UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF CONNECTICUT, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF LOUISIANA, THE COMMONWEALTH OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW HAMPSHIRE, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF NORTH CAROLINA, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE COMMONWEALTH OF VIRGINIA, THE STATE OF WISCONSIN, AND THE DISTRICT OF COLUMBIA, *ex rel.* RONALD J. STRECK Plaintiffs, v. ALLERGAN, INC., AMGEN, INC., ASTRAZENECA PHARMACEUTICALS LP, AZTRAZENECA LP, BIOGEN IDEC, INC., BRADLEY PHARMACEUTICALS INC. n/k/a NYCOMED US, INC., CEPHALON, INC., EISAI, INC., GENZYME CORPORATION, MALLINCKRODT INC., NOVO NORDISK, INC., RELIANT PHARMACEUTICALS, INC., SEPRACOR n/k/a SUNOVION PHARMACEUTICALS INC., and UPSHER-SMITH LABORATORIES, INC., Defendants.	**RELATOR'S FOURTH AMENDED COMPLAINT PURSUANT TO THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§3729 *ET SEQ.* AND SUPPLEMENTAL STATE FALSE CLAIMS ACTS** CIVIL ACTION NO. 08-5135 **JURY TRIAL DEMANDED**

1. Ronald J. Streck ("Relator") brings this action on behalf of the United States, the State of California, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Hampshire, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, and the State of Wisconsin (the "Plaintiff States" and collectively with the United States, the "Government Plaintiffs"), for violations of the Federal False Claims Act, 31 U.S.C. §§3729 *et seq.*, as well as for violations of the following state false claims acts: The California False Claims Act, Cal. Gov't Code §§12650 *et seq.*; The Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301b; The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§1201 *et seq.*; The District of Columbia False Claims Act, D.C. Code Ann. §§2-308.03 *et seq.*; The Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq.*; The Georgia False Medicaid Claims Act, Ga. Code Ann. §§49-4-168 *et seq.*; The Hawaii False Claims Act, Haw. Rev. Stat. §§661-21 *et seq.*; The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. Ann. §§175/1 *et seq.*; The Indiana False Claims and Whistleblower Protection Act, Indiana Code §5-11-5.5; The Louisiana Medical Assistance Programs Integrity Law, La. R.S. 46:437.1 *et seq.*; The Massachusetts False Claims Act, Mass. Ann. Laws. Ch. 12, §§5A *et seq.*; The Michigan Medicaid False Claims Act, MCLS §§400.601 *et seq.*; Montana False Claims Act, Mont. Code Anno. §§17-8-401 et *seq.*; The Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*; The New Hampshire False Claims Act, RSA tit. XII, Ch. 167: 61-b; The New Jersey False Claims Act, N.J. Stat. §2A:32C-1 *et seq.*; The New Mexico Medicaid False Claims

Act, N.M. Stat. Ann. §§ 27-14-1 *et seq.*; The New York False Claims Act, NY CLS St. Fin. §§187 *et seq.*; The North Carolina False Claims Act, 2009-554 N.C. Sess. Laws §§1-605 *et seq.*; The Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§5053 *et seq.*; The Rhode Island False Claims Act, R.I. Gen. Laws §§9-1.1-1 *et seq.*; The Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-171 *et seq.*; The Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code §§36.001 *et seq.*; The Virginia Fraud Against Taxpayers Act, Va. Code §§8.01-216.1 *et seq.* and the Wisconsin False Claims for Medical Assistance Act, Wis. Stats. §§20.931 (hereinafter referred to as the "State False Claims Acts") to recover all damages, civil penalties and all other recoveries provided for under the Federal False Claims Act and the State False Claims Acts against the following defendants, and their affiliates, subsidiaries, agents, successors and assigns: Allergan, Inc., Amgen, Inc., AstraZeneca Pharmaceuticals LP, Biogen Idec, Inc., Bradley Pharmaceuticals, Inc., Cephalon, Inc., Eisai, Inc., Genzyme Corporation, Mallinckrodt Inc., Novo Nordisk, Inc., Reliant Pharmaceuticals, Inc., Sepracor, Inc., and Upsher-Smith Laboratories, Inc. (collectively, "Defendants").

I. SUMMARY

2. Congress established the Medicaid Drug Rebate Program to ensure that Medicaid, the government health care program for the indigent, would enjoy the same discounts on the price of prescription drugs as other large public and private purchasers. Congress therefore decided to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108.

3. To ensure that state Medicaid programs receive the best or lowest possible price for pharmaceuticals, the Social Security Act ("SSA") requires manufacturers whose products are sold to Medicaid beneficiaries to execute a rebate agreement with the federal government. 42

U.S.C. § 1396r-8(a)(1). Under this agreement, manufacturers pay rebates to state Medicaid programs. The amounts of the rebates are based on the Average Manufacturer's Price ("AMP") each manufacturer reports for its prescription drugs.

4. AMPs are reported by manufacturers to the Centers for Medicaid and Medicare Services ("CMS"). Since Medicaid rebates depend entirely on pricing data that the pharmaceutical manufacturers self-report to CMS, the accuracy of the data is critical.

5. Generally, the higher the AMP reported by a manufacturer, the greater the rebate owed by the manufacturer to Medicaid. The necessity of paying rebates incentivizes unscrupulous manufacturers to minimize their reported AMPs.

6. The Defendants named in this Complaint knowingly reported materially inaccurate AMPs to CMS from 2004 through the present (the "Relevant Time Period"), and thereby defrauded the Government Plaintiffs.

7. Beginning no later than 2004, Defendants and the pharmaceutical industry's wholesalers began executing and implementing distribution services agreements ("Service Agreements"). Service Agreements provide for a new trade structure known as "fee-for-service." Service Agreements generally obligate manufacturers to pay a fee to wholesalers (also referred to herein as "distributors") in exchange for services the wholesalers provide (the "Service Fee"). The Service Fee is typically an amount equal to a set percentage of the wholesalers' gross purchases of the manufacturers' products. For example, if a wholesaler's Service Fee is 2% of gross purchases, and gross purchases for a given quarter are $100, the Service Fee owed by the manufacturer is $2.

8. In exchange for the Service Fee, the wholesaler provides certain services to the manufacturer. While the Service Agreements at issue in this case differ in certain particulars,

many of the primary services addressed in the various Service Agreements are similar and include distribution services (buying, storing, packing and shipping drugs), inventory management services (maintaining an adequate supply of the manufacturer's drugs in inventory, without "over-purchasing" drugs), and data reporting services (providing detailed daily, weekly or monthly reports of sales and inventory data). *See* Section V below for a more detailed discussion of the services provided under the Service Agreements.

9. Defendants use these Service Fees to artificially lower their reported AMPs, which enables them, in violation of law, to materially underpay rebates to the state Medicaid programs. Each of the Defendants executed this fraud through one of two schemes: a) the "Discount Scheme," or b) the "Service Fee Scheme." Accordingly, the Defendants in this case fall into two categories which can be denoted as follows: a) the "Discount Defendants," and b) the "Service Fee Defendants."

10. The Discount Defendants – In calculating AMP, manufacturers must include all discounts they offer to wholesalers and other purchasers. 42 U.S.C. §1396r-8(k)(1); Medicaid Rebate Agreement, §I(a). The practical effect of including a discount in AMP is to *lower* AMP by the amount of the discount.

11. For reasons which are discussed in detail later in this Complaint, each of the services provided by a wholesaler has value to the manufacturer who purchases the service. That is to say, in the absence of a wholesaler to perform these services, the manufacturer would have to pay a third party to perform the services (or perform those services on its own at a substantial cost to the company). As such, the fees paid for these services are *bona fide*.

12. Notwithstanding the bona fide nature of the Service Fees they pay, the Discount Defendants fraudulently characterized their payments to wholesalers for these services as

"discounts" to the wholesalers, as opposed to what they were: fees for valuable services actually rendered. Since discounts, by law, are included in the calculation of AMP, this knowing mischaracterization of the fees paid to wholesalers reduced the manufacturers' reported AMPs by the amount of the "discount." Consequently, the Discount Defendants fraudulently understated their rebate obligations to the Government Plaintiffs.

13. The Service Fee Defendants – As noted above, manufacturers *must include all price increases in AMP*. Price increases cause AMP to rise, resulting in higher rebate obligations for manufacturers. However, all *bona fide* service fees are *excluded* from AMP. Thus, to the extent a manufacturer can disguise a price increase by hiding it within its contractual definition of "Service Fee," the price increase will not cause the manufacturer's reported AMP – and its consequent rebate obligations to the Government Plaintiffs – to rise.

14. The Service Agreements at issue in this case contain so-called "price appreciation" clauses. These clauses provide that when a manufacturer *increases* its prices on a particular drug, the Service Fee owed by the manufacturer to the wholesaler is *lowered* by the amount of the wholesaler's units in inventory (of that drug), multiplied by the amount of the price increase. Thus, when a manufacturer raises the price of a drug, that price increase *applies retroactively to the wholesaler's inventory*, even though the wholesaler previously purchased that inventory at a lower price.

15. The effect of these "price appreciations" is that the wholesaler retroactively pays the manufacturer in the amount of the price increase, dollar for dollar. Price "appreciations," therefore, are retroactive price increases. However, no invoice is sent from the manufacturer to the wholesaler for these price increases. For purposes of this Complaint, "price appreciations on inventory" and "price appreciation credits" will be referred to as "off-invoice price increases."

16. Under the Medicaid Drug Rebate Program, manufacturers must include all price increases – including off-invoice price increases – in their calculations of AMP. In violation of this obligation, the Service Fee Defendants disguised these off-invoice price increases by cramming them into the definition of Service Fee. This led to a reduction in the Service Fee by the amount of the off-invoice price increase, rather than an increase in AMP by the amount of the off-invoice price increase, thus providing Service Fee Defendants with a convenient but illegal method to exclude off-invoice price increases from their AMP calculations.

17. Through these two schemes, the Discount Defendants and the Service Fee Defendants knowingly reported, and continue to report, materially deflated AMPs for the drugs governed by the Service Agreements (the "Relevant Drugs"). By purposely and materially understating their AMPs, both the Discount Defendants and the Service Fee Defendants paid and continue to pay materially inadequate rebates to the Government Plaintiffs.

II. JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1345, 28 U.S.C. §1367, and 31 U.S.C. §3732.

19. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. §3732(a).

20. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), because Defendants transact business in this District.

III. PARTIES

21. Relator Ronald J. Streck is a lawyer and pharmacist. He has worked in the pharmaceutical industry for more than 40 years in various capacities, including sales, regulatory affairs and association management, including 11 years as the president and chief executive officer of the Healthcare Distribution Management Association. The active members of the

Healthcare Distribution Management Association include prescription drug wholesalers. At the time of the filing of this complaint, Relator served as the president and chief executive officer of Rx Distribution Network ("the Network"), a network of regional pharmaceutical wholesalers. In his capacity as CEO of the Network, Relator has negotiated the terms of agreements between pharmaceutical manufacturers and the wholesalers the Network represents, including the agreements at issue in this *qui tam* action.

22. Through his work as CEO of the Network, Relator became thoroughly familiar with the distribution agreements that manufacturers, including Defendants, execute with wholesalers. Relator discovered that Defendants, as a matter of contract, misreported and continue to misreport AMP data to government programs.

23. The United States is a plaintiff in this action. Throughout the Relevant Time Period, the United States Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS") were agencies of the United States and their activities, operations and contracts were paid from United States funds. Throughout the Relevant Time Period, Defendants' Relevant Drugs were provided to Medicaid recipients and the cost of those prescriptions were paid for in part by the United States.

24. The above-named States are plaintiffs in this action. Throughout the Relevant Time Period, Defendants' Relevant Drugs were provided to Medicaid recipients in each of the Plaintiff States, and those prescriptions were paid for in part by the Plaintiff States' respective Medicaid programs.

