Tablet (NDC 00093-8344-10) had a reported AWP of \$660.54. The available price for the same 1000-count package was \$89.77 (a 120% discount from the reported WAC of \$197.75). The intentionally false and misleading AWP was 636% over the available price and 234% over the reported WAC. Iowa reimbursed for Teva Group's 1000-count package of Glyburide 5 mg Tablet in 2003 based on the false and misleading wholesale price information. Additional fraudulent spreads for Glyburide 5 mg Tablet are set forth in Exhibit B-31.

572. The vast majority of Teva Group spread percentages between AWP and the available price as well as the spread percentages between AWP and WAC (irrespective of the available price) are consistently more than 100% and sometimes in the thousands of percent. *See* Exhibit B-31. For example, in July 2002, Teva Group's 100-count package of Piroxicam 20 mg Capsule (NDC 00093075701) had a reported AWP of \$263.90. The available price for the same

100-count package was \$3.57 (a 177% discount from the reported WAC of \$9.89). The intentionally false and misleading AWP was 7292% over the available price and 2568% over the reported WAC. Iowa reimbursed Teva Group's 100-count package of Piroxicam 20 mg Capsule in 2002 based on this false and misleading wholesale price information. Additional fraudulent spreads for Piroxicam 20 mg are set forth in Exhibit B-31.

573. The Teva Group defendants facilitated the false and misleading nature of its wholesale pricing information by reporting or causing to be reported a deceptive 20% mark-up spread from WAC to AWP to hide the true wholesale pricing of certain of its drugs. For example, in April 2003, Teva Group's 5 ml vial of Haloperidol DEC 100 mg/ml (NDC 00703-7023-01) had a reported AWP of \$144.00. The available price for the same 5 ml vial was \$43.11 (a 178% discount from the reported WAC of \$120.00). The intentionally false and misleading AWP was 234% over the generally available market price, yet on the surface the AWP deceptively appeared to be only 20% over the reported WAC. Iowa reimbursed Teva Group's Haloperidol DEC 100 mg/ml 5 ml vial in 2003 based on this false and misleading wholesale price information. Additional fraudulent spreads for Haloperidol are set forth in Exhibit B-31.

574. In addition to the above, Plaintiffs have also continued to obtain information relating to Teva Group's wholesale pricing information of their drugs, including material obtained by the original *qui tam* whistleblower (Ven-A-Care), complaints in various state government actions discussed herein and prices available to buyers other than Iowa Medicaid, and have found that the evidence uniformly supports the conclusion that Teva Group has pervasively inflated the wholesale pricing information of their drugs.

575. In connection with the wrongful conduct described herein, Teva Group, or its constituent parts, has been sued by Alaska, Massachusetts, California, Alabama, Illinois,

Hawaii, Idaho, Kentucky, Mississippi, Missouri, South Carolina, Wisconsin, the City of New York and 42 New York Counties in connection with the wrongdoing alleged herein.

576. Illinois and Wisconsin allege the following spreads:

<b>Defendant TEVA GROUP</b>						
<b>Drug</b>	<b>Size</b>	<b>NDC Code</b>	<b>2000 AWP</b>	<b>2000 Available Price</b>	<b>Spread \$</b>	<b>Spread %</b>
Naproxen 500mg	100s	00093-0149-01	\$113.70	\$6.75	\$106.95	1584%
Ranitidine 150mg	500s	55953-0544-70	\$740.00	\$40.00	\$700.00	1750%
Fluphenazine 25mg/ml	5ml	00703-5003-01	\$52.56	\$5.53	\$47.03	850%
Etoposide 20ml/ml	25ml	00703-5646-01	\$209.00	\$40.00	\$169.00	423%

577. In 2000, Iowa reimbursed Teva Group's 100-count and 1000-count packages of Ranitidine 150 mg based on the same intentionally false and misleading wholesale price information.

