UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ex rel. JILL OSIECKI, STATE OF CALIFORNIA, ex rel. JILL OSIECKI, STATE OF COLORADO, ex rel. JILL OSIECKI, STATE OF CONNECTICUT ex rel. JILL OSIECKI, STATE OF DELAWARE, ex rel. JILL OSIECKI, STATE OF FLORIDA, ex rel. JILL OSIECKI, STATE OF GEORGIA, ex rel. JILL OSIECKI; STATE OF HAWAII, ex rel. JILL OSIECKI; STATE OF ILLINOIS, ex rel. JILL OSIECKI, STATE OF INDIANA, ex rel. JILL OSIECKI, STATE OF LOUISIANA, ex rel. JILL OSIECKI, STATE OF MARYLAND, ex rel. JILL OSIECKI; COMMONWEALTH OF MASSACHUSETTS, ex rel. JILL OSIECKI, STATE OF MICHIGAN, ex rel. JILL OSIECKI, STATE OF MINNESOTA, ex rel. JILL OSIECKI, STATE OF MONTANA, ex rel. JILL OSIECKI, STATE OF NEW YORK, ex rel. JILL OSIECKI, STATE OF NORTH CAROLINA, ex rel. JILL OSIECKI, STATE OF NEVADA, ex rel. JILL OSIECKI, STATE OF NEW HAMPSHIRE, ex rel. JILL OSIECKI, STATE OF NEW JERSEY, ex rel. JILL OSIECKI, STATE OF NEW MEXICO, ex rel. JILL OSIECKI, STATE OF OKLAHOMA, ex rel. JILL OSIECKI, STATE OF RHODE ISLAND, ex rel. JILL OSIECKI, STATE OF TENNESSEE, ex rel. JILL OSIECKI, STATE OF TEXAS, ex rel. JILL OSIECKI, COMMONWEALTH OF VIRGINIA, ex rel. JILL OSIECKI, STATE OF WISCONSIN, ex rel. JILL OSIECKI, NEW YORK CITY, ex rel. JILL OSIECKI, CITY OF CHICAGO, ex rel. JILL OSIECKI, and the DISTRICT OF COLUMBIA, ex rel. JILL OSIECKI; and JILL OSIECKI individually, Plaintiffs, v. AMGEN, INC., ONCOLOGY SUPPLY, INC, AMERISOURCE BERGEN SPECIALTY GROUP, INC, AMERISOURCE BERGEN CORP., CARDINAL HEALTH SPECIALTY PHARMACEUTICAL DISTRIBUTION, INTERNATIONAL ONCOLOGY NETWORK, NATIONAL ONCOLOGY ALLIANCE, ONCOLOGY THERAPEUTICS, INC., WYETH, WYETH PHARMACEUTICALS, and PFIZER, INC., Defendants.	§	CIVIL ACTION NO. 05-5025 FOURTH AMENDED COMPLAINT FILED UNDER SEAL JURY TRIAL DEMANDED (Johnson, J.) (Levy, MJ)

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FOURTH AMENDED COMPLAINT

The United States of America *ex rel.* Jill Osiecki (the "United States") and the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin, and the District of Columbia, New York City, and the City of Chicago *ex rel.* Jill Osiecki (collectively "Plaintiff States"), and Jill Osiecki individually (hereinafter "Osiecki"), allege as follows in support of their Fourth Amended Complaint against the Defendants Amgen, Inc. ("Amgen"), Oncology Supply Inc., Amerisource Bergen Specialty Group, Amerisource Bergen Corp., Cardinal Health Specialty Pharmaceutical Distribution, International Oncology Network, National Oncology Alliance, Oncology Therapeutics, Inc., Wyeth, Wyeth Pharmaceuticals and Pfizer, Inc. (hereinafter collectively the "Defendants") based upon the personal knowledge of and documents in the possession of Osiecki:

I. NATURE OF THE CASE

1. This is an action by the United States of America and the Plaintiff States (collectively the United States and the Plaintiff States shall hereinafter be referred to as the "Government Plaintiffs") by and through Osiecki, against Defendants to redress violations of the federal False Claims Act 31 U.S.C. §§ 3729-3730 and the analogous laws of the Plaintiff States.