25. Defendant Allergan, Inc. ("Allergan") is a Delaware corporation, headquartered at 2525 Dupont Drive, Irvine California 92612. Allergan's drug products include those in the specialty areas of eye care, neurosciences, medical dermatology and urologics. During the

Relevant Time Period, the company's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

26. Defendant Amgen, Inc. ("Amgen") is a Delaware corporation, headquartered at One Amgen Center Drive, Thousand Oaks, CA 91320-1799. Amgen specializes in human therapeutics including those to treat cancer, kidney disease and rheumatoid arthritis. During the Relevant Time Period, the company's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

27. Defendant AstraZeneca Pharmaceuticals LP ("AstraZeneca") is a Delaware corporation, headquartered in Wilmington, Delaware. AstraZeneca's pharmaceutical products are concentrated in six therapeutic areas: gastrointestinal, cardiovascular, neuroscience, respiratory, oncology and infection. During the Relevant Time Period, the company's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

28. Defendant Biogen Idec, Inc. ("Biogen") is a Delaware corporation, headquartered at 14 Cambridge Center, Cambridge, MA 02142. During the Relevant Time Period, the company's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

29. Defendant Bradley Pharmaceuticals, Inc. n/k/a Nycomed US, Inc. ("Bradley") was a Delaware corporation, headquartered in West Fairfield, NJ. In 2008, Nycomed US, Inc., a New York corporation based in Melville, NY, acquired Bradley Pharmaceuticals, Inc., and

integrated Bradley's pharmaceuticals into its PharmaDerm division. Bradley's "Distribution Services Agreement" dated July 1, 2004 provides that it is binding upon the parties and their respective successors and assigns. During the Relevant Time Period, the company's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

30. Defendant Cephalon, Inc. ("Cephalon") is a company incorporated under the laws of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania, 19355. Cephalon's pharmaceutical products treat central nervous system disorders, pain and cancer. During the Relevant Time Period, the company's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

31. Defendant Eisai, Inc. ("Eisai") is the wholly owned U.S. subsidiary of Eisai, Ltd., a Japanese corporation. Eisai is headquartered at 100 Tice Boulevard, Woodcliff Lake, NJ 07677. Eisai sells and markets pharmaceutical products for the treatment of Alzheimer's disease, acid reflux and epilepsy. During the Relevant Time Period, the company's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

32. Defendant Genzyme Corporation ("Genzyme") is a Massachusetts corporation, headquartered at 500 Kendall Street, Cambridge, MA 02142. Genzyme's product portfolio is focused on rare disorders, renal diseases, orthopedics, organ transplant, diagnostic and predictive testing, and cancer. During the Relevant Time Period, the company's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

33. Defendant Mallinckrodt Inc. ("Mallinckrodt") is a Delaware corporation, headquartered in St. Louis, Missouri. Mallinckrodt's pharmaceutical products include generic and brand drugs for the treatment of depression, and the treatment of cold-related cough. During the Relevant Time Period, the company's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

34. Defendant Novo Nordisk, Inc., ("Novo Nordisk") is a Delaware corporation with its principal office in Princeton, New Jersey. Novo Nordisk's product line focuses on diabetes care, growth hormone therapy and hormone replacement therapy. During the Relevant Time Period, the company's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

35. Defendant Reliant Pharmaceuticals Inc. is a Delaware corporation, headquartered at 110 Allen Road, Liberty Corner, NJ 07938. Reliant Pharmaceuticals Inc.'s product line focuses on cardiovascular drugs. In 2007, GlaxoSmithKline, PLC ("Glaxo") acquired Reliant Pharmaceuticals Inc. Reliant's "Distribution Services Agreement" dated February 1, 2005 provides that it is binding upon the parties and their respective successors and assigns. Reliant Pharmaceuticals Inc. and Glaxo are referred to collectively herein as "Reliant." During the Relevant Time Period, the Reliant's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

36. Defendant Sepracor, Inc. n/k/a Sunovion Pharmaceuticals Inc. ("Sepracor") was a Delaware corporation, headquartered in Marlborough, MA. In 2009, Dainippon Sumitomo

Pharma Co., Ltd, a Japanese company, acquired Sepracor. In 2010, Sepracor's name was changed to Sunovion Pharmaceuticals Inc. Sepracor's "Distribution Services Agreement" dated January 1, 2007 provides that it is binding upon the parties and their respective successors and assigns. During the Relevant Time Period, Sepracor's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

37. Defendant Upsher-Smith Laboratories, Inc. ("Upsher-Smith"), is a Minnesota corporation, headquartered at 6701 Evenstad Drive, Maple Grove, MN 55369. Upsher-Smith's product portfolio is focused in the areas of women's health, dermatology and cardiology. During the Relevant Time Period, the company's Relevant Drugs were paid for by the Government Plaintiffs, and the company materially and fraudulently underpaid its Medicaid rebate obligations to the Government Plaintiffs.

IV. THE APPLICABLE LAW

A. The Federal and State False Claims Acts

38. The Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, provides, *inter alia*, that any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, or any person who knowingly makes uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, is liable to the United States for treble damages and a civil monetary penalty. 31 U.S.C. § 3729(a)(1)(A)-(B).[1]

39. The FCA further provides that any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money

[1] Prior to the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Public Law 111-21 (enacted May 20, 2009), Section 3729(a)(1)(A) was Section 3729(a)(1), which imposed liability on any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval."

or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States for treble damages and a civil monetary penalty. 31 U.S.C. § 3729(a)(1)(G).[2]

40. The terms "knowing" and "knowingly" are defined to mean "that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

41. "[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

42. Each of the Plaintiff States has individually enacted a False Claims Act. Each of those Acts is modeled after the Federal FCA, and each contains provisions similar to those quoted above. Relator asserts claims under the State FCAs for the State portion of Medicaid false claims detailed in this complaint.

B. The Medicaid Drug Rebate Program

43. To curb mounting Medicaid drug expenditures, Congress created the Medicaid Drug Rebate Program ("Medicaid Rebate Program" or "Rebate Program") under the Omnibus Budget Reconciliation Act of 1990. To receive Medicaid coverage for outpatient prescription drugs, drug manufacturers are required to enter into a Medicaid Rebate Agreement with the Secretary of Health and Human Services. *See* 42 U.S.C. § 1396r-8(a)(1).

44. Under the Rebate Program, manufacturers pay a rebate to each individual state's Medicaid program for all outpatient pharmaceuticals paid for by that state's Medicaid program.

[2] Prior to FERA, Section 3729(a)(1)(G) was formerly Section 3729(a)(7), which imposed liability on any person who "knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government."

That is, Medicaid reimburses retail pharmacies for the cost of prescriptions and then, under the terms of the Rebate Program, the state Medicaid programs receive rebates from manufacturers. This process is designed to give Medicaid the benefit of the lowest price at which a manufacturer sold a drug to any commercial customers.

45. Medicaid is a jointly-funded federal-state program. 42 U.S.C. §1396b(a)(1); 42 U.S.C. §1396r-8(b)(1)(B). The amount paid by the federal government is known as the Federal Matching Assistance Percentage ("FMAP").

46. Each state's request for money from the federal government and the corresponding FMAP is submitted to CMS on Form CMS-64. This form includes exact dollar figures reflecting the "Drug Rebate Offset" as well as a "Medicaid Drug Rebate Schedule." The amount received by a state in Medicaid rebates is considered a reduction in the total amount expended under that state's Medicaid plan. Therefore, the less any individual state receives in Medicaid rebates, the greater the total amount expended by the state, and the more the federal government must correspondingly pay to the state to meet the federal government's share of the joint costs.

47. More specifically, each quarter, state Medicaid programs report to CMS their utilization data – the quantity of each drug paid for by each state Medicaid program during that quarter. 42 U.S.C. § 1396r-8(b)(2). At or about the same time, manufacturers report to CMS the AMPs of their drugs for that quarter. *Id.* § 1396r-8(b)(3). Relying on the accuracy of the data provided by manufacturers, CMS calculates the unit rebate amount ("URA"), which the states then use to invoice each manufacturer for the rebate it owes.

48. The amount of the rebate on a generic drug is calculated as the product of: (1) the total number of each dosage form and strength paid for during the rebate period and (2) 11% of

the AMP for the rebate period (or, from Jan. 1, 2010 to the present, 13% of the AMP for the rebate period). *See* The Patient Protection and Affordable Care Act, Pub. Law No. 111-148, §2501(a) and (b); 42 U.S.C. §1396r-8(c)(3).

49. For a brand-name drug, the total amount owed by a manufacturer in rebates is the sum of its two principal components: 1) the Basic Unit Rebate Amount ("Basic Rebate"), and 2) the Additional Unit Rebate Amount ("Additional Rebate"). 42 U.S.C. §1396r-8(c)(1).

50. The Basic Rebate for brand drugs is equal to the product of: (1) the total number of each dosage form and strength paid for during the rebate period and (2) the greater of (a) the difference between AMP and the best price ("BP") [3] for the dosage form and strength of the drug, or (b) 15.1% of the AMP for the rebate period (or, from Jan. 1, 2010 to the present, 23.1% of the AMP for the rebate period). *See* The Patient Protection and Affordable Care Act, Pub. Law No. 111-148, §2501(a) and (b); 42 U.S.C. §1396r-8(c)(1).

51. When the percentage increase in AMP for a dosage form and strength of a drug exceeds the percentage increase in the Urban Consumer Price Index ("CPI") since the initial sale of the drug, the manufacturer owes an Additional Rebate.[4]

52. During the Relevant Time Period, pharmaceutical prices for brand name drugs have risen annually at a pace which far exceeds increases in the CPI. Consequently, nearly every one of Defendants' price increases during the same period exceeded the growth in the CPI. Appended as Exhibit A is a chart, hereby incorporated by reference as if fully set forth herein,

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[3] Specifically, Best Price is "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States . . . ." *See* 42 U.S.C. §1396r-8(c)(1)(C)(i). Best Price includes all discounts, rebates, or other price concession. *See* 42 U.S.C. §1396r- 8(c)(1)(C)(ii).

[4] *See* 42 U.S.C. §1396r-8(c)(2) (describing the calculation of additional rebate as the amount by which the AMP "for the dosage form and strength of the drug for the period exceeds the [AMP] for. . . for the calendar quarter beginning July 1, 1990. . . increased by the percentage by which the consumer price index for all urban consumers for the month in which the rebate period begins exceeds such index for September 1990").

showing drugs manufactured by each Defendant, and the corresponding prices for those drugs.[5] This chart shows actual price increases for each Defendant's products and the percentage increase over the previous price.[6] Appended hereto as Exhibit B is a chart, hereby incorporated by reference as if fully set forth herein, showing the increase in the CPI during the Relevant Period. This data demonstrates that, with respect to the Relevant Drugs, prices increased far faster than the CPI over the same period, and thus Additional Rebates are owed by Defendants.

(i) The Definition of AMP

53. From the beginning of the Relevant Time Period until November 2010, the SSA defined AMP 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." 42 U.S.C. §1396r-8(k)(1) (Feb. 2010). That definition confirms that: 1) discounts are included in AMP (because they lower the price "paid to the manufacturer"), and 2) fees paid in exchange for services should be excluded from AMP, because such fees are payments for legitimate services rendered by wholesalers (and thus are not related to drug prices).

54. Through the rulemaking process, CMS promulgated a regulation effective July 2007 which stated what was already obvious: *bona fide* Service Fees are excluded from the calculation of AMP. 72 Fed. Reg. 39142 (July 17, 2007) (codified at 42 C.F.R. Part 447) ("2007 AMP Regulation")("AMP excludes . . . [b]ona fide service fees"). 42 C.F.R. §447.504(h)(19).

55. The 2007 AMP Regulation defined *bona fide* service fees as:

> fees paid by a manufacturer to an entity, that represent fair market value for a *bona fide*, itemized service actually performed on

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[5] These prices are based on Wholesale acquisition cost ("WAC"), which is the price at which a pharmaceutical company typically sells a drug to a wholesaler, less any applicable discounts. Because AMP data is Defendants' proprietary information and is inaccessible to Relator, Relator uses WAC here to approximate AMP.

[6] This data comes from Medi-Span, which is a commercial publisher of drug transaction data which is relied upon by government agencies and health care providers across the United States.

> behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

42 C.F.R. §447.502.

56. This definition encompasses the following four elements:

1) The fee paid must be for a *bona fide*, itemized service that is actually performed on behalf of the manufacturer;

2) The manufacturer would otherwise perform or contract for the services in the absence of the service arrangement;

3) The fee represents fair market value; and

4) The fee is not passed on in whole or part to a client or customer of an entity.

See 71 Fed. Reg. 69624, 69667-9 (Dec. 1, 2006) (ASP regulations' definition of *bona fide* service fees); 72 Fed. Reg. 39142, 39182 (2007 AMP Regulation expressly adopts the interpretation of the definition of *bona fide* service fees as set forth in the ASP regulations). CMS interprets the first two elements "to encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs." 71 Fed. Reg. at 69667-9. With respect to the third element that the fee must represent fair market value, CMS recognizes that it is appropriate to either calculate fair market value for a set of itemized services, or to calculate fair market value on a per-service basis. *Id.* As to the fourth element that the fee is "not passed on," if the fee meets the first three requirements, the manufacturer may presume it was not passed on to a client or customer of an entity. *Id.*

57. In November 2010, the definition of AMP was re-codified to specifically state what was already obvious, i.e., that *bona fide* service fees are excluded from AMP:

> (i) In general. – The average manufacturer price for a covered outpatient drug shall exclude –

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> (II) *bona fide* service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);

42 U.S.C. § 1396r-8(k)(1).[7]

58. Further, as to the Discount Defendants, the Medicaid Rebate Statute again expressly states that discounts must be included in AMP: "any discounts, rebate payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the [AMP] for a covered outpatient drug." *Id.*

(ii) The Medicaid Rebate Agreement

59. The Medicaid Rebate Agreement entered into by all manufacturers participating in Medicaid – which includes all of the Defendants in this lawsuit – states that AMP is "the average unit price paid to the Manufacturer for the drug . . . by wholesalers." Medicaid Rebate Agrmt, § I(a). The Rebate Agreement further clarifies that "AMP includes cash discounts allowed and all other price reductions . . . which reduce the actual price paid." *Id.* Also, the Rebate Agreement requires manufacturers to revise AMP for previous quarters if "discounts or other arrangements subsequently adjust the prices actually realized." *Id.*

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[7] This Medicaid Rebate Statute amendment was part of the March 23, 2010 passage of the Patient Protection and Affordable Care Act ("ACA"). Among its provisions, the ACA amended section 1927(k) of the Social Security Act, 42 U.S.C. §1396r-8(k), clarifying the definition of AMP. 75 Fed. Reg. 69591, 69592 (Nov. 15, 2010). This was partly in response to previous litigation by the National Association of Chain Drug Stores and others against the Department of Health and Human Services, challenging the calculations of federal upper limits based on the definition of AMP. *National Ass'n of Chain Drug Stores v. U.S. Dep't of Health & Human Servs.*, 631 F. Supp.2d 17, 18 (D.D.C. 2009). As a result of this Medicaid Rebate Statute amendment, CMS withdrew its 2007 AMP Regulation. *See* 75 Fed. Reg. 69591.

(iii) The Medicaid Rebate Operational Training Guide

60. The Medicaid Rebate Operational Training Guide, F11 (2001), states that AMP should be reduced by discounts:

> Basically, AMP is calculated as NET quarterly sales divided by the number of units sold.
>
> "Net quarterly sales" are derived after all required adjustments are made (e.g., discounts, rebate for state-only programs, breakage, etc.).