578. The Teva Group is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

579. In addition, on June 26, 2003, as part of its investigations, the House Committee of Energy and Commerce requested information from the three largest pharmaceutical wholesalers (Cardinal Health, Inc., AmerisourceBergen Corporation, McKesson Drug Co.) about matters related to pricing, sales and marketing of several generic drugs, some of which are manufacturer by Teva Group.

580. On January 14, 2004, as part of its investigations, the House Committee of Energy and Commerce requested information from the five largest retail pharmacies (Walgreens,

Eckerd, CVS, Rite-Aid and Walmart Stores) about matter related to about matters related to pricing, sales and marketing of several pharmaceutical manufacturers, including Teva Group.

581. During 2004, 29% of Teva USA's sales were made to drug store chains, 40% to drug wholesalers, 21% through partner marketing arrangements, 5% to generic distributors, hospitals and affiliated organizations and 5% to others, including mail order distributors, governmental institutions and managed care institutions. (Teva Ltd. SEC Form 20-F (FY 2004, 3/17/05).

582. The Teva Group markets and sells its drugs to chain drug stores, drug wholesalers, health maintenance organizations, pharmacy buying groups and nursing homes. The Teva Group also contacts its retail customers and supports its wholesale selling effort with telemarketing as well as professional journal advertising and exhibitions at key medical and pharmaceutical conventions. *See id.*

583. In marketing its drugs to its customer, Teva Group instructed its sales force to reference and rely on the AWP information published in industry compendia, including those published by Medi-Span's *Red Book* and First DataBank's *NDDF Pricing File*.

584. The Teva Group further masks the false and misleading nature of its wholesale pricing information through the off-invoice, market share rebates, volume discounts and free goods. For example, documents obtained by the federal government, show that Teva Group's Sicor implemented the strategy of targeting top 40 AIDS hospitals with a "\$54.00 price in conjunction with a 10% free goods program, which masked the final price" and resulted in an effective price of \$48.60. *See* 146 Cong. Rec. E1622 (2000).

585. The Teva Group has strategic alliances and marketing arrangements with defendant Abbott, defendant Baxter and defendant Alpharma, among others.

586. On information and belief, the wrongful conduct complained of herein permeates to and from each defendant participating in these mutually beneficial agreements and alliances resulting in the knowing sale and marketing of pharmaceutical products based on false and misleading wholesale price information.

587. Teva is among the pharmaceutical companies now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. The Committee has requested detailed reports on pricing practices, including records concerning the “spread” between actual market prices and payments by Medicaid. The basis of this investigation is “indicia from a number of sources, including utilization data, drug price/reimbursement spreads, and other relevant information.”

#### **FF. THE WATSON GROUP**

588. As summarized in Exhibit A, Iowa Medicaid spent over \$36 million for the 1310 at-issue Watson Group NDCs between 1992 and 2005 alone.<sup>39</sup> The specific Watson NDCs for which Iowa seeks relief are set forth in Exhibit B-32 hereto. Iowa alleges both AWP and FUL fraud claims against the Watson Group defendants.

589. At all times relevant hereto, the Watson Group has known that it can promote its drugs by selling them at substantial undisclosed discounts, while at the same time maintaining false and inflated reimbursement prices. As evidenced by Exhibit B-32, hereto, the Watson Group has routinely created such spreads.

590. In connection with the wrongful conduct described herein, Watson has been investigated by at least the DOJ, the DHHS OIG, and the Attorneys General for the states of California, Montana, Pennsylvania and Wisconsin. Schein, Watson’s subsidiary since 2000,

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<sup>39</sup> Iowa’s claims are not confined to this time period.

has been investigated by the Office of the Attorney General of Texas in connection with a state investigation of “possible false reporting of information regarding the marketing of and prices for drugs” used to establish reimbursement rates for Texas Medicaid drugs, and has received notices or subpoenas from the Attorneys General of various other states, including Florida, Nevada, California, Texas and New York.