2. Amgen is a California corporation with its principal place of business located at One Amgen Center Drive, Thousand Oaks, California. In 2002, Amgen acquired Immunex Corporation ("Immunex"), a Washington corporation with its principal place of business at 51 University Street, Seattle, Washington.

3. Amgen and Immunex (collectively referred to as "Amgen") are highly diversified healthcare companies that individually, and in combination with one another, engage in the business of manufacturing, distributing, marketing and selling prescription drugs purchased and/or reimbursed by the Government Plaintiffs, through, *inter alia*, the Medicare and Medicaid programs. The Amgen drugs at issue in this case include Epogen (epoetin alfa) and Aranesp (darbepoetin alfa), which are FDA-approved for use, *inter alia*, in cancer patients with chemotherapy-induced anemia; Enbrel (etanercept) and Kineret (anakinra), which are used to treat rheumatoid arthritis; Neuopegen and Neulasta (pegfilgrastim), which are used to reduce the risk of infection in some cancer patients; and, Sensipar (cinacalcet HCI), which is used to help treat dialysis patients with imbalances of phosphorus, calcium and PTH, known as secondary hyperparathyroidism.

4. Osiecki was employed by Amgen as a sales representative from on or about November 1, 1990 through December 2, 2005. In that capacity, Osiecki was responsible for the marketing of Amgen pharmaceutical products, including Aranesp, in the Wisconsin and Illinois region. Osiecki was a member of the Great Lakes Region which, over this period, has at various times included the states of New York, Pennsylvania, Ohio, West Virginia, Kentucky, Indiana, Michigan, Illinois, Wisconsin, Iowa, Minnesota, North Dakota, South Dakota, Missouri, Nebraska, and Kansas.

5. Osiecki also regularly attended various Regional and National Sales meetings, typically held from 2-4 times per year. The dates on which such meetings were held included December of 2003 (National Meeting), January of 2004 (District Meeting), June of 2004 (District Meeting), July of 2004 (National Meeting) and October 2004 (District Meeting). Osiecki also participated in all Amgen national training seminars *via* teleconference or web link.

6. The information, materials and training provided at these meetings confirmed the uniform, nationwide scope of Amgen's unlawful schemes in marketing its drugs that caused the submission of false claims to government-funded healthcare programs.

II. JURISDICTION AND VENUE

7. This is a civil action arising under the laws of the United States to redress violations of 31 U.S.C. §§3729-3730 and the analogous laws of the Plaintiff States.

8. This Court has jurisdiction over the subject matter of this action: (i) pursuant to 31 U.S.C. §3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730; (ii) pursuant to 28 U.S.C. §1331, which confers federal subject matter jurisdiction; and, (iii) pursuant to 28 U.S.C. §1345, because the United States is a plaintiff. This Court has supplemental jurisdiction over the state law claims brought in this complaint.

9. This Court has jurisdiction over Defendants under 31 U.S.C. §3732(a) because Defendants can be found in, are authorized to transact business in, and are now transacting business in this District. In addition, acts proscribed by 31 U.S.C. §3729 have occurred in this District.

10. Venue is proper in the Eastern District of New York because Defendants conduct business in this District and, upon information and belief, acts giving rise to this action occurred within this District.

11. This suit is not based upon prior public disclosures of allegations or transactions in a criminal, civil or administrative hearing, lawsuit or investigation or in a Government Accounting Office or Auditor General's report, hearing, audit or investigation, or from the news media.

12. To the extent that there has been a public disclosure unknown to Osiecki, Osiecki is an original source under 31 U.S.C. §3730 (e)(4) and the analogous provisions of the Plaintiff States' whistleblower statutes. She has direct and independent knowledge of the information on which the

allegations are based and voluntarily provided the information to the government before filing a *qui tam* action based on the information.

13. At the time she filed her original complaint in this action in the District of Massachusetts, Osiecki concurrently provided to the Attorney General of the United States and to the United States Attorney for the District of Massachusetts a statement summarizing known material evidence and information related to this Complaint, in accordance with the provisions of 31 U.S.C. §3730(b)(2). The disclosure statement is supported by material evidence.