(iv) Conclusion: AMP Includes Discounts and Excludes Service Fees Throughout the Relevant Time Period

61. Although the AMP statute, the AMP regulation, the Rebate Agreement, and the Medicaid Rebate Operational Training Guide have been amended over time, three things have remained consistent. First, discounts are included in AMP because they affect prices actually realized by manufacturers. Second, fees paid in exchange for services rendered are not discounts. Third, off-invoice price increases cannot be excluded from AMP by cramming those price increases into a self-serving definition of Service Fees or by offsetting Service Fees by off-invoice price increases.

62. In addition, there is a parallel statutory drug pricing benchmark – average sales price ("ASP") – which directly corroborates Relator's statement of the law.

63. ASP is a pricing benchmark which applies to Medicare Part B, while AMP is a pricing benchmark which applies to Medicaid. Both serve a similar function: to limit or "cap" the government's prescription drug costs.

64. ASP expressly states that discounts should be included in the ASP calculation. 42 U.S.C. § 1395w-3a(c)(1), (c)(3). Further, in 2006, CMS enacted ASP regulations defining *bona fide* Service Fees. The regulations expressly re-affirmed that Service Fees are payments for

legitimate services rendered (and thus are not related to the price of the drug), and thus manufacturers must exclude *bona fide* Service Fees from ASP. *See* 71 Fed. Reg. 69624, 69668 (Dec. 1, 2006) (relevant sections codified at 42 C.F.R. § 414.802, 414.804).

V. DEFENDANTS' SCHEMES TO DEFRAUD GOVERNMENT PAYERS

65. Starting no later than 2004, manufacturers and wholesalers developed a new trade structure which involved the use of Service Agreements. Under Service Agreements, manufacturers periodically pay wholesalers Service Fees. Service Fees are calculated by multiplying a wholesaler's gross purchases of a manufacturer's product by a certain percentage.

66. While the Service Agreements at issue in this case differ in certain particulars, many of the primary services provided by wholesalers pursuant to Service Agreements are as follows:

- **Distribution Services** – buying storing, packing and shipping drugs from the manufacturer to customers. This includes emergency delivery services – delivering the manufacturer's products on an emergency 24/7/365 basis.

- **Data Reporting Services** – generating daily, weekly, or monthly inventory reports (EDI 852 data) and sales reports (EDI 867 data).

  The inventory reports (852 data) provides the manufacturer with aggregate sales, the wholesaler's inventory levels (on-hand and on-order), demand forecasts, "morgue inventory" (returned goods), special needs forecast by the distributor for particular events, units ordered by customers, and orders filled by the wholesaler.

  The sales reports (867 data) provides the manufacturer with specific information regarding the distributors' customers, including the identity and location of the customer, and the amounts ordered and amounts returned by the customer.

- **Inventory Management** – maintaining an adequate supply of the manufacturer's drugs in inventory, without "over-purchasing" drugs in anticipation of a price increase (also known as "speculative buying" or "spec buying"), including using automated inventory balancing systems, and maintaining environmentally controlled storage facilities.

67. Other categories of services, described more fully below, include:

- Chargeback and returns processing services
- Customer service support
- New product launch services
- Consolidated deliveries to providers
- Consolidated accounts receivable management
- The provision of sophisticated ordering technology

A. The Discount Defendants' Scheme

68. Under the law defining AMP during the Relevant Time Period, all discounts are included in AMP. The practical effect of including a discount in AMP is to *lower* AMP by the amount of the discount.

69. As noted above, each of the services provided for in the Service Agreements has real value to the manufacturer/purchaser. That is to say, in the absence of wholesalers to perform these services, the manufacturer would have to pay third parties to perform the services (or perform those services on its own at a substantial internal cost).

70. Distribution services, including emergency delivery services, are valuable to Defendants. If wholesalers did not provide distribution services to the manufacturers, the manufacturers would be required to pay a third party logistics company – e.g., FedEx – to pick up, pack, and ship its products. These costs can be particularly high when emergency delivery is needed on a 24/7/365 basis.

71. The 852 inventory data service is valuable to Defendants – among other things, it permits Defendant to use a series of numeric metrics to make critical decisions regarding when and how much of their products need to be manufactured. If the wholesalers did not provide 852 data services to the manufacturers, the manufacturers would be required to pay a third party to for this information, including aggregate sales data, inventory levels (on-hand and on-order), demand forecasts, "morgue inventory" (returned goods), special needs forecasts for particular events, units ordered by customers, and orders filled.

72. The 867 sales data service is valuable to Defendants – among other things, it permits Defendants to understand who their customers are (including their "problem" customers who return an undue amount of products), and, conversely, to see which potential customers are *not* buying from the manufacturer (and thus who the manufacturer should target for marketing/sales). If the wholesalers did not provide 867 data services to the manufacturers, the manufacturers would be required to pay a third party for this information.

73. Inventory management services are valuable to Defendants. By requiring wholesalers to maintain an adequate supply of the manufacturer's drugs in inventory, without "over-purchasing" drugs in anticipation of a price increase (also known as "speculative buying"), manufacturers are able to retain profits which would otherwise inure to wholesalers. Additionally, by requiring wholesalers to use and maintain environmentally-controlled storage facilities for inventory, manufacturers avoid the cost and expense of paying a third party to store its products in such an environment.

74. Based on the Service Agreements themselves, the Discount Defendants fraudulently characterized their payments to wholesalers as "discounts," as opposed to what they were: payments for *bona fide* services rendered. Since discounts, by law, are included in AMP, this artificial device created by the Discount Defendants worked: it served to *reduce* AMP by the amount of the "discount." Consequently, the Discount Defendants knowingly and fraudulently understated their rebate obligations to the Government Plaintiffs.

B. The Service Fee Defendants' Scheme

75. As noted above, *bona fide* service fees are *excluded* from AMP. Thus, to the extent a manufacturer can disguise a price increase by offsetting it against a Service Fee which it excludes from its AMP calculations, the price increase will not cause the manufacturer's AMP – and its rebate obligations to the Government Plaintiffs – to rise as it should.

76. Also as noted above, the Service Agreements executed by the Service Fee Defendants contain "price appreciation" clauses. These clauses provide that when a manufacturer increases its prices, the Service Fee owed by the manufacturer to the wholesaler is *lowered* by the amount of the wholesaler's units in inventory, multiplied by the amount of the price increase. No invoice is sent from the manufacturer to the wholesaler for these price increases. Instead, the Service Fee Defendants simply reduce the Service Fees they owe to the wholesaler by the amount of the price increase on inventory. Thus, when a manufacturer raises the price of a drug, that price increase applies to the wholesaler's inventory, even though the wholesaler previously purchased that inventory at a lower price. The Service Fee Defendants thereby bury these off-invoice price increases in their accounting for Service Fees.[8]

77. "Price appreciation" on inventory a wholesaler has previously purchased at a lower price, therefore, is a retroactive price increase that manufacturers must include in their AMP calculations. The effect of the offset against the Service Fee, however, is to disguise the price increase and to illegally exclude it from the calculation of AMP.

78. The Service Fee Defendants' definition of Service Fee has enormous evidentiary and legal impact:

- The legal definition of AMP excludes *bona fide* Service Fees.
- As a matter of contract, the Service Fee Defendants defined Service Fees in a manner which "absorbed" off-invoice price increases on inventory.
- The Service Agreements provide direct written evidence that the Service Fee Defendants crammed off-invoice price increases into their respective definitions of Service Fees.

[8] It should be noted that during the Relevant Time Period, the Relator has attended numerous industry conferences which addressed Service Agreements. The issue of appreciation clauses as they relate to and affect service fees, rebates and reimbursements was not disclosed or discussed to the Relator's knowledge. Nor did comments by the industry regarding the proposed CMS Rule on AMP ever mention or discuss the presence of price appreciation clauses. *See* Federal Register, Vo. 72, No. 136 (July 17, 2007), 42 C.F.R. Part 447 [CMS-2238-FC].

- Since Service Fees are excluded from AMP, and the Service Fee Defendants included off-invoice price increases in their calculation of Service Fees, *a priori*, the Service Fee Defendants knowingly *did not* factor off-invoice price increases into their AMP calculations.

- This knowing failure violated the Medicaid Rebate Statute and the Medicaid Rebate Agreement, and caused substantial financial harm to the Government Plaintiffs.

79. In sum, the law requires manufacturers to factor all price increases into AMP. Defendants knowingly failed to include off-invoice prices increases on inventory into their AMP calculations, thereby fraudulently reducing their rebate obligations to the Government Plaintiffs.

VI. SPECIFIC ALLEGATIONS AGAINST EACH DEFENDANT

A. Service Fee Defendants

1. Allergan

80. Allergan is a Service Fee Defendant.

81. On January 1, 2006, Allergan executed a "Distribution Services Agreement" with a national wholesaler ("Allergan DSA").[9] According to the Allergan DSA, the purpose of the agreement is for Allergan to purchase certain services from the wholesaler including "distribution services, logistics and inventory management services, data reporting services, administrative services, and financial services, and Customer wishes to purchase such services from Service Supplier."

82. Article 2 of the Allergan DSA states that "Customer agrees to compensate Service Supplier in accordance with the fee structure set forth on Schedule A for each of the services described below and provided by Service Supplier to Customer"

83. In § 2.1 of the Allergan DSA, the wholesaler agrees to provide "Base Distribution Services[,]" including the provision of sophisticated ordering technology, daily deliveries to

[9] A redacted version of this agreement is attached within Exhibit C and is incorporated by reference as if fully set forth herein.

providers, emergency shipments to providers, contract and chargeback administration, returns processing, customer service support, adequate inventories, and licensed and environmentally controlled facilities.

84. Section 2.2 requires the wholesaler to provide certain "Inventory Management Services[,]" including inventory maintenance levels, purchase limits and best efforts to ensure product availability. Section 2.3 requires the wholesaler to provide certain "Data/Reporting Services[,]" including daily inventory reports ("852 data") and weekly sales reports ("867 data") for all products and formulations. In addition, the Allergan DSA requires the wholesaler to provide certain service levels, order monitoring, new product launch support, and purchase forecast requirements, *see* § 2.4-2.6. The Allergan DSA expressly describes the relationship between Allergan and the wholesaler as that of a "service buyer-seller." Allergan DSA § 4.1.

85. In exchange for these services, Allergan agrees to pay the wholesaler a "Value Guarantee" (i.e., a service fee), of 3.3% on its products[10] on a yearly basis. *See* Art. 2 Preamble; Schedule A. The salient portions of Schedule A are excerpted below.

> Value Guarantee and Credits: During each year of this Agreement, Service Supplier will receive a total of 330 Basis Points (3.30%) of value on Service Supplier's total Net Product Purchases excluding Botox® or Botox® Cosmetic (which are handled separately as set forth below) (the "Value Guarantee"). For purposes of this Schedule A, "Net Product Purchases" are defined as gross purchases less shortage claims, product refusals, product damaged in transit and refused by Service Supplier, and product returns. **Customer will receive credit towards the Value Guarantee for all margins earned by Service Supplier on Aggregate Inventory – DSD and Aggregate Inventory – Brokerage resulting from a pricing action by Customer, quarterly promotions, deals, off-invoice allowances, discounts, incremental service opportunities, or any other promotional undertaking or method, excluding those that are intended for Providers** (collectively "Value Credits"). Within thirty (30) days of the end of each year during the term of this Agreement, Customer will perform a true-up and make payment of remuneration payable to Service Supplier under this paragraph, and in event the amount of the Value Guarantee exceeds the amount of the Value

[10] Except Botox® and Botox Cosmetic®, which are handled separately in another portion of the Allergan DSA.

> Credits, then Customer shall pay to Service Supplier such difference within sixty (60) days of the end of such year. (emphasis added).

86. Although the Allergan DSA references various contractually defined terms and uses otherwise camouflaged language, the bottom line is that in return for services rendered, the wholesaler contracted to receive a Service Fee of 3.3% on its purchases from Allergan, and Allergan contracted to subtract any off-invoice price increases from the Service Fee. In other words, the parties agreed that Allergan would not invoice the wholesaler for price increases on products previously purchased by the wholesaler, but rather would collect that price increase by cutting back the Service Fee on a dollar-for-dollar basis. This artificial device – purely a creature of contract – "permitted" Allergan to disguise retroactive, off-invoice price increases within the definition of Service Fee. Consequently, since Service Fees are *excluded* from AMP, Allergan was able to exclude these price increases from its AMP reporting by the terms of its own contract, AMP was knowingly understated, and Allergan failed to meet its rebate obligations to the Government Plaintiffs.

87. There is further evidence that Allergan did not factor off-invoice price increases into its AMP calculations. In 2005, Relator questioned Allergan about the legality of certain distribution practices. Then-Vice President and Assistant General Counsel at Allergan, Matthew Maletta, responded in a December 8, 2005 letter to Relator, stating:

> the issue of fee-for-service agreements bears no relation to the prices Allergan charges for its products. Allergan's prices are not affected in any way by fee-for-service arrangements. In fact, these arrangements do not involve Allergan selling any product or service; to the contrary, where Allergan has entered into such arrangements, Allergan is the purchaser.

88. Through the Allergan DSA and the above letter, Allergan has admitted that it did not factor Service Fees – which Allergan expressly defined to include price increases on inventory – into its AMPs, and thus fraudulently understated its rebate obligations to the

Government Plaintiffs. During the Relevant Time Period, Defendant Allergan participated in the Medicaid Program and Allergan's Relevant Drugs were paid for by all of the Government Plaintiffs. For example, Allergan's drug, Alphagan P Opthalmic Solution 0.15%, 5 units, NDC# 00023-9177-05,[11] had approximately $74,940,721.98 in Medicaid utilization from 2004 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

89. Further, the prices on Allergan's Relevant Drugs increased during the Relevant Time Period. *See* Exhibit A (showing price increases on Allergan's Relevant Drugs). For example, the price of Alphagan P Opthalmic Solution 0.15%, increased a total of 87.22%, with prices increases occurring on the following dates: 1/10/2004; 2/5/2005; 1/22/2006; 2/3/2007; 1/19/2008; 8/2/2008; 1/3/2009; 5/2/2009; 8/1/2009; and 7/10/2010. *See* Exhibit A (showing price increases on Amgen's Relevant Drugs).