591. In a 2000 report published by the DHHS, the DOJ documented at least 12 instances where the published AWP for various dosages of drugs manufactured by Watson were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug.

592. The below table is an analysis of certain dosages of Watson drugs (when Watson was called Schein), from a Schein Product Status Report, dated February 1996:

<b>Drug</b>	<b>AWP</b>	<b>WAC</b>	<b>% Spread</b>
Fluphenazine HCL 1 mg	\$46.08	\$15.71	193%
Gemfibrozil 600mg	\$55.65	\$7.95	600%
Imipramine HCL 10 mg	\$4.45	\$1.32	237%
Nadolol 20 mg	\$85.32	\$42.95	98%
Perphenazine 2 mg	\$42.53	\$19.76	115%

593. The Watson Group has been sued by Alabama, Alaska, Hawaii, Idaho, Illinois, Kentucky, Massachusetts, Mississippi, Montana, Missouri, Nevada, South Carolina, Wisconsin, the City of New York and 42 New York Counties in connection with the wrongdoing alleged herein.

594. In 2000 Watson sold Dicyclomine 20 mg (a subject drug) for \$7.31 per pack of hundred, while reporting an AWP of \$33.11, thereby creating a spread of 353%.

595. In 2000 Watson sold Methylphenidate 10 mg tablets (a subject drug) for \$23.52 per pack of hundred, while reporting an AWP of \$47.40 creating a spread of 103%.

596. As part of its investigation of Watson, the Massachusetts Attorney General issued a subpoena to Watson for documents related to pricing, Medicaid rebate compliance, and Medicaid reimbursement.

597. The Massachusetts Attorney General subsequently brought suit against Watson, alleging that Watson's AMPs were materially lower than the wholesale prices Watson reported for reimbursement purposes and that Watson consequently had underpaid Medicaid rebates.

598. To the extent that Iowa reimbursement is based on the same fraudulent AMP and AWP data, Watson's false reporting of inflated wholesale price information for reimbursement purposes and under-reporting of AMP have damaged Iowa.

599. Watson's Schein reported in its 10-Q for the quarterly period ended June 24, 2000, that it was a defendant in a federal *qui tam* action brought in 1995 under the U.S. False Claims Act in the Federal District Court for the Southern District of Florida. Schein stated that it "believe[d] that the matter relates to pharmaceutical pricing issues and whether 19 allegedly improper efforts by pharmaceutical manufacturers led to increased payments by Medicare and/or Medicaid."

600. Watson also is among the pharmaceutical companies referred to above now under investigation by the House Committee on Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

## **GG. WYETH**

601. As summarized in Exhibit A, Iowa Medicaid spent over \$55 million on the 333 at-issue Wyeth NDCs between 1992 and 2005 alone.<sup>40</sup> The specific Wyeth NDCs for which

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<sup>40</sup> The claims of the State are not confined to this time period.

Iowa seeks relief are set forth in Exhibit B-33 hereto. Iowa alleges both AWP and FUL fraud claims against Wyeth.

602. At all times relevant hereto, Wyeth has known that it can promote its drugs by selling them at substantial undisclosed discounts while at the same time maintaining a false and inflated reimbursement prices. As evidenced by Exhibit B-33 hereto, Wyeth has routinely created such spreads.

603. Wyeth's marketing strategy for Protonix makes clear the degree of falsity of its reported wholesale price information. In order to compete in the crowded proton pump inhibitor field, Wyeth devised a strategy whereby it would set AWPs (through its reporting of other wholesale price information) at a level below its competitors in order to appeal to the managed care customers. Next, Wyeth prepared to offer its sales force the option of offering discounts of up to 25% off of Protonix's list price/WAC, resulting in a significant discount of around 40% off of AWP. However, as shown below, Wyeth later offered much greater discounts on Protonix. Iowa's specific fraudulent spreads for Protonix are set forth in Exhibit B-33.