14. Osiecki's disclosure statement, all supplemental disclosure statements, and all documents and materials produced therewith are incorporated herein by reference.

III. PARTIES

15. The United States and the Plaintiff States (collectively the "Government Plaintiffs") are the plaintiffs for whom recovery is sought for false and fraudulent claims submitted to federally funded government programs and programs jointly funded by the United States and the Plaintiff States.

16. Osiecki is a citizen and resident of the State of Wisconsin. She brings this action on her own behalf and on behalf of the United States and the Plaintiff States pursuant to 31 U.S.C. §3730(b)(1) and the analogous laws of the Plaintiff States. She is a former employee of Amgen, as detailed herein, and is an original source of the allegations commenced against Amgen. In furtherance of the Government Plaintiffs' investigation into the unlawful acts of Defendants set forth in this Fourth Amended Complaint, Osiecki, in collaboration with government investigators, made several consensual recordings of Amgen events and conversations in the course and scope of her employment during the time frame of approximately October 2004 through November 2005. The consensual recordings include two Amgen District Meetings which took place in approximately

October 2004 and the first half of 2005; two Amgen Annual Meetings which were held in the summer of 2005 and approximately November 2005; one ride along with Osiecki's Regional Manager; and two "ride alongs" with her District Manager. In addition, Osiecki made and provided to the Government Plaintiffs her own consensual recordings made from approximately June 2004 through early December 2005 and said recordings corroborate the allegations set forth herein concerning the payment of kickbacks as well as Amgen drug pricing information. These recordings were made in accordance with all applicable federal and state law.

17. Defendant Amgen, a California corporation, is a research-based, global pharmaceutical company, with its principal place of business located at One Amgen Center Drive, Thousand Oaks, California.

18. Defendant Oncology Supply, Inc. (hereinafter OSI) is a wholly-owned subsidiary of Amerisource Bergen Specialty Group, Inc. (hereinafter ABSG). OSI is an Alabama corporation with its principal place of business located at 2801 Horace Shepard drive, Dothan, Alabama 36303.

19. Defendant ABSG is a Texas corporation with its principal place of business located at 4006 Belt Line Road, Addison, TX 75000.

20. Defendant Amerisource Bergen Corporation (hereinafter ABC), a Delaware corporation, is a global pharmaceutical service company, focusing on the pharmaceutical supply chain, providing drug distribution and related services to pharmaceutical manufacturers and healthcare providers. Its principal place of business is located at 1300 Morris Drive, Chesterbrook, PA 19087.

21. Defendant Cardinal Health, Specialty Pharmaceutical Distribution (hereinafter SPD) is a wholly-owned division of Cardinal Health, Inc. SPD's principal place of business is located at 401 Mason Road, La Vergne, TN 37081. Cardinal Health, SPD is a pharmaceutical wholesaler that

entered into contracts with Amgen. Amgen has funneled kickbacks and discounts through Cardinal Health, SPD to end customers to avoid Best Price Reporting obligations as well as to avoid compliance with the AKS

22. Defendant International Oncology Network (hereinafter ION) is a Maryland corporation with its principal place of business located at The World Trade Center, 11th floor, 401 East Pratt Street, Baltimore, MD 21202. ION is ostensibly a group purchasing organization ("GPO"). A legitimate GPO is a group of doctors, clinics, hospitals or other health care providers organized for many purposes, including the ability to make large volume purchases of prescription drugs at substantial discounts. Upon information and belief, ION does not qualify as a GPO and instead is in reality a marketing arm of Amgen through which Amgen funneled kickbacks to end customers to avoid Best Price Reporting obligations as well as to avoid compliance with the AKS. Further, ION has accepted kickbacks from Amgen in the form of rebates and chargebacks in exchange for purchasing Amgen products.