90. By contrast, the CPI for the period 2004-2010 rose less than 3% per year. *See* Exhibit B. A similar analysis applies to the remainder of this Defendant's Relevant Drugs. Utilization data for each of the Government Plaintiffs is attached as Exhibit E and is incorporated herein by reference as if fully set forth herein.

91. By failing to factor its off-invoice price increases in its AMP calculations, Allergan: (1) caused CMS to underreport the unit rebate amounts to the states, (2) caused itself to pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to from Allergan, and (4) caused the federal government to pay more than it should have in FMAP funds to the states. As a result of this fraudulent conduct, Allergan violated

[11] NDC stands for National Drug Code.

Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

2. Amgen

92. Amgen is a Service Fee Defendant.

93. On February 1, 2007, Amgen executed a "Wholesale Distribution Agreement" ("Amgen WDA") with a national wholesaler.[12] The Amgen WDA provides that the wholesaler will distribute Amgen products and provide certain other services, including maintaining sufficient inventory, providing environmentally controlled storage facilities, and providing particularized sales information reports. The Agreement further states that "relationship between Amgen and Wholesaler is that of a buyer and a seller and a service provider and recipient." Amgen WDA § 12.9.

94. With respect to price, Section 4.1 states that the price to the wholesaler "shall be Amgen's WAC prevailing at the time of ordering by [the wholesaler]."

95. Amgen agreed in Section 4.6 to make payments to the wholesaler but reserved the right to offset any such payments with any price increases on product. Specifically:

> Amgen Payments to Wholesaler. Amgen shall make the payments to Wholesaler as described in, and subject to the conditions set forth in, Exhibit 4.6. Notwithstanding the foregoing, Amgen shall have the right to set off any such payments against any amounts payable by Wholesaler hereunder pursuant to and in accordance with Section 12.10 herein.

96. Exhibit 4.6 to the Amgen WDA details the itemized services that the wholesaler provides and the fee that Amgen pays for each service in return. For example, Section 1 of Exhibit 4.6 describes the "Order Fulfillment Service Fee" whereby Amgen pays a fee to the wholesaler of up to $1,189,200 based on the wholesaler's order fulfillment rate. Section 2 details

[12] A redacted version of this agreement is attached within Exhibit C and is incorporated by reference as if fully set forth herein. The parties amended the Amgen WDA, twice, on June 29, 2007 without materially altering its terms. Those amendments are also attached within Exhibit C and are incorporated by reference as if fully set forth herein.

information services that the wholesaler provides in exchange for monthly "Data Fees" of up to $261,076. Section 3 details an "inventory management performance fee" of up to $396,400. As Amgen and the wholesaler agreed that these Service Fees represent the fair-market value of the services the wholesaler performs, the Amgen WDA intends that the parties treat the Service Fees as *bona fide*.

97. The Amgen WDA further supports the *bona fide* nature of the Service Fees. Specifically, Section 8.6 of the Amgen WDA states:

> [The wholesaler] represents and warrants that prices it charges customers for drugs shall not be related in any way to the service fees earned by the wholesaler pursuant to this agreement, and that no such amounts received by the wholesaler through this agreement shall be passed on, directly or indirectly, to any such customer. Wholesaler represents and warrants that the fees earned in this agreement represent fair market value for bona fide services Wholesaler provides on behalf of Amgen. Wholesaler shall cooperate with Amgen or its valuation consultant in confirming the foregoing.

98. As noted above, the Amgen WDA provides that off-invoice price increases are netted against Service Fees. More specifically, Section 5 of Exhibit 4.6 states:

> **Price increase deduction**. Following any Product price increase, Amgen shall calculate the value of any price increase by taking the value, at the pre-price increase WAC of [The wholesaler's] inventory on-hand at the time of the price increase ("Wholesaler Inventory Value") and multiplying the Wholesaler Inventory Value by the percent price increase ("Inventory Value Change"). Amgen shall have the right to deduct the Inventory Value Change from any fees payable by Amgen hereunder. In the event the Inventory Value Change exceeds the amount of fees payable by Amgen, Amgen shall notify [The wholesaler] of same in writing, and [The wholesaler] shall pay to Amgen the amount of the Inventory Value Change within thirty (30) days of such written notice.

99. By deducting Inventory Value Changes (i.e., off-invoice prices increases) from the Service Fees it pays, Amgen crams off-invoice price increases into its contractual definition

of Service Fees. Since Service Fees are excluded from AMP, Amgen was able to exclude these price increases from its AMP reporting by the terms of its own contract. Amgen's knowing failure to factor off-invoice price increases in its AMP calculations resulted in understated AMPs, and in turn, less money in rebate payments to the Government Plaintiffs.

100. As alleged above, during the Relevant Time Period, Defendant Amgen participated in the Medicaid Program and Amgen's Relevant Drugs were paid for by all of the Government Plaintiffs. For example, Sensipar Oral Tablet 30 MG, 30 units, 55513-0073-30 had approximately $134,207,171.01 in Medicaid utilization from 2004 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

101. Further, the prices on Amgen's Relevant Drugs increased during the Relevant Time Period. For example, the price of Sensipar Oral Tablet 30 MG increased a total of 52.35%, with prices increases occurring on the following dates: 4/5/2004; 4/1/2005; 4/1/2006; 12/1/2006; 9/6/2007; 8/1/2008; 5/8/2009; 1/8/2010; 9/9/2010. *See* Exhibit A (showing price increases on Amgen's Relevant Drugs).

102. By contrast, the CPI for the period 2004-2010 rose less than 3% per year. *See* Exhibit B. A similar analysis applies to the remainder of Defendant's Relevant Drugs. Utilization data for each of the Government Plaintiffs is attached as Exhibit E and is incorporated herein by reference as if fully set forth herein.

103. By failing to factor its off-invoice price increases in its AMP calculations, Amgen: (1) caused CMS to underreport the unit rebate amounts to the states, (2) caused itself to pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to from Amgen, and (4) caused the federal government to pay more than it should

have in FMAP funds to the states. As a result of this fraudulent conduct, Amgen violated Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

3. Bradley

104. Bradley is a Service Fee Defendant.

105. On March 7, 2005, Bradley executed a "Distribution Services Agreement" ("Bradley DSA") with a national wholesaler. The agreement states that it is effective as of July 1, 2004. The parties executed an amendment to the Bradley DSA on August 1, 2007.[13]

106. The Bradley DSA provides that the wholesaler will distribute Bradley's products and provide other services, including logistics and inventory management services, administrative services, financial services and "certain additional services . . . as needed and agreed upon by both parties." In Section 2.1 of the Bradley DSA, the wholesaler agrees to provide "Base Distribution Services," including, without limitation, ordering technology, daily consolidated deliveries to providers, consolidated accounts receivable management, contract and chargeback administration and customer service support.

107. Section 2.2 of the Bradley DSA requires the wholesaler to provide certain "Inventory Management Services," including but not limited to inventory maintenance levels, purchase limits, and best efforts to ensure product availability. Section 2.3, requires the wholesaler to provide certain Data/Reporting services, including weekly Inventory Reports (852 data) and monthly Sales Reports (867 data). In addition, the contract provides for service levels, order monitoring, new product launch support, and purchase forecast requirements.

[13] A redacted version of this agreement and the amendment are attached within Exhibit C and are incorporated by reference as if fully set forth herein.

108. Consistent with the above, Section 4.1 of the Bradley DSA describes the relationship between Bradley and The wholesaler as that of a "service buyer-seller." Thus, by the terms of its DSA, Bradley pays the wholesaler a *bona fide* service fee.

109. In return for these services, the preamble to Article 2 of the Bradley DSA refers to Schedule A for a fee structure. For the first three years of the Bradley DSA, the fee, broken into a Base Service Fee and a Purchase Forecast Requirement Fee, ranged from 7%-7.5%.[14] However, in the event of a "price appreciation" on inventory after a "pricing action," (i.e., a retroactive, off-invoice price increase), Bradley is entitled to "credit" toward the Service Fee.

110. More specifically, Schedule A to the Bradley DSA defines "Service Fee Credits" as credits toward the Service Fee, resulting from "price appreciation on inventory on hand after a Customer pricing action," and "[m]argin earned on quarterly promotions, deals, off-invoice allowances, or any other method, excluding those that are intended for Service Supplier's Providers." Schedule A to the August 2007 amendment further describes the credits to which Bradley is entitled for "Inventory Appreciation." Under the modified arrangement, Bradley continues to adjust the Service Fee by "the difference in value of on hand inventory and on order inventory actually received at the lower price immediately preceding a price increase and the value of such inventory immediately after a price increase for Product."

111. By virtue of the *bona fide* nature of the services the wholesaler provides to Bradley, the express terms of the Bradley DSA indicate that Bradley treats the Service Fees it pays as *bona fide*, thus "allowing" Bradley to exclude those fees from its calculations of AMP. By netting off-invoice price increases against the Service Fees, Bradley improperly excludes

[14] In Schedule A to the amendment to the Bradley DSA, the fee dropped to 6.75% from August 1, 2007 and thereafter.

price increases from its AMP calculations, in turn understates its AMP, and consequently underpays the rebates it owes to the Government Plaintiffs.

112. As alleged above, during the Relevant Time Period, Defendant Bradley participated in the Medicaid Program and Bradley's Relevant Drugs were paid for by all of the Government Plaintiffs. For example, Bradley's drug, Solaraze Transdermal Gel 3 %, 100 units, 10337-0803-01 had approximately $36,103,097.03 in Medicaid utilization from 2005 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

113. Further, the prices on Bradley's drugs increased during the Relevant Time Period. For example, the price of Solaraze Transdermal Gel 3 %, increased a total of 110.15%, with prices increases occurring on the following dates: 11/22/2006; 3/30/2007; 6/14/2007; 9/22/2007; 4/28/2008; 12/1/2008; 6/1/2009; 12/4/2009; 7/15/2010; 10/15/2010; 4/5/2011. *See* Exhibit A.

114. By contrast, the CPI for the period 2004-2010 rose less than 3% per year. *See* Exhibit B. A similar analysis applies to the remainder of this Defendant's Relevant Drugs. Utilization data for each of the Government Plaintiffs is attached as Exhibit E and is incorporated herein by reference as if fully set forth herein.

115. By failing to factor its off-invoice price increases in its AMP calculations, Bradley: (1) caused CMS to underreport the unit rebate amounts to the states, (2) caused itself to pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to from Bradley, and (4) caused the federal government to pay more than it should have in FMAP funds to the states. As a result of this fraudulent conduct, Bradley violated Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

4. Eisai

116. Eisai is a Service Fee Defendant.

117. On March 1, 2006, Eisai executed a "Manufacturer Service Agreement" ("Eisai Service Agreement") with Rx Distribution Network (the "Network"), a group of small, regional wholesalers.[15]

118. The Eisai Service Agreement provides that Eisai will pay the Network for distribution and additional "value added" services on a fee-for-service basis. Section I of the Eisai Service Agreement describes the services to be performed by the Network, including, but not limited to: sales and distribution services, management updates, product launch support, and financial reporting.

119. Further, the Agreement lists additional "Value Added Services" in Section II, including, but not limited to: "Core Distribution Services[,]" "Inventory Management" services and sales reporting services. The Network must provide "Core Distribution Services" including pick, pack and ship services, and emergency shipments on a 24/7/365 basis. Eisai Service Agreement, Exhibit B. For sales reporting, the Network must provide daily inventory reports (852 data) and weekly sales reports (867 data).

120. In exchange for these services, Eisai agrees to pay a 0.85% Service Fee. At the end of each financial quarter, Eisai determined the Service Fee through a simple four-step process. First, Eisai multiplied 0.85% by the wholesaler's gross purchases from Eisai during the quarter (the "Gross Service Fee"). Second, Eisai determined the amount of product the wholesaler had in inventory – on hand and/or on order – at the time of each price increase during the quarter. Third, Eisai multiplied the amount of product in inventory by the amount of the

[15] A redacted copy of this agreement is attached within Exhibit C and is incorporated by reference as if fully set forth herein.

price increases (the "Gross Price Increase"). Fourth, the Gross Price Increase was subtracted from the Gross Service Fee, which resulted in the "Service Fee."

121. If the Gross Service Fee was greater than the Gross Price Increase, the wholesaler got paid the difference, i.e., the wholesaler received a Service Fee. Contrariwise, if the Gross Price Increase was greater than the Gross Service Fee, the wholesaler actually *owed the manufacturer money*, even though the wholesaler provided the numerous services outlined in the contract. The example below will illustrate this series of calculations.

122. Relator can state that members of the Network represent approximately 2% of Eisai's U.S. distributor sales. During the first quarter of 2007, the Network members' sales of Eisai products amounted to $1,787,000, on which they earned a service fee of $151,879 ($1,787,000 x .085%). The sum of Eisai's Gross Price Increase during the same quarter was $251,244. As such, the members of the Network actually received no Service Fee, and in fact ended up owing $99,365 to Eisai during Q1 2007 ($151,879 minus $251,244).

123. Since Eisai contractually defined Service Fee to include Gross Price Increases, and since Service Fees are statutorily excluded from AMP, Eisai was able to use the terms of its own contract as a pretext for excluding these price increases from its AMP reporting.

124. In terms of quantifying the fraud, Eisai's principal products include Aciphex, Aricept, Fragmin, Targretin and Zonegran, all of which are covered and paid for by the Government Plaintiffs. From January, 2004 until January, 2007, each product increased in price an average of nearly 20%.