604. At all times relevant hereto, Wyeth has known that it can promote its drugs by creating the spread and selling its products at substantial discounts off WAC, while at the same time maintaining a false and inflated AWP.

605. Defendant King Group has a co-promotion agreement with defendant Wyeth to promote and sell Monarch's Altace throughout the United States, including Iowa.

606. The California Attorney General sued Wyeth for AWP manipulation. California documented the following acquisition costs, which resulted in the following spreads between Wyeth's published AWPs and actual wholesale prices for many of its drugs:

### Defendant Wyeth's Prices & Spreads for Ativan

Drug	NDC	Blue Book AWP	AC's (Provider) acquisition fee	Provider's Gross Profit or "Spread"	Spread as a % of VAC Price
Ativan 2mg/ml 10ml vial	00008-0581-01	\$87.74	\$11.20	\$76.54	683.39%
Ativan 2mg/ml 10ml vial	00008-0581-02	\$126.70	\$20.08	\$106.62	530.98%
Ativan 2mg/ml 1ml 25s	00008-0581-15	\$209.25	\$28.75	\$180.50	627.83%
Ativan 2mg/ml 10mls 10s	00008-0581-13	\$745.80	\$110.00	\$635.80	578.00%
Ativan 2mg/ml 10mls 10s	00008-0581-52	\$126.70	\$20.08	\$106.62	530.98%
Ativan 2mg/ml 1ml 10s	00008-0581-53	\$126.70	\$20.08	\$106.62	530.98%
Ativan 2mg/ml 1ml 10s	00008-0581-04	\$9.85	\$1.40	\$8.45	603.57%
Ativan 4mg/ml 1ml 10s	00008-0570-02	\$126.70	\$31.40	\$95.30	303.50%
Ativan 4mg/ml 1ml 10s	00008-0570-15	\$256.00	\$53.75	\$202.25	376.28%
Ativan 4mg/ml 1ml 10s	00008-0570-50	\$126.70	\$31.40	\$95.30	303.50%
Ativan 4mg/ml 1ml 10s	00008-0570-51	\$126.70	\$31.40	\$95.30	303.50%
Ativan 4mg/ml 10ml ea	00008-0570-01	\$109.66	\$16.00	\$93.66	585.38%
Ativan 4mg/ml 1ml ea	00008-0570-04	\$12.05	\$2.15	\$9.90	460.47%

607. Wyeth is the subject of the investigation by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is inappropriately using the nominal price exception to the Best Price reporting requirements.

608. This investigation complements documents from the Specialty Hospital of New Orleans that reveal widespread discounting of Wyeth products Protonix 40 mg tablets at prices that are a fraction of the reported AWP. These documents are part of an exhibit in a Qui Tam action naming TAP as a defendant.<sup>41</sup>

<sup>41</sup> *U.S. ex. rel. St. John LaCorte, MD v. TAP Pharmaceuticals, Inc.*, CV 03-1483, (E.D.L.A.).

609. Exhibits filed in the Louisiana action show that in the year 2002, Wyeth sold 40 mg Protonix tablets to the Specialty Hospital of New Orleans for \$0.16 per dose.<sup>42</sup> Yet, at the same time Wyeth's per pill AWP for 40 mg Protonix (NDCs 00008-0841-81 and 00008-0841-99) were reported or caused to be reported as \$3.13 per pill. *See also* Exhibit B-33 for particular Protonix spreads.

610. On information and belief Wyeth did not account for these deep discounts in its calculation of the year 2002 \$3.13 per pill AWP, nor were they accounted for in Wyeth's calculation of Best Price.

611. Iowa reimbursed based on the false Protonix 40 mg AWP in 2002, paying \$2.82 per pill (AWP – 10%, excluding co-pays and dispensing fees). Iowa thus paid over 1760% more for Protonix 40 mg than the amount charged to the Specialty Hospital of New Orleans.