23. Defendant National Oncology Alliance (hereinafter NOA) is a Delaware corporation with its principal place of business located at Suite 350, 750 Lindaro Street, San Rafael, California, 94901. NOA is ostensibly a group purchasing organization ("GPO"). A legitimate GPO is a group of doctors, clinics, hospitals or other health care providers, organized for many purposes, including the ability to make large volume purchases of supplier products at substantial discounts. Upon information and belief, NOA does not qualify as a GPO and instead is a marketing arm of Amgen through which Amgen has funneled kickbacks to customers to avoid Best Price Reporting obligations as well as to avoid compliance with the AKS. Further, NOA has accepted kickbacks from Amgen in the form of rebates and chargebacks in exchange for purchasing Amgen products.

24. Defendant Oncology Therapeutics, Inc. (hereinafter OTN) is a California corporation with its principal place of business located at Suite 500, 399 Oyster Point Boulevard, South San Francisco, CA 94080. OTN is a pharmaceutical wholesaler that entered into contracts with Amgen to purchase various pharmaceutical products for the "list price" of the drugs. Amgen has funneled kickbacks and discounts through OTN to end customers to avoid Best Price Reporting obligations as well as to avoid compliance with the AKS

25. Defendants Wyeth and/or Wyeth Pharmaceuticals (hereinafter collectively Wyeth) manufacture and market both generic and prescription drugs. Prior to its acquisition on or about October 15, 2009, Wyeth was a publicly-traded company registered in Delaware. Wyeth is now a wholly-owned subsidiary of Pfizer, Inc. and conducts business throughout the United States (including Massachusetts and New York) and in many countries. Its headquarter office is located at 5 Giralda Farms, Madison, New Jersey, 07940.

26. Defendant Pfizer Inc. (hereinafter Pfizer) is a publicly-traded company, incorporated under the laws of Delaware with its principal place of business in New York, New York. Pfizer is engaged in the development, manufacture, distribution, and sale of pharmaceutical and health care products throughout the United States. On or about October 15, 2009, Pfizer completed its acquisition of Wyeth for a total purchase price of approximately $68 million pursuant a merger agreement. At that time, Wyeth became a wholly-owned subsidiary of Pfizer. By virtue of its acquisition of Wyeth, Pfizer is liable as the successor-in-interest to Wyeth. Defendants Pfizer and Wyeth shall hereinafter collectively be referred to as Wyeth.

IV. BACKGROUND

27. Generally speaking, Amgen engaged in at least six (6) schemes in furtherance of its improper marketing practices that, *inter alia*, caused the submission of false claims to government-funded healthcare programs:

- Marketing and promoting prescription drugs "off-label" without proper authority or medical support in violation of Federal Drug Administration rules and regulations;
- Intentionally establishing (through false price reporting discussed *infra*) and promoting the "spread" between medical providers' cost to acquire Amgen's drugs and the amount of reimbursement paid to such providers by government-funded healthcare programs ("marketing the spread");
- Providing materials and goods to existing customers with the knowledge and/or expectation that medical providers and other purchasers would increase and maintain their volume of purchases of Amgen products, with these purchases subsequently billed to the federal government;
- Providing other financial incentives and inducements, as detailed more fully herein, to induce sales of Amgen's drugs at artificially inflated prices;
- False or fraudulent reporting of the actual "best price" and/or "average manufacturer's price" for Amgen's drugs in quarterly CMS Best Price Reports submitting pursuant to Amgen's Rebate Agreement with CMS, and instead (i) reporting of higher prices and (ii) excluding discounts and other inducements described herein offered to hospitals and clinics that resulted in lower prices than the prices reported to the Medicaid Program as well as resulted in Amgen decreasing or avoiding entirely its obligations to make quarterly rebate payments to the Medicaid program; and,
- False or Fraudulent of the Average Sales Price ("ASP") for Aranesp and other drugs.

28. The remaining defendants acted in concert with Amgen in furtherance of the above referenced schemes.

29. With regard to marketing the spread, Amgen has engaged in an unfair and deceptive marketing and sales scheme pursuant to which Amgen provided improper incentives and inducements to medical providers and other purchasers of Amgen's drugs calculated to increase sales of those drugs at artificially inflated prices throughout the United States.