125. Had Eisai followed the law, Eisai would have added Gross Price Increases into its calculation of AMP, and thereby paid a 15.1% Basic Rebate on those price increases. Further, given that Eisai has increased the prices of its products by nearly 20% since 2004, many of these

price increases exceeded the CPI. Accordingly, had Eisai followed the law, every off-invoice price increase which exceeded the CPI would have been factored into AMP, and Eisai would have paid an Additional Rebate on said price increases.

126. In late 2008, in an effort to renegotiate the Service Agreement and render it more beneficial to the Network members, Relator engaged Eisai in negotiations over an extension and a modification of the Service Agreement. In the course of several letters, presentations and phone calls, Relator called to the attention of senior Eisai executives certain liabilities that Eisai was incurring to government programs as a function of the Service Agreement.

127. On November 20, 2008, Relator conducted a conference call with Eisai for the purpose of negotiating the terms of the Service Agreement extension. The participants on that call included Relator and Eisai executives Sean Spears ("Spears"), Andy Cohen ("Cohen"), and Steven Brown ("Brown"). According to Spears, he, Cohen and Brown were the Eisai executives who were the decision-makers concerning Service Agreements with wholesalers.

128. Relator told Spears, Cohen and Brown that Eisai was required to include price increases on inventory in its AMP calculations, thus increasing both AMP and the rebate Eisai owed to the Government Plaintiffs.

129. Relator conveyed this to the Eisai executives using numbers from the actual results under the Service Agreement with the Network members. Relator stated that, with respect to a particular time period, Eisai owed the Network members Gross Service Fees amounting to $1,697,000. During that same time period, Eisai clawed-back $750,000 via off-invoice price increases on inventory. Relator told Eisai that the $750,000 had to be included in AMP. In addition, given Eisai's significant price increases beyond the CPI, Relator explained, Eisai owed an Additional Rebate.

130. To increase the Network members' margins and simultaneously to reduce the rebates Eisai would owe, Relator suggested an alternative agreement with Eisai. He recommended that Eisai reduce its Service Fees to Network members from 0.85% to 0.35%, while simultaneously eliminating "clawing back" off-invoice price increases from the wholesalers. Relator explained that his proposed alternative arrangement would enable Eisai to reduce its rebate obligations by eliminating off-invoice price increases on inventory.

131. The Eisai executives agreed that the Service Fees Eisai paid to the Network members were *bona fide* Service Fees, and they admitted that Eisai did not include off-invoice price increases on inventory in its calculation of AMP. Rather, according to Spears, Cohen, and Brown, these price increases had no relation to AMP or Medicaid rebates. By its own admission, therefore, Eisai failed to include off-invoice price increases on inventory in its AMP calculations, thereby materially reducing the rebates owed to the Government Plaintiffs.

132. On December 23, 2008, Relator conducted another phone call with Eisai executive Spears. Spears stated that a distributor should not benefit from an Eisai product price increase through inventory appreciation. According to Spears, Eisai's agreement to pay a Service Fee is based on there being no price increases during the quarter. Spears concluded that any excess profit that a distributor receives from inventory appreciation due to an Eisai product price increase, therefore, is a windfall and belongs to Eisai. Thus, Eisai conceded that each time it claws back price increases on inventory by subtracting same from the Service Fee, the prices for the drugs sold during the rebate period increases and the manufacturer is paid more for those drugs, i.e, these price increases on inventory "adjust the prices actually realized." Medicaid Rebate Agreement, Section I(a).

133. As alleged above, during the Relevant Time Period, Defendant Eisai participated in the Medicaid Program and Eisai's Relevant Drugs were paid for by all of the Government Plaintiffs. For example, Eisai's drug, Aciphex Oral Tablet Delayed Release 20 MG, 30 units, 62856-0243-30, had approximately $296,645,774.82 in Medicaid utilization from 2004 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

134. Further, the prices on Eisai's drugs increased during the Relevant Time Period. For example, the price of Aciphex Oral Tablet Delayed Release 20 MG increased a total of 65.97%, with prices increases occurring on the following dates: 1/5/2005; 8/18/2005; 3/21/2006; 2/15/2007; 8/9/2007; 2/25/2008; 8/26/2008; 1/7/2009; 7/23/2009; 1/5/2010; 7/28/2010. *See* Exhibit A.

135. By contrast, the CPI for the period 2004-2010 rose less than 3% per year. *See* Exhibit B. A similar analysis applies to the remainder of this Defendant's Relevant Drugs. Utilization data for each of the Government Plaintiffs is attached as Exhibit E and is incorporated herein by reference as if fully set forth herein.

136. By failing to factor its off-invoice price increases in its AMP calculations, Eisai: (1) caused CMS to underreport the unit rebate amounts to the states, (2) caused itself to pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to from Eisai, and (4) caused the federal government to pay more than it should have in FMAP funds to the states. As a result of this fraudulent conduct, Eisai violated Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

5. Mallinkrodt

137. Mallinkrodt is a Service Fee Defendant.

138. On April 1, 2007, Mallinkrodt and a national wholesaler executed a "Distribution Services Agreement" ("Mallinkrodt DSA").[16] According to the Mallinkrodt DSA, the purpose of the agreement is for Mallinkrodt to purchase certain services from the wholesaler, "including but not limited to logistics and inventory management services, administrative services, and financial services."

139. In Section 2.1 of the Mallinkrodt DSA, the wholesaler agrees to provide "Base Distribution Services[,]" including the provision of sophisticated ordering technology, daily deliveries to providers, emergency shipments to providers, contract and chargeback administration, returns processing, customer service support, adequate inventories, and licensed and environmentally controlled facilities.

140. Section 2.2 requires the wholesaler to provide certain "Inventory Management Services[,]" including inventory maintenance levels, purchase limits and best efforts to ensure product availability.

141. Section 2.3 requires the wholesaler to provide certain "Data/Reporting Services[,]" including weekly inventory reports (852 data) and sales reports (867 data) for each product and formulation. In addition, the agreement provides for service levels, order monitoring, new product launch support and purchase forecast requirements. *See* Sections 2.4-2.7.

142. Section 4.1 of the Mallinkrodt DSA describes the relationship between Mallinkrodt and the wholesaler as that of a "service buyer-seller."

143. In exchange for these services, Mallinkrodt agrees to pay the wholesaler a service fee of 2.875%. See Article 2 Preamble; Schedule A. The service fee will be calculated and paid

[16] A redacted copy of this agreement is attached within Exhibit C and is incorporated by reference as if fully set forth herein.

quarterly in the form of a credit memo and will be reduced by the value of the inventory appreciation. Section 2.2; Schedule A. That is, Section 2.2. states that "[u]pon a price increase, [the wholesaler] and [Mallinkrodt] will calculate the inventory appreciation associated with the on-hand inventory and [Mallinkrodt] can reduce the Service Fee . . . by such amount."

144. By virtue of the fact that the Service Fees paid by Mallinkrodt to the wholesaler were *bona fide*, and the fact that Mallinkrodt netted off-invoice price increases against those Service Fees, Mallinkrodt is precluded from factoring off-invoice price increases into its calculations of AMP. Consequently, Mallinkrodt improperly excludes price increases from its AMP calculations, in turn understating its AMPs, and consequently underpaying Medicaid rebates it owes to the Government Plaintiffs.

145. As alleged above, during the Relevant Time Period, Defendant Mallinkrodt participated in the Medicaid Program and Mallinkrodt's Relevant Drugs were paid for by all of the Government Plaintiffs. For example, Mallinkrodt's drug, Restoril Oral Capsule 7.5 MG, 100 units, 00406-9915-01, had approximately $79,353,491.85 in Medicaid utilization from 2004 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

146. Further, the prices on Mallinkrodt's drugs increased during the Relevant Time Period. For example, the price of Restoril Oral Capsule 7.5 MG increased a total of 327%, with prices increases occurring on the following dates: 4/25/2005; 10/1/2005; 4/8/2006; 10/1/2006; 3/31/2007; 9/29/2007; 2/2/2008; 6/28/2008; 1/24/2009; 10/10/2009; 10/2/2010. *See* Exhibit A.

147. By contrast, the CPI for the period 2004-2010 rose less than 3% per year. *See* Exhibit B. A similar analysis applies to the remainder of this Defendant's Relevant Drugs.

Utilization data for each of the Government Plaintiffs is attached as Exhibit E and is incorporated herein by reference as if fully set forth herein.

148. By failing to factor its off-invoice price increases in its AMP calculations, Mallinkrodt: (1) caused CMS to underreport the unit rebate amounts to the states, (2) caused itself to pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to, and (4) caused the federal government to pay more than it should have in FMAP funds to the states. As a result of this fraudulent conduct, Mallinkrodt violated Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

6. Novo Nordisk

149. Novo Nordisk is a Service Fee Defendant.

150. On October 11, 2005 and October 19, 2005, respectively, the wholesaler and Novo Nordisk executed a "Core Distribution Services Agreement" ("Novo DSA").[17] According to the Novo DSA, Novo "wishes to obtain certain distribution information and services . . . to enable it to more efficiently and effectively manage its promotional, marketing and sales activities, and for such other reasons as are deemed necessary."

151. Section 1.3 details the obligations of the wholesaler, including transmitting daily inventory data (852 data) and weekly inventory data (867 data). The wholesaler also agrees to pick, pack and ship Novo Nordisk products to the wholesaler's customers, and to "perform back-end administrative services to support the distribution of Novo Nordisk's products and the maintenance of efficient inventory levels for servicing customers."

[17] A redacted copy of this agreement is attached within Exhibit C and is incorporated by reference as if fully set forth herein.

152. The Novo DSA includes "Attachment A" which further defines and describes the "Core Services" the wholesaler agrees to provide. Attachment A also provides more particularity with respect to the data services the wholesaler must provide, defines purchase commitments, eliminates speculative buying, and establishes inventory levels.

153. In exchange for these Core Distribution Services, the Novo CDSA binds Novo Nordisk to pay the wholesaler a "Core Services Fee." Attachment A, Section 4(a), describes the Core Services Fee for each of 2005, 2006 and 2007, beginning the first year with a $5 million flat fee in exchange for the wholesaler's performing the Core Distribution Services. For 2006, Novo Nordisk agreed to pay a quarterly fee equal to $1.25 million, multiplied by "1 plus the percentage change in the CPI index between 2005 and 2006. . . , subject to a minimum multiplier adjustment of 1.025." Novo Nordisk would also adjust the wholesaler's fee to reflect the percentage increase or decrease in product sales by the wholesaler between 2005 and 2006. The Core Services Fee Novo Nordisk was entitled to in 2007 was its 2006 fee, adjusted upward by the CPI multiplier, and adjusted either up or down based on the sales increase or decrease 2007 over 2006.

154. Regarding the Service Fees and payment for same, the Novo DSA indicates that the parties consider the services *bona fide*. Section 2.2 states:

> The Fee has been determined through good faith and arms-length bargaining to be the fair market value or less of the Core Services. No amount paid hereunder is intended to be, nor shall it be construed as, an offer, or payment made, whether directly or indirectly, to induce the referral of business, the purchase, lease or order of any item or other service, or the recommending or arranging for the purchase, lease or order of any item or service.

155. In addition, in Attachment A, Section 4(c)(iv), the wholesaler "represents and warrants that the service fees earned pursuant to this Agreement shall not be passed on in whole or in part to a wholesaler client or customer." These statements – in Section 2.2 and in

Attachment A – directly express the parties' understanding that the Core Services Fee is a *bona fide* Service Fee. According to the terms of the Novo DSA, therefore, Novo Nordisk excluded the Core Service Fees it paid to the wholesaler from its AMP calculations.

156. The Novo DSA provides for Novo Nordisk to offset the Core Services Fee it paid by off-invoice price increases. According to Attachment A, Section 4(c)(ii), "if a price increase occurred during the quarter invoiced, Novo Nordisk shall be entitled to reduce any Core Services Fee due by the amount of price benefit obtained to the wholesaler due to the price increase (soft appreciation)." The Novo DSA further provides: "if the benefit from the price increase exceeds the invoiced amount, the credit due Novo Nordisk will be applied against any future quarterly invoices." Thus, Novo Nordisk nets price appreciation against Core Service Fees owed, thereby excluding off-invoice price increases from its AMP calculations.

157. By virtue of the fact that the Service Fees paid by Novo to the wholesaler were *bona fide*, and the fact that Novo netted off-invoice price increases against those Service Fees, Novo is precluded from factoring off-invoice price increases into its calculations of AMP. Consequently, Novo improperly excludes price increases from its AMP calculations, in turn understating its AMPs, and consequently underpaying Medicaid rebates it owes to the Government Plaintiffs.

158. As alleged above, during the Relevant Time Period, Defendant Novo Nordisk participated in the Medicaid Program and Novo Nordisk's Relevant Drugs were paid for by all of the Government Plaintiffs. For example, Novo Nordisk's drug, Prandin Oral Tablet 2 MG, 100 units, 00169-0084-81, had approximately $36,609,457.70 in Medicaid utilization from 2004 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

159. Further, the prices on Novo Nordisk's drugs increased during the Relevant Time Period. For example, the price of Prandin Oral Tablet 2 MG increased a total of 102.72%, with prices increases occurring on the following dates: 2/28/2004; 1/19/2005; 1/15/2006; 2/12/2007; 11/15/2007; 5/30/2008; 11/13/2008; 6/18/2009; 4/7/2010. *See* Exhibit A.

160. By contrast, the CPI for the period 2004-2010 rose less than 3% per year. *See* Exhibit B. A similar analysis applies to the remainder of this Defendant's Relevant Drugs. Utilization data for each of the Government Plaintiffs is attached as Exhibit E and is incorporated herein by reference as if fully set forth herein.