612. On information and belief, at all times relevant hereto, 1) the deep discounting programs as alleged here have been widely used by Wyeth, (2) these deeply discounted prices have not been included in Wyeth's Best Price reporting or calculations, and 3) these deeply discounted prices have not been included in the AWP and other wholesale price information Wyeth reports or causes to be reported to publishers.

613. On information and belief, Wyeth routinely offers its products to commercial customers for prices less than 10% of AMP and (a) does not account for these sales in its calculation of WAC or AWP and (b) does not account for these deeply discounted sales in its calculation of Best Price nor report them as their Best Price.

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<sup>42</sup> *See* Oral Proton Pump Inhibitors Cost Analysis, Exhibit L., Complaint For Money Damages and Civil Penalties under the False Claims Act, Filed May 23, 2003, *U.S. ex. rel. St. John LaCorte, MD v. TAP Pharmaceuticals, Inc.*, CV 03-1483, (E.D.L.A.).

## **XI. DAMAGES TO IOWA MEDICAID PROGRAMS**

614. Iowa Medicaid spent over \$1.6 billion for defendants' drugs in state and federal dollars from 1992 through 2005 alone. A substantial portion of this huge sum is the result of the inflation of prescription drug prices pursuant to the false price reporting scheme alleged herein, and the failure to pay the full rebate amounts required by law.

615. Applying even the most conservative estimates of improper AWP/FUL spread and failures to report accurate Best Prices or pay proper rebates, these abuses result in millions of dollars in excessive payments by Iowa Medicaid for Medicaid-covered drugs.

616. Iowa now seek, *inter alia*, to recover the excess payments. Defendants' misconduct has unjustly enriched the defendants at the expense of Iowa's health care system, and ultimately, taxpayers in Iowa and nationwide.

## **XII. FRAUDULENT CONCEALMENT**

617. By controlling the process by which the AWPs and other reimbursement price information for covered drugs were inflated and reported falsely to publishers, each defendant concealed its fraudulent conduct from the State of Iowa. Each defendant prevented Iowa from knowing what the true actual prices for the covered drugs were, and concealed the standard discounts, chargebacks, off-invoice transactions, free samples and other financial incentives routinely provided to lower the actual costs for its drugs.

618. Each defendant who reported WAC or Direct Price or AWP or other reimbursement price information to the publishers concealed that the reimbursement prices did not accurately reflect the true prices at which defendants' products were sold.

619. Each defendant concealed that it sold the vast majority of its drugs at discounts off of WAC and AWP, pursuant to negotiated contracts or otherwise.

620. Each defendant concealed its fraudulent conduct by instructing drug distribution chain intermediaries not to report the prices they paid for the covered drugs.

621. Each defendant worked with and motivated provider and drug distribution chain intermediaries to halt investigations or changes in the AWP/ reimbursement price system.

622. Each defendant concealed that its calculation of Medicaid rebates, based on Best Price and AMP, did not account for all discounts, rebates or incentives as required by law and/or was based on improper use of the nominal price exception.

623. Each defendant concealed that it was selling substantial quantities of its drugs for less than 10% of AMP to commercial entities to avoid Best Price reporting obligations, an abuse of the Nominal Price exception. This unlawful practice has only come to light recently, in the wake of Congressional investigations and a January 2007 report issued by Senator Grassley, and annexed hereto as Exhibit F.

624. Each defendant further concealed the true Best Prices from the federal agencies to which it reports those price indicators.

625. Each defendant concealed that it was not paying proper rebates to the states.

626. Each defendant purposely concealed its pricing structures, promotional practices and sales figures for the covered drugs.

627. Each defendant concealed that it purposely inflated its reimbursement price information and/or did not disclose its discounting practices in order to create a spread between reimbursement price and acquisition cost.

628. Each defendant's efforts to conceal its pricing structures for the drugs at issue is evidence that it knew that its conduct was fraudulent.