161. By failing to factor its off-invoice price increases in its AMP calculations, Novo Nordisk: (1) caused CMS to underreport the unit rebate amounts to the states, (2) caused itself to pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to, and (4) caused the federal government to pay more than it should have in FMAP funds to the states. As a result of this fraudulent conduct, Novo Nordisk violated Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

7. Reliant

162. Reliant is a Service Fee Defendant.

163. On February 1, 2005, Reliant and The wholesaler executed a "Distribution Services Agreement" ("Reliant DSA"). In the first quarter of 2007, the parties executed an Amendment to the Reliant DSA (the "Reliant Amendment").[18]

[18] A redacted copy of the agreement and the amendment are attached within Exhibit C and are incorporated by reference as if fully set forth herein.

164. According to the Reliant DSA, the purpose of the agreement is for Reliant to purchase certain services from the wholesaler, "including but not limited to logistics and inventory management services, administrative services, and financial services."

165. In Section 2.1 of the Reliant DSA, the wholesaler agrees to provide "Distribution and Inventory Management Services[,]" including the provision of sophisticated ordering technology, daily deliveries to providers, emergency shipments to providers, consolidated accounts receivable management, contract and chargeback administration, returns processing, customer service support, adequate inventories, and licensed and controlled facilities.

166. Section 2.2 requires the wholesaler to provide certain "Additional Inventory Management Services[,]" including inventory maintenance levels, purchase limits, best efforts to ensure product availability, and data reporting services (852 data and 867 data). In addition, the Reliant DSA provides for service levels, order monitoring, new product launch support and purchase forecast requirements. Reliant DSA § 2.2.

167. Section 6.1 of the Reliant DSA describes the relationship between Reliant and The wholesaler as that of a "service buyer-seller." Further, the wholesaler represents "that the services hereunder are *bona fide* and the consideration there for is no greater than the fair market value for such services and as such are not discounts as defined in the CMS December 9, 2004 letter with respect to Average Sales Price." Reliant DSA § 6.1.

168. In exchange for each of these services, Reliant agrees to pay the wholesaler a Service Fee of 6% through 2007; and a Service Fee from 3.95% to 4.90% after 2007. *See* Article 2 Preamble; Schedule A; the Reliant Amendment. The Service Fee will be calculated and paid quarterly in the form of a credit memo and will be reduced by the value of the "Price

Appreciation on Aggregate Inventory" after a price increase. *See* Schedule A; the Reliant Amendment.

169. By virtue of the fact that the Service Fees paid by Reliant to the wholesaler were *bona fide*, and the fact that Reliant netted off-invoice price increases against those Service Fees, Reliant is precluded from factoring off-invoice price increases into its calculations of AMP. Consequently, Reliant improperly excludes price increases from its AMP calculations, in turn understating its AMPs, and consequently underpaying Medicaid rebates it owes to the Government Plaintiffs.

170. As alleged above, during the Relevant Time Period, Defendant Reliant participated in the Medicaid Program and Reliant's Relevant Drugs were paid for by all of the Government Plaintiffs. For example, Reliant's drug, Lovaza Oral Capsule 1 GM, 120 units, 65726-0425-27 had approximately $17,782,634.14 in Medicaid utilization from 2007 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

171. Further, the prices on Reliant's drugs increased during the Relevant Time Period. For example, the price of Lovaza Oral Capsule 1 GM increased on a total of 11.18%, with prices increases occurring on the following dates: 7/9/2007; 10/1/2007; 7/22/2008. *See* Exhibit A.

172. By contrast, the CPI for the period 2004-2010 rose less than 3% per year. *See* Exhibit B. A similar analysis applies to the remainder of this Defendant's Relevant Drugs. Utilization data for each of the Government Plaintiffs is attached as Exhibit E and is incorporated herein by reference as if fully set forth herein.

173. By failing to factor its off-invoice price increases in its AMP calculations, Reliant: (1) caused CMS to underreport the unit rebate amounts to the states, (2) caused itself to

pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to, and (4) caused the federal government to pay more than it should have in FMAP funds to the states. As a result of this fraudulent conduct, Reliant violated Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

8. Sepracor

174. Sepracor is a Service Fee Defendant.

175. On January 1, 2007, Sepracor and a national wholesaler executed a "Wholesaler Purchase and Distribution Agreement" (the "Sepracor Agreement").[19] The Sepracor Agreement provides for the wholesaler to buy and distribute Sepracor's products in exchange for a Service Fee. Section 2.2 and Exhibits D and D1 describes the "Services and Fees." Services include, but are not limited to, monitoring customer orders to limit speculative buying by customers, collaborative forecasting, new product support, environmentally controlled storage, service level requirements, inventory level requirements, the use of the wholesaler's logistics center, and access to the wholesaler's marketing programs.

176. Inventory management and service level commitments involve the wholesaler maintaining a specified level of on-hand and on order inventory and a minimum order fulfillment level of 97%. Distribution services include, *inter alia*, having less than 1% of returned goods and providing new product launch support. Data services require the wholesaler to send daily inventory reports (852 data) and weekly sales reports (867 data).

177. In exchange for these services, Sepracor agrees to pay the wholesaler a Service Fee, ranging from 3.25% to 5% and based on the services performed and quarter in which they

[19] A redacted copy of this agreement is attached within Exhibit C and is incorporated by reference as if fully set forth herein.

were performed. Sepracor Agreement §2.2(c); Exhibit D, D1. The parties intended the fees paid for the services under the Sepracor Agreement to be considered *bona fide* Service Fees. Specifically, in Section 3.1(c), the Sepracor Agreement states:

> Wholesaler further represents and warrants that it has performed an analysis of the value of the services to be provided to Sepracor hereunder and that the compensation described in this Agreement constitutes fair market value, or less, for such services. Wholesaler represents and warrants that none of the services to be provided hereunder would be provided to Sepracor by Wholesaler in the absence of this Agreement. Wholesaler further represents and warrants that any compensation for services it performs hereunder is specifically not intended to be passed through as [a] discount or rebate to Wholesaler's Customers.

178. The Sepracor Agreement further provides that the wholesaler should invoice Sepracor for the Service Fees after each calendar quarter. Sepracor will pay the invoice amounts except that Sepracor will receive credit towards Service Fees for "price appreciation on Aggregate Inventory plus On-Order quantities that are eventually received by [The wholesaler]." Sepracor Agreement §2.2(c), (d). Thus, Sepracor reduced the Service Fees it paid by the amount of any off-invoice price increases, i.e., Sepracor defined Service Fees to camouflage price increases on inventory.

179. By virtue of the *bona fide* nature of the services the wholesaler provides to Sepracor, and the express terms of the Sepracor Agreement indicate that Sepracor treats the service fees it pays as *bona fide*, Sepracor "properly" excludes those fees from its calculations of AMP. However, by netting off-invoice price increases against those Service Fees, Sepracor improperly excludes material price increases from its AMP calculations, in turn understating its AMPs, and consequently underpaying Medicaid rebates it owes to the Government Plaintiffs.

180. As alleged above, during the Relevant Time Period, Defendant Sepracor participated in the Medicaid Program and Sepracor's Relevant Drugs were paid for by all of the

Government Plaintiffs. For example, Sepracor's drug, Xopenex Inhalation Nebulization Solution 1.25 MG/3ML, 3 units, 63402-0513-24, had approximately $566,967,727.20 in Medicaid utilization from 2004 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

181. Further, the prices on Sepracor's drugs increased during the Relevant Time Period. For example, the price of Xopenex Inhalation Nebulization Solution 1.25 MG/3ML increased a total of 117.13%, with prices increases occurring on the following dates: 1/18/2005; 1/11/2006; 7/3/2007; 11/1/2007; 6/18/2008; 12/2/2008; 1/1/2010; 7/1/2010; 4/1/2011. *See* Exhibit A.

182. By contrast, the CPI for the period 2004-2010 rose less than 3% per year. *See* Exhibit B. A similar analysis applies to the remainder of this Defendant's Relevant Drugs. Utilization data for each of the Government Plaintiffs is attached as Exhibit E and is incorporated herein by reference as if fully set forth herein.

183. By failing to factor its off-invoice price increases in its AMP calculations, Sepracor: (1) caused CMS to underreport the unit rebate amounts to the states, (2) caused itself to pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to, and (4) caused the federal government to pay more than it should have in FMAP funds to the states. As a result of this fraudulent conduct, Sepracor violated Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

9. Upsher-Smith

184. Upsher-Smith is a Service Fee Defendant.

185. Effective January 1, 2007, Upsher-Smith and a national wholesaler executed the Wholesaler Health Developing Suppliers Program Distribution Services Agreement ("Upsher DSA").[20]

186. Under Section 1.1, the wholesaler agrees to provide services including "sophisticated ordering technology, daily consolidated deliveries to providers, emergency shipments to providers 24/7/365, consolidated accounts receivable management, contract and chargeback administration, returns processing, customer service support, adequate working inventories to meet customer needs, [and] licensed, environmentally controlled, PDMA compliant secure facilities."

187. In addition, the wholesaler agrees to provide additional services and commitments, including committing to certain inventory levels, providing daily inventory reports (852 data) and weekly sales reports (867 data), and providing "business development support."

188. In exchange for the wholesaler's provision of these services, pursuant to Section 1.3, Upsher-Smith owes a "Service Fee" as set forth in Exhibits B and C to the Upsher DSA. Exhibit B to the Upsher DSA details the Service Fees due to the wholesaler as well as certain offsets thereto. Contingent upon the wholesaler provided the specified services, Upsher-Smith owes a quarterly Service Fee of 4.57% of actual product purchased, measured at WAC. Upsher-Smith, however, offset the Service Fee by netting "Inventory Appreciation" against the Service Fee. According to Exhibit B, Inventory Appreciation "means the difference in the value of on hand and on order inventory actually received (or on order) immediately preceding a price increase and the value of such inventory after a price increase for Product." Thus, Upsher-Smith netted off-invoice price increases against its Service Fees.

[20] A redacted copy of this agreement is attached within Exhibit C and is incorporated by reference as if fully set forth herein.

189. With respect to the Service Fees, Section 3.11 of the Upsher DSA manifests the parties' understanding as to their *bona fide* nature. In discussing each party's compliance with applicable federal and state laws, the wholesaler "represents and warrants that any fees required of [Upsher-Smith] under this Agreement reflect the fair market value of the services for which such fees are being assessed."

190. Thus, by the terms of the Upsher DSA, Upsher-Smith considered the Service Fees it paid *bona fide*. Consequently, Upsher-Smith excluded the Service Fees it paid from its AMP calculations. In excluding the Service Fees from its AMP calculations, however, Upsher-Smith also excludes the off-invoice price increases, because these price increases are netted against the Service Fees. By netting off-invoice price increases against its Service Fees, Upsher-Smith improperly excludes material price increases from its AMP calculations, in turn understates its AMP, and consequently underpays Medicaid rebates it owes to the Government Plaintiffs.

191. As alleged above, during the Relevant Time Period, Defendant Upsher-Smith participated in the Medicaid Program and Upsher-Smith's Relevant Drugs were paid for by all of the Government Plaintiffs. For example, Upsher-Smith's drug, Upsher-Smith's drug, Klor-Con Oral Tablet 10 MEQ, 500 units, 00245-0041-15, had approximately $136,313,185 in Medicaid utilization from 2004 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

192. Further, the prices on Upsher-Smith's drugs increased during the Relevant Time Period. For example, the price of Klor-Con Oral Tablet 10 MEQ increased a total of 277.61%, with prices increases occurring on the following dates: 1/15/2004, 12/15/2004, 12/20/2005, 10/15/2007, 7/18/2008 and 8/11/2010. *See* Exhibit A.

193. By contrast, the CPI for the period 2004-2010 rose less than 3% per year. *See* Exhibit B. A similar analysis applies to the remainder of this Defendant's Relevant Drugs. Utilization data for each of the Government Plaintiffs is attached as Exhibit E and is incorporated herein by reference as if fully set forth herein.

194. By failing to factor its off-invoice price increases in its AMP calculations, Upsher-Smith: (1) caused CMS to underreport the unit rebate amounts to the states, (2) caused itself to pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to, and (4) caused the federal government to pay more than it should have in FMAP funds to the states. As a result of this fraudulent conduct, Upsher-Smith violated Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

B. Discount Defendants

1. AstraZeneca

195. AstraZeneca is a Discount Defendant.

196. AstraZeneca's "Wholesale Distribution Services Agreement" ("AZ Agreement") with wholesalers became effective in 2005.[21] The "[w]hereas" clause in the AZ Agreement includes a description of the contract's purpose, namely: 1) to provide services including inventory management to ensure access for downstream customers and to better forecast future product demand, 2) to provide certain data to assist AstraZeneca in formulating forecasts and its inventory management efforts, and 3) to restrict the wholesaler from speculative/investment buying.

[21] A redacted copy of this agreement is attached within Exhibit C and is incorporated by reference as if fully set forth herein.

197. Sections 2, 5 and 7 set forth the wholesaler's inventory management requirements including the prohibition on speculative buying, maintenance of target inventory levels, and data reporting. With respect to the data reporting requirements, the wholesaler must report daily sales data (852 data) and monthly transaction data (867 data) to AstraZeneca. Moreover, the wholesaler is required to provide AstraZeneca with 28-day purchase forecasts.

198. Section 3 of the AZ Agreement describes the wholesaler's "Core Distribution Services," including pick, pack and ship services, accounts receivable management, contract and chargeback administration, returns processing, customer service support and adequate inventory maintenance.

199. In exchange for the wholesaler providing these services, AZ pays the wholesaler a quarterly Service Fee. The amount of the Service Fee ranges from 1.2% and 1.25% of gross purchases, less off-invoice price increases on inventory. AZ Agreement, § 4, 4.2.3.

200. Notwithstanding the *bona fide* nature of these Service Fees – indeed, they are the very same Service Fees that the Service Fee Defendants admit are *bona fide* – AstraZeneca unlawfully elected to characterize these Service Fees as *discounts*. AstraZeneca admits as much in its agreement: Section 13 states: "AstraZeneca believes the Service Fees paid hereunder are a discount . . . ."

201. As discussed in detail above, discounts are excluded from AMP by statute, regulation, the Medicaid Rebate Agreement, and the Medicaid Rebate Operational Training Guide. In blatant defiance of the law, AstraZeneca improperly includes these "discounts" in its AMP calculations, in turn understates its AMP, and consequently underpays the Medicaid rebates it owes to the Government Plaintiffs.

202. In addition to the AZ Agreement, an internal AstraZeneca PowerPoint further underscores the *bona fide* value of the services provided by the wholesaler.[22] In the document, AstraZeneca describes the components of the AZ Agreement and notes that it "includes several metrics designed to *increase the value* of our wholesale vendor relationships" (emphasis added). The document goes on to state that "[f]ee adjustments [are] mostly weighted on inventory adherence (i.e., the fees are partly contingent on performance). Moreover, the PowerPoint describes the value of the data provided from the wholesaler to AstraZeneca pursuant to the data reporting requirements. The document further supports the *bona fide* value of the fees paid pursuant to the AZ Agreement by stating that "To Begin *Earning* Service Fees" the wholesaler is required to meet a series of milestones, and that "To Be *Eligible* for Payment" several other milestones are required to be met by the wholesaler (emphasis added).

203. The PowerPoint also states that a company known as "ValueCentric" is "AstraZeneca's service provider responsible for the technical implementation and ongoing application support of the DSA agreement." The PowerPoint then states that "All EDI transactions will be sent to ValueCentric who will manage and process the 852 and 867 data transaction sets." The value of the 852 data and the 867 data – and the other information provided by the wholesaler pursuant to the DSA – is made clear on ValueCentric's website, which states:

> ValueCentric receives data on a daily basis from over 100 wholesaler entities, including the Big 3: Cardinal Health, McKesson and AmerisourceBergen. ValueCentric gathers sales, inventory, orders, chargebacks and returns data to help manufacturers make more accurate business decisions, measure the effectiveness of their sales operations and marketing efforts, and reduce costs by proactively managing their product inventories.

[22] A redacted copy of this PowerPoint is attached within Exhibit C and is incorporated by reference as if fully set forth herein.

> With wholesaler data, manufacturers are able to drive increased revenue by ensuring appropriate product availability at the wholesaler distribution center, thereby preventing stock-outs. Complete, timely and accurate views of the supply channel make it possible for manufacturers to proactively manage their manufacturing facilities and their order-to-cash process.

204. It is beyond dispute that the services provided by the wholesaler pursuant to the DSA were valuable to AstraZeneca, and that payment for these services was contingent on the services being rendered. Payments for services rendered are not "discounts."

205. During the Relevant Time Period, Defendant AstraZeneca participated in the Medicaid Program and AstraZeneca's Relevant Drugs were paid for by all of the Government Plaintiffs. For example, AstraZeneca's drug, Seroquel Oral Tablet 300 MG, 60 units, 00310-0274-60 had approximately $1,768,392,407.43 in Medicaid utilization from 2004 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

206. AstraZeneca's DSA, discussed in detail above, improperly characterizes *bona fide* service fees as discounts and, thereby, illegally understates its AMP calculations.

207. By understating its AMP calculations, AstraZeneca: (1) caused CMS to underreport the unit rebate amounts to the states, (2), caused itself to pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to, and (4) caused the federal government to pay more than it should have in FMAP funds to the states. As a result of this fraudulent conduct, AstraZeneca violated Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

2. Biogen

208. Biogen is a Discount Defendant.

209. Biogen and a national wholesaler executed a "Services Agreement" ("Biogen SA"), effective April 1, 2005.[23]

210. According to the Biogen SA, the purpose of the agreement is for Biogen to purchase certain services from the wholesaler, including, but not limited to, distribution services, logistics and inventory management services, administrative services, and financial services.

211. Section 7 of the Biogen SA details the services the wholesaler must provide, including inventory maintenance levels, purchase limits, product availability. Also, the wholesaler is required to provide Inventory Reports (852 data) and Sales Reports (867 data) on a weekly basis. In addition, the Biogen SA provides for customer monitoring, service levels, deductions reconciliation, and contract and chargeback administration.

212. In return for these services, Biogen agrees to pay the wholesaler a Service Fee in the form of a quarterly credit memo. Biogen SA § 8. According to Appendix A to the Biogen SA, Biogen agrees to pay the wholesaler a Service Fee equal to 1% of the total volume of all products purchased.

213. The services for which Biogen pays the Service Fee are strikingly similar to *bona fide* services the Service Fee Defendants receive from wholesalers. Under the Biogen SA, the wholesaler agrees to provide distribution services, inventory management services and data services, such as weekly inventory and sales reports. Despite this, and despite the wholesaler's express position in the agreement that "the fees are *bona fide* fees for service[,]" Biogen unlawfully elected to rename these fees "discounts." Indeed, Biogen expressly states that it will recognize the Service Fees as discounts in its "government pricing calculations." Biogen SA § 8.c.

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[23] A redacted copy of this agreement is attached within Exhibit C and is incorporated by reference as if fully set forth herein.

214. As discussed in detail above, discounts are excluded from AMP by statute, regulation, the Medicaid Rebate Agreement, and the Medicaid Rebate Operational Training Guide. In blatant defiance of the law, Biogen Idec improperly includes these "discounts" in its AMP calculations, in turn understates its AMP, and consequently underpays the Medicaid rebates it owes to the Government Plaintiffs.

215. During the Relevant Time Period, Defendant Biogen participated in the Medicaid Program and Biogen's Relevant Drugs were paid for by all of the Government Plaintiffs. For example, Biogen's drug, Avonex Prefilled Intramuscular Kit 30 MCG/0.5ML, 1 unit, 59627-0002-05, had approximately $424,352,841.72 in Medicaid utilization from 2004 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

216. Biogen's DSA, discussed in detail above, improperly characterizes *bona fide* service fees as discounts and, thereby, illegally understates its AMP calculations.

217. By understating its AMP calculations, Biogen: (1) caused CMS to underreport the unit rebate amounts to the states, (2), caused itself to pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to, and (4) caused the federal government to pay more than it should have in FMAP funds to the states. As a result of this fraudulent conduct, Biogen violated Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

3. Cephalon

218. Cephalon is Discount Defendant.

219. On March 31, 2006, Cephalon and a national wholesaler executed a "Distribution Services Agreement" ("Cephalon DSA").[24] The purpose of the Cephalon DSA is to ensure "the availability and integrity" of Cephalon's products to patients. In Section 2, Cephalon expressed its desire, through the Cephalon DSA, to "maximize[e] service levels for wholesalers, and improve[e] the efficiency of its manufacturing, forecasting, warehousing, and distribution efforts."

220. The Cephalon DSA defines the manner in which the wholesaler will be paid as the "Wholesaler Discount Program." Cephalon DSA §3. In return for the wholesaler's "handling all distribution and related support service functions," the wholesaler "earns discounts from its purchases of Product for performing the activities as set forth in Exhibit C." The Cephalon DSA continues that "the discount to the Wholesaler is intended to be 2.00% of sales of Cephalon Pharmaceutical Products. . . ." Cephalon DSA §3.

221. That Cephalon unlawfully treated the payment it made to the wholesaler in exchange for the services the wholesaler provided as a discount cannot be disputed. In Section 3(b)(iii) of the Cephalon DSA, the parties state:

> [The wholesaler] acknowledges that Cephalon's position is that the payments made hereunder are a discount and that Cephalon will recognize such payments as a discount in its own books and records and in its government pricing calculations. Cephalon acknowledges that [The wholesaler's] position is that the payments are a bona fide fee for service provided under this Agreement.

222. As for the services themselves, they are virtually the same a those the Service Fee defendants properly characterize as *bona fide*. For example, Exhibit C describes the "Discount Program Breakdown," itemizes services the wholesaler performs, and states the fees to which the

[24] This agreement is attached within Exhibit C and is incorporated by reference as if fully set forth herein. The agreement was amended on October 2, 2006. The amendment is also attached within Exhibit C and is incorporated by reference as if fully set forth herein.

wholesaler entitled as follows: Inventory Management services, Customer Service Level services, Returns Management Services, Deduction Management Services, and Data Submission Services. For Data Submission, the wholesaler earns from zero (0) basis points for providing no data to twenty-five (25) basis points for providing all data Section 5 requires. Similarly, the wholesaler can earn up to seventy-five (75) basis points for maintaining proper levels of inventory.

223. As discussed in detail above, discounts are excluded from AMP by statute, regulation, the Medicaid Rebate Agreement, and the Medicaid Rebate Operational Training Guide. In blatant defiance of the law, Cephalon improperly includes these "discounts" in its AMP calculations, in turn understates its AMP, and consequently underpays the Medicaid rebates it owes to the Government Plaintiffs.

224. During the Relevant Time Period, Defendant Cephalon participated in the Medicaid Program and Cephalon's Relevant Drugs were paid for by all of the Government Plaintiffs. For example, Cephalon's drug, Provigil Oral Tablet 100 MG, 100 units, 63459-0201-01, had approximately $388,790,375.97 in Medicaid utilization from 2004 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

225. Cephalon's DSA, discussed in detail above, improperly characterizes *bona fide* service fees as discounts and, thereby, illegally understates its AMP calculations.

226. By understating its AMP calculations, Cephalon: (1) caused CMS to underreport the unit rebate amounts to the states, (2), caused itself to pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to, and (4) caused the federal government to pay more than it should have in FMAP funds to the states. As a result of

this fraudulent conduct, Cephalon violated Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

4. Genzyme

227. Genzyme is a Discount Defendant.

228. On December 5, 2005, Genzyme transmitted a letter agreement described as an "Inventory Management Agreement" ("Genzyme IMA") to a national wholesaler. The wholesaler counter-executed this letter agreement on December 16, 2005. On September 22, 2006 and October 3, 2006 respectively, Genzyme and the wholesaler executed the "First Amendment to Inventory Management Agreement."[25]

229. Genzyme expressed the goal of its IMA as "ensur[ing] that wholesalers establish and maintain inventory levels that reflect true customer demand and continue to provide inventory management services." From its opening, the Genzyme IMA describes a 2.25% "discount" it will provide if the wholesaler provides certain services as described in the agreement. Genzyme agrees to apply the "Inventory Management Discount" to the WAC of its products in the form of a rebate at the end of each calendar quarter.

230. The services for which Genzyme pays the Inventory Management Discount are strikingly similar to *bona fide* services the Service Fee Defendants receive from wholesalers. Included in the services the wholesaler provides to Genzyme are daily 852 inventory data and weekly 867 sales data (via EDI Transaction Data Reports). The wholesaler also agrees to meet certain inventory maintenance levels, purchase requirements, and to process returns in accordance with Genzyme's returns policy.

[25] This agreement is attached within Exhibit C and is incorporated by reference as if fully set forth herein. The amendment is also attached within Exhibit C and is incorporated by reference as if fully set forth herein.

231. Although Genzyme acknowledges the wholesaler's "position that the fees paid hereunder are bona fide inventory management services," Genzyme maintains that the service fees it pays are discounts. Indeed, in the context of requests for information from Medicare or Medicaid programs, the Genzyme IMA mandates that the wholesaler "shall report the net Product purchase price and, to the extent required by law or as requested by a government agency, the Inventory Management Discount received under this agreement."

232. As discussed in detail above, discounts are excluded from AMP by statute, regulation, the Medicaid Rebate Agreement, and the Medicaid Rebate Operational Training Guide. In blatant defiance of the law, Genzyme improperly includes these "discounts" in its AMP calculations, in turn understates its AMP, and consequently underpays the Medicaid rebates it owes to the Government Plaintiffs.

233. During the Relevant Time Period, Defendant Genzyme participated in the Medicaid Program and Genzyme's Relevant Drugs were paid for by all of the Government Plaintiffs. For example, Genzyme's drug, Renagel Oral Tablet 800 MG, 180 units, 58468-0021-01, had approximately $296,645,774.82 in Medicaid utilization from 2004 to 2010. *See* Exhibit D (national and state Medicaid utilization for this particular product, which is incorporated by reference as if fully set forth herein).

234. Genzyme's DSA, discussed in detail above, improperly characterizes *bona fide* service fees as discounts and, thereby, illegally understates its AMP calculations.

235. By understating its AMP calculations, Genzyme: (1) caused CMS to underreport the unit rebate amounts to the states, (2), caused itself to pay less in rebates than it actually owed, (3) caused the states to receive less in rebates than they were entitled to, and (4) caused the federal government to pay more than it should have in FMAP funds to the states. As a result of

this fraudulent conduct, Genzyme violated Section 3729(a)(1)(A) and (G) of the Federal False Claims Act and comparable "reverse false claim" sections of the State False Claims Acts.

VII. CONCLUSION

236. As fully detailed above, Defendants knowingly reported falsely deflated AMPs for their Relevant Drugs. This caused CMS to inaccurately calculate URAs. The States then used inaccurate URAs to invoice Defendants for the rebates Defendants owed. Defendants thus unlawfully underpaid their rebates as a consequence of their own false reporting, the States expended more of their own funds, and the States sought more in federal matching funds through their quarterly requests for Medicaid payments on CMS Form-64.[26] Consequently, the Government Plaintiffs were defrauded by Defendants.

COUNT I

Federal False Claims Act

31 U.S.C. §3729(a)(1)[1986] and 31 U.S.C. §3729(a)(1)(A)[2009] (Against All Defendants)

237. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

238. During the Relevant Time Period, Defendants provided to CMS false quarterly reports of their AMPs with respect to the Relevant Drugs. As a result of these submissions, Defendants knowingly caused the States and the District of Columbia to present false and inflated claims for Medicaid payments to officials of the United States in violation of 31 U.S.C. §3729(a)(1)[1986], and 31 U.S.C. §3729(a)(1)(A)[2009].

[26] An exemplar of such a claim is attached as Exhibit F and is incorporated by reference as if fully set forth herein.