629. Thus, each defendant concealed that, (i) its AWP, WACs and Direct Prices and other reported wholesale prices were highly inflated and false notwithstanding defendants' obligation to "turn square corners" when dealing with the government, (ii) it was manipulating the WACs, AWP and other reported prices of the covered drugs, (iii) the AWP bore no relationship to the actual prices paid for, or the pricing structure of, the subject drugs, and (iv) it was not accurately reporting its Best Prices and not accurately calculating its Medicaid rebates.

630. Deutsche Bank's Barbara Ryan, a large-cap pharmaceutical analyst concurs:

"[W]e all look at list price, because it's the only thing that is known to us. But list price is increasingly absolutely irrelevant. It's [more important] what goes on behind the curtain. Now we don't know what goes on behind the curtain, we can only imagine, but we can judge the results. So we see that some companies, like Pfizer, have been more successful behind the curtain than others. The breadth of your product portfolio and the importance of that portfolio to any payor certainly plays a role. If you have a one-off drug that you're trying to position and it might be in a therapeutic category that's quite crowded, it is very difficult to have any traction."

*The Pink Sheet* 2004/2005 Almanac.

631. Defendants veiled information vital to the pursuit of these claims, without any fault or lack of diligence on the part of the State of Iowa. Iowa could not reasonably have discovered the fraudulent nature of all the published prices and of the Medicaid rebate amounts calculated or Best Prices reported by defendants. Because of their knowing, affirmative, and active concealment of the fraudulent nature of pricing information, defendants are estopped from relying on any statutes of limitations.

632. Any applicable statutes of limitations have been tolled by defendants' knowing and active concealment and denial of the facts alleged herein. At all times relevant the

defendants have been and are under a continuing duty to disclose to the State of Iowa that the AWP's they reported or caused to be reported bear no relationship to the actual prices paid for their drugs, that defendants manipulated the WACs, AWP's and other published prices to create a spread, and that the Medicaid rebates that defendants pay are reduced by the use of false and inaccurate pricing information and abuse of the Nominal Price exception.

## **CLAIMS FOR RELIEF**

### **COUNT I**

#### **VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. § 1396r-8 (FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)**

633. Iowa realleges and incorporates the preceding paragraphs as if fully set forth herein.

634. Each of the defendant pharmaceutical companies is a manufacturer of a drug covered by Medicaid.

635. Pursuant to 42 U.S.C. § 1396r-8, each of the defendant pharmaceutical manufacturers of single source and brand name innovator drugs entered into a rebate agreement with the Medicaid program pursuant to which the defendant agreed to report its Best Price.

636. In keeping with their artificial price inflation scheme, each such defendant did not report the actual Best Price but instead reported incorrect Best Prices by, *inter alia*, excluding routine discounts (*e.g.*, volume and prompt pay discounts and discounts to repackagers), rebates, off-invoice transactions, free samples and other inducements offered to participants in the drug distribution chain and through abuse of the Nominal Price Exception ("NPE") to Best Price Reporting requirements. As a result, defendants reported false and inflated "Best Prices" to the Medicaid Program and paid lower rebates than they were legally obligated to pay.

637. Each of the defendants violated 42 U.S.C. § 1396r-8 by their systematic submission of untrue, incomplete, inaccurate, and misleading information used to determine the amount of rebates under the Medicaid program.

638. As set forth herein, acting with the intent to defraud and in order to obtain authorization to qualify as a provider and to provide specific goods, each defendant made or caused to be made false statements and incorrect payments while promising that it would comply with the mandates of 42 U.S.C. § 1396r-8.

639. Defendants knew, or by virtue of their position, authority or responsibility should have known, of the falsity of pricing information submitted and that the rebates they were paying were incorrectly calculated.

640. As a result of defendants' inaccurate reporting of Best Price, defendants did not comply with their obligations pursuant to the Federal Medicaid rebate provision and the State of Iowa was deprived of a portion of the rebates to which it was entitled.

641. Iowa is an express third-party beneficiary of the Federal Rebate Agreement each defendant has signed and is within the class of entities for whose benefit the rebate provision was enacted.

642. Medicaid pharmacy costs for Iowa are higher than they would have been if defendants had accurately reported Best Price. Iowa has therefore suffered actual injury as a direct result of defendants' misconduct. That injury would be redressed through a favorable decision on this claim.

## **COUNT II**

### **BREACH OF CONTRACT**

643. Iowa realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.

644. As required by 42 U.S.C. § 1396r-8, and to effectuate its purpose of reducing state Medicaid drug expenditures, each defendant entered into a Rebate Agreement with the Secretary of HHS.

645. The Secretary of HHS entered into this Rebate Agreement, “on behalf of the States.”

646. The Medicaid statute provides that “the State or local agency administering such plan will take all reasonable measures to ascertain the legal liability of third parties for any overcharges and submit to the Secretary of Health and Human Services a plan for pursuing such claims.” 42 U.S.C. § 1396a (a)(25)(A).

647. At the time each defendant entered into a Rebate Agreement, the Secretary of HHS expressly had approved Iowa’s Medicaid plan.

648. Iowa is an express intended third-party beneficiary of these rebate agreements. The rebate agreements expressly provide that the Secretary is entering into the agreements “on behalf of the states.” *See* Exhibit E hereto.

649. Contrary to the express requirements of the Rebate Agreements, each defendant did not report accurate Best Prices for its drugs or pay correct Medicaid rebates.

650. Rather, each defendant reported false and inflated Best Prices that, among other things, excluded routine discounts including prompt pay and bundled discounts, rebates, chargebacks and other inducements and incentives offered to drug selecting entities to create market share, and abused the Nominal Price Exception.

651. Defendants have therefore breached their rebate agreements and caused massive foreseeable damage to Iowa, which is and was an express intended third-party beneficiaries of the rebate agreement.

### COUNT III

#### IOWA CONSUMER FRAUD ACT Iowa Code § 714.16

652. Iowa realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.

653. As set forth herein and in the Exhibits hereto, defendants' reporting of inaccurate, false and misleading wholesale pricing information for their drugs constituted deception pursuant to Iowa Code § 714.16(1)(f) and unfair practices pursuant to Iowa Code § 714.16(1)(n) and, therefore, was unlawful pursuant to Iowa Code § 714.16(2)(a).

654. Defendants' conduct as alleged in this Complaint constitutes deception and unfair practices in connection with the advertisement or sale of merchandise in that:

(a) Defendants misrepresented that the wholesale pricing information they submit reflects the true wholesale prices of the drug products they sell, and that the Best Prices they report are the actual Best Prices paid;

(b) Defendants made false and misleading statements regarding the true wholesale pricing information and true Best Prices paid for their medications, which are the bases of Iowa's Medicaid pharmacy cost payments, in order to drive up the prices paid by Iowa through Medicaid and deny Iowa proper Medicaid rebates; and

(c) Defendants made false representations by representing that the wholesale pricing information provided is an accurate reflection of the wholesale prices paid for their drugs, and that their reported Best Prices are in fact the Best Prices paid for their drugs.

655. The wrongful conduct alleged in this Complaint occurs and continues to occur in the ordinary course of defendants' business and has caused great harm to Iowa. Iowa

has overpaid millions of dollars in Medicaid pharmacy costs due to defendants' deceptive and unfair practices.

656. Pursuant to Iowa Code § 714.16(7), except in an action for the concealment, suppression or omission of a material fact with intent that others rely upon it, it is not necessary in an action under section § 714.16 for reimbursement or an injunction, to allege or to prove reliance, damages, intent to deceive, or that the person who engaged in an unlawful act had knowledge of the falsity of the claim or ignorance of the truth.