239. By virtue of the false or fraudulent claims that Defendants caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT II

Federal False Claims Act

31 U.S.C. §3729(a)(1)(B)[2009]
(Against All Defendants)

240. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

241. During the Relevant Time Period, Defendants knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims to the United States. Specifically, Defendants knowingly submitted to CMS false quarterly reports of their AMPs with respect to the Relevant Drugs which improperly reduced their respective rebate obligations to the States and the District of Columbia under the Medicaid Drug Rebate Program. Defendants' false reports caused the States and the District of Columbia to submit false and inflated claims for Medicaid payments to the United States in violation of 31 U.S.C. §3729(a)(1)(B)[2009].

242. By virtue of the false or fraudulent claims that Defendants caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT III

Federal False Claims Act

31 U.S.C. §3729(a)(7)[1986] and 31 U.S.C. §3729(a)(1)(G)[2009] (Against All Defendants)

243. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

244. Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their respective Relevant Drugs. Defendants also knew that their AMP submissions would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the States and the District of Columbia.

245. Since Defendants submitted false AMPs, the States and the District of Columbia received less in Medicaid rebates from Defendants with respect to the Relevant Drugs, and the United States paid more to the States and the District of Columbia in Medicaid payments. Had Defendants properly reported their respective AMPs for the Relevant Drugs during the Relevant Time Period, Defendants would have had a larger financial obligation to the Government Plaintiffs in the form of higher Medicaid rebates.

246. By virtue of this conduct, Defendants knowingly made, used, or caused to be made or used, false records or statements in order to conceal, avoid, or decrease their respective obligations to pay or transmit money or property to the Medicaid programs of the States and the District of Columbia, which are jointly funded by the United States and the States and the District of Columbia, thus resulting in significant financial loss to the United States, all in violation of 31 U.S.C. §3729(a)(7)[1986].

247. By virtue of this conduct, Defendants further knowingly made, used or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the United States, and/or Defendants knowingly concealed, or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the United States, in violation of 31 U.S.C. §3729(a)(1)(G)[2009].

COUNT IV

California False Claims Act
Cal Gov't. Code §12651(a)(7)
(Against All Defendants)

248. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

249. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of California. Since Defendants submitted false AMPs, the State of California received less money in Medicaid Rebates.

250. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of California, within the meaning of Cal Gov't. Code §12651(a)(7). The State of California has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT V

Connecticut False Claims Act
Conn. Gen. Stat. § 17b-301b(a)(7)
(Against All Defendants)

251. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

252. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Connecticut. Since Defendants submitted false AMPs, the State of Connecticut received less money in Medicaid Rebates.

253. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Connecticut, within the meaning of Conn. Gen. Stat. § 17b-301b(a)(7). The State of Connecticut has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT VI

Delaware False Claims And Reporting Act
6 Del Code §1201(a)(7)
(Against All Defendants)

254. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

255. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the

United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Delaware. Since Defendants submitted false AMPs, the State of Delaware received less money in Medicaid Rebates.

256. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Delaware, within the meaning of 6 Del. Code §1201(a)(7). The State of Delaware has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT VII

Florida False Claims Act
Fla. Stat. Ann. §68.082(2)(g)
(Against All Defendants)

257. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

258. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Florida. Since Defendants submitted false AMPs, the State of Florida received less money in Medicaid Rebates.

259. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Florida, within the meaning of Fla. Stat. Ann. §68.082(2)(g). The State of Florida has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT VIII

Georgia False Medicaid Claims Act
Ga. Code Ann. §49-4-168.1(7)
(Against All Defendants)

260. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

261. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Georgia. Since Defendants submitted false AMPs, the State of Georgia received less money in Medicaid Rebates.

262. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Georgia, within the meaning of Ga. Code Ann. §49-4-168.1(7). The State of Georgia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT IX

Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)(7)
(Against All Defendants)

263. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

264. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the

United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Hawaii. Since Defendants submitted false AMPs, the State of Hawaii received less money in Medicaid Rebates.

265. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Hawaii, within the meaning of Haw. Rev. Stat. §661-21(a)(7). The State of Hawaii has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT X

Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. §175/3(a)(7)
(Against All Defendants)

266. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

267. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Illinois. Since Defendants submitted false AMPs, the State of Illinois received less money in Medicaid Rebates.

268. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Illinois, within the meaning of 740 Ill. Comp. Stat. §175/3(a)(7). The State of Illinois has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XI

Indiana False Claims and Whistleblower Protection Act
IC 5-11-5.5-2(b)(6)
(Against All Defendants)

269. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

270. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Indiana. Since Defendants submitted false AMPs, the State of Indiana received less money in Medicaid Rebates.

271. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Indiana, within the meaning of IC 5-11-5.5-2(b)(6). The State of Indiana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XII

Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. § 46:438.3(C)
(Against All Defendants)

272. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

273. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the

United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Louisiana. Since Defendants submitted false AMPs, the State of Louisiana received less money in Medicaid Rebates.

274. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Louisiana, within the meaning of La. Rev. Stat. § 46:438.3(C). The State of Louisiana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XIII

Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(8)
(Against All Defendants)

275. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

276. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the Commonwealth of Massachusetts. Since Defendants submitted false AMPs, the Commonwealth of Massachusetts received less money in Medicaid Rebates.

277. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Massachusetts, within the meaning of Mass. Gen. Laws ch. 12 §5B(8). The Commonwealth of Massachusetts has

thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XIV

Michigan Medicaid False Claims Act
§400.607(3)
(Against All Defendants)

278. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

279. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Michigan. Since Defendants submitted false AMPs, the State of Michigan received less money in Medicaid Rebates.

280. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Michigan, within the meaning of §400.607(3). The State of Michigan has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XV

Montana False Claims Act
Mont. Code Ann. 17-8-403(1)(g)
(Against All Defendants)

281. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

282. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Montana. Since Defendants submitted false AMPs, the State of Montana received less money in Medicaid Rebates.

283. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Montana, within the meaning of Mont. Code Ann. 17-8-403(1)(g). The State of Montana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XVI

Nevada Submission of False Claims to State or Local Government Act Nev. Rev. Stat. Ann. §357.040(1)(g) (Against All Defendants)

284. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

285. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Nevada. Since Defendants submitted false AMPs, the State of Nevada received less money in Medicaid Rebates.

286. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Nevada, within the meaning of Nev. Rev. Stat. Ann. §357.040(1)(g). The State of Nevada has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XVII

New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §167:61-b(I)(e)
(Against All Defendants)

287. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

288. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of New Hampshire. Since Defendants submitted false AMPs, the State of New Hampshire received less money in Medicaid Rebates.

289. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Hampshire, within the meaning of N.H. Rev. Stat. Ann. §167:61-b(I)(e). The State of New Hampshire has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XVIII

New Jersey False Claims Act
N.J. Stat. §2A:32C-3(g)
(Against All Defendants)

290. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

291. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of New Jersey. Since Defendants submitted false AMPs, the State of New Jersey received less money in Medicaid Rebates.

292. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Jersey, within the meaning of N.J. Stat. §2A:32C-3(g). The State of New Jersey has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XIX

New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-14-3(a)(7)
(Against All Defendants)

293. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

294. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the

United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of New Mexico. Since Defendants submitted false AMPs, the State of New Mexico received less money in Medicaid Rebates.

295. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Mexico, within the meaning of N.M. Stat. Ann. § 27-14-3(a)(7). The State of New Mexico has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XX

New York False Claims Act
NY CLS St. Fin. §189(g)
(Against All Defendants)

296. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

297. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of New York. Since Defendants submitted false AMPs, the State of New York received less money in Medicaid Rebates.

298. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New York, within the meaning of NY CLS St. Fin. §189(g). The State of New York has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XXI

North Carolina False Claims Act
2009-554 N.C. Sess. Laws §1-607(a)(7)
(Against All Defendants)

299. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

300. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of North Carolina. Since Defendants submitted false AMPs, the State of North Carolina received less money in Medicaid Rebates.

301. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of North Carolina, within the meaning of 2009-554 N.C. Sess. Laws §1-607(a)(7). The State of North Carolina has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XXII

Oklahoma Medicaid False Claims Act
Okla. Stat. tit. 63, §5053.1B (7)
(Against All Defendants)

302. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

303. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs.

Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Oklahoma. Since Defendants submitted false AMPs, the State of Oklahoma received less money in Medicaid Rebates.

304. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Oklahoma, within the meaning of Okla. Stat. tit. 63, §5053.1B (7). The State of Oklahoma has thereby suffered actual damages and is entitled to recover treble Oklahoma damages and a civil penalty for each false claim.

COUNT XXIII

Rhode Island State False Claims Act
R.I. Gen. Laws §9-1.1-3(7)
(Against All Defendants)

305. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

306. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Rhode Island. Since Defendants submitted false AMPs, the State of Rhode Island received less money in Medicaid Rebates.

307. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Rhode Island, within the meaning

of R.I. Gen. Laws §9-1.1-3(7). The State of Rhode Island has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XXIV

Tennessee False Claims Act and Medicaid False Claims Act
Tenn. Code Ann. §§ 4-18-103(a)(7) and 71-5-181(a)(1)(D)
(Against All Defendants)

308. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

309. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Tennessee. Since Defendants submitted false AMPs, the State of Tennessee received less money in Medicaid Rebates.

310. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Tennessee, within the meaning of Tenn. Code Ann. §§ 4-18-103(a)(7) and 71-5-181(a)(1)(D). The State of Tennessee has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XXV

Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code Ann. §36.002(12)
(Against All Defendants)

311. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

312. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Texas. Since Defendants submitted false AMPs, the State of Texas received less money in Medicaid Rebates.

313. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Texas, within the meaning of Tex. Hum. Res. Code Ann. §36.002(12). The State of Texas Texas has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XXVI

Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(7)
(Against All Defendants)

314. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

315. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the Commonwealth of Virginia. Since Defendants submitted false AMPs, the Commonwealth of Virginia received less money in Medicaid Rebates.

316. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Virginia, within the meaning of Va. Code Ann. §8.01-216.3(a)(7). The Commonwealth of Virginia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XXVII

Wisconsin False Claims For Medical Assistance Act
Wis. Stat. §20.931(2)(g)
(Against All Defendants)

317. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

318. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the State of Wisconsin. Since Defendants submitted false AMPs, the State of Wisconsin received less money in Medicaid Rebates.

319. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Wisconsin, within the meaning of Wis. Stat. §20.931(2)(g). The State of Wisconsin has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT XXVIII

District of Columbia False Claims Act
D.C. Code Ann. §2-308.14(a)(7)
(Against All Defendants)

320. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

321. During the Relevant Time Period, Defendants were aware of their obligations to make and to use truthful records or statements regarding the AMPs for their Relevant Drugs. Defendants also knew that their AMP submissions for their Relevant Drugs would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Defendants were obligated to pay to the District of Columbia. Since Defendants submitted false AMPs, the District of Columbia received less money in Medicaid Rebates.

322. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District of Columbia, within the meaning of D.C. Code Ann. §2-308.14(a)(7). The District of Columbia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against the Defendants as follows:

B. that Defendants cease and desist from violating 31 U.S.C. §3729 *et seq.*, and the counterpart provisions of the state statutes set forth above;

C. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. §3729;

D. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §1651(a);

E. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Conn. Gen. Stat. § 17b-301b;

F. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

G. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Fla. Stat. Ann. §68.082(2);

H. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Ga. Code Ann. §49-4-168.1.

I. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-21(a);

J. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

K. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants' actions, plus a civil penalty of at least $5,000 for each violation of IC 5-11-55;

L. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §437 et. seq.;

M. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

N. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of MI Public Act 337;

O. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mont. Stat. Ann. 17-8-401;

P. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

Q. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of Defendants' actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b(I);

R. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus a civil penalty of $11, 000 for each violation of N.J. Stat. §2A:32C-3;

S. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of N.M. Stat. Ann. §27-2F-4;

T. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty of $12,000 for each violation of NY CLS St. Fin. §189;

U. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions, plus a civil penalty or $11,000 for each violation of 2009-554 N.C. Sess. Laws §1-607(a);

V. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Okla. Stat. tit. 63, §5053.1B;

W. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of R.I. Gen. Laws §9-1.1-3;

X. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. §§4-18-103(a) and 71-5-182(a)(1);

Y. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

Z. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Va. Code Ann. §8.01-216.3(a);

AA. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Wis. Stat. §20.931(2);

BB. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. §2-308.14(a);

CC. that Relator be awarded the maximum amount allowed pursuant to§3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

DD. that Relator be awarded all costs of this action, including attorneys' fees and expenses; and

EE. that Relator recovers such other relief as the Court deems just and proper.

JURY DEMAND

323. Plaintiff Relator demands a trial by jury.

Dated: September 7, 2011

Respectfully Submitted:

FARUQI & FARUQI, LLP

/s/ Jacob A. Goldberg JAG 3869
Kendall S. Zylstra
(Pa Bar No. 64006)
Jacob A. Goldberg
(Pa Bar No. 66399)
2600 Philmont Avenue, Suite 324
Huntingdon Valley, PA 19006
Tel: (215) 914-2460
Email:kzylstra@faruqilaw.com
jgoldberg@faruqilaw.com

BERGER & MONTAGUE, P.C.
Todd S. Collins
Daniel R. Miller
Joy Clairmont
1600 Locust Street
Philadelphia, PA 19103
Tel: (215) 875-3000
Email: tcollins@bm.net
dmiller@bm.net
jclairmont@bm.net

RAWLINGS & ASSOCIATES, PLLC
Mark D. Fischer
Jeffrey C. Swann
325 W. Main Street
Louisville, KY 40202
Tel: (502) 587-8060
Email: mfischer@rawlingsandassociates.com
js5@rawlingsandassociates.com

Attorneys for Relator Ronald J. Streck

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