657. Pursuant to Iowa Code § 714.16(7), Iowa is entitled to full reimbursement of the monies it has unnecessarily paid as a result of defendants' wrongful practices, civil penalties, costs and attorneys' fees.

#### **COUNT IV**

#### **FRAUD**

658. Iowa realleges and incorporates the preceding paragraphs as if fully set forth herein.

659. As detailed in the Complaint and Exhibits hereto, defendants have engaged in actual fraudulent reporting of pricing information on which Medicaid reimbursements are based, and defendants have acted intentionally and with actual malice.

660. Defendants have made false representations with knowledge of their falsity, have concealed material facts with the purpose of overcharging Iowa and Iowa has relied upon such misrepresentations. Direct, proximate and foreseeable injury has occurred as a result of such foreseeable and intended reliance.

661. Defendants also had knowledge of facts or intentionally disregarded facts that created a high probability of injury to Iowa and deliberately proceeded to act in conscious or intentional disregard of, or with indifference to, the high probability of this injury.

662. Defendants' knowing and intentional submission of inflated WACs/AWPs and other wholesale pricing data to publishers for the express purpose of effectuating the WAC/AWP scheme alleged herein, and their knowing and intentional failures to report accurate Best Prices and failure to pay correct Medicaid rebates constitute intentional frauds pursuant to Iowa common law.

## **COUNT V**

### **UNJUST ENRICHMENT**

663. Iowa realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.

664. To the extent the Court determines there is no contractual relationship between Iowa and the defendants, as a direct and proximate result of the unlawful conduct described above, defendants have been and will continue to be unjustly enriched.

665. Defendants have benefited from their unlawful acts through the increased sales of covered drugs with the greatest spread. It would be inequitable for defendants to retain any of their ill-gotten gains earned as a result of the scheme alleged herein, which gains would not exist but for the overpayments made by Iowa Medicaid Program and other Medicaid payors.

666. Iowa is entitled to an accounting and the establishment of a constructive trust consisting of all excess payments made by the Iowa' Medicaid Programs for covered drugs.

## **PRAYER FOR RELIEF**

WHEREFORE, plaintiff the State of Iowa prays for judgment against each and every defendant, jointly and severally, as follows:

667. Adjudging and decreeing that defendants engaged in the intentional fraudulent conduct alleged herein in violation of Iowa Code § 714.16 and 42 U.S.C. § 1396r-8;

668. An order permanently enjoining each of the Defendants (as applicable) and each Defendant's directors, officers, agents, representatives, subsidiaries, affiliates, successors, assigns or acquired predecessors, parent or controlling entities and all other persons, corporations or other entities acting in concert who have actual or constructive notice of the Court's injunction from continuing to engage in the unlawful practices described in this Complaint;

669. Awarding Iowa actual, statutory, and all other available money damages, with interest, for defendants' violation of Iowa Code § 714.16 in an amount to be determined at trial;

670. Awarding Iowa actual and compensatory damages in an amount to be determined at trial, with interest, for defendants' breach of contract;

671. Awarding Iowa actual and punitive damages in an amount to be determined at trial, with interest, for defendants' intentional fraud in respect of matters of significant public interest;

672. Ordering defendants each to prepare an accounting to determine the amounts defendants have illegally profited at Iowa Medicaid Programs' expense, and disgorgement of such monies, with interest;

673. Imposing a constructive trust and ordering defendants to pay restitution to the State of Iowa in the amount Iowa Medicaid has been overcharged for covered drugs, with interest;

674. Awarding plaintiff the costs of the suit, including reasonable attorneys' and experts' fees pursuant to Iowa Code § 714.16(11), and any other applicable federal and state statutes or common law; and

675. Such other further and different relief as the Court deems just and proper.

### **JURY DEMAND**

COMES NOW, Plaintiff the State of Iowa, by and through its counsel, and hereby demands a trial by jury.

Dated: October 9, 2007.

Respectfully submitted,

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