30. This unfair and deceptive marketing and sales scheme caused harm to the Government Plaintiffs by causing government-funded health care programs to pay more for Amgen's drugs than they otherwise would have paid in the absence of Amgen's unlawful conduct.

31. Plaintiff Osiecki further alleges that Amgen, in full knowledge of government prohibitions against the reimbursement of self-administered drugs, has created a scheme whereby the Government Plaintiffs paid for self-administered drugs under the "incident to physician care" regulations, with full knowledge that these products can be safely and effectively administered by the patient.

32. For example, Amgen's Neulasta is provided in single-dose, pre-filled syringes. The FDA labeling requires no additional patient testing or intervention after administration. In furtherance of its schemes, Amgen has instructed its sales representatives *not* to volunteer any information to medical providers and other purchasers about the fact that administration of Neulasta does not require physician assistance. At the same time, Amgen's sales representatives have been instructed to actively discourage the writing of retail prescriptions for Neulasta because retail prescriptions would allow the patient to self-administer the drugs and consequently the physicians would have to forego reimbursement for office visits and administering injections to patients.

33. These improper marketing and sales schemes were formulated as part of an overall plan by Amgen to engage in unlawful and improper methods of competition in the marketing and sale of its drugs to the detriment of the Government Plaintiffs.

34. The goal of these unlawful marketing and sales schemes is to cause Amgen's drugs to be favored by medical providers and other purchasers above all other drug therapies and modes or methods of healthcare treatment for particular health conditions. This goal is achieved by improperly persuading medical providers and other purchasers of the Amgen products at issue to

administer these drugs "in office," thereby allowing medical providers to profit from administering these drugs while benefiting Amgen by artificially inflating its market share.

35. In carrying out its schemes, Amgen representatives have advised integrated healthcare institutions as to what site of service was the most profitable, suggesting that hospital outpatient centers direct the provision of Amgen products (Neupogen, Neulasta and Aranesp) to their associated clinics because the government reimbursement rates were higher in the clinic settings, and the customers could thereby increase the "spread" that was realized on the provision of the products.

36. This activity occurred after the institution of the first Outpatient Prospective Payment System (OPPS) by Medicare, in which hospital outpatient reimbursement was set by Medicare at a different rate than in the physician clinic setting. The details of the new OPPS rule were made public in October 2002.

37. For example, Amgen representatives in Northern Wisconsin and Michigan encouraged their hospital clients to outsource the treatment of patients receiving Amgen drugs (Neulasta, Neupogen and Aranesp) to their hospital-owned clinics who were billing under the physician clinic reimbursement mechanism. The representatives demonstrated the higher profit that could be obtained for the hospital by purchasing the drugs in the hospital setting (with very steep discounts), and then transferring the product to the hospital-owned clinics to be administered in a setting with higher government reimbursement.

38. In several locations in northern and central Wisconsin, at the direction of Amgen sales representatives, the hospitals were used to purchase the drugs and the clinics were used to administer the drugs to maximize the spread reimbursement to the physicians. This spread marketing scheme was discussed in several district meetings for the Minneapolis District, occurring

on January 17, 2004, in Minneapolis, MN at the Grand Hotel; on April 23rd and 24th at the Airport Marriott in Bloomington, MN; and on October 3-4, 2004, at the American Club in Kohler, WI.

39. Amgen's recommendation to customers that they transfer patients from their traditional site of service to a different, more costly site of service caused Medicare and other government programs to incur unnecessary and increased treatment costs. This recommendation, in connection with the promotion of drug profit or spread, and the differential profit in different treatment settings, constituted an illegal inducement with the net effect of making it more attractive for physicians and health systems to use more of Amgen's products.

40. Additionally, the financial benefits of a hospital purchasing Aranesp under the hospital contract and billing it under the clinic billing system (HCFA 1500 billing form) was discussed and presented at district meetings at the American Club in Kohler, WI on October 3-4, 2003 and at Le Meridien in Minneapolis, MN on January 16-17, 2004.

41. Moreover, Amgen is well aware that their injectable products Aranesp and Neulasta were at risk of being declared self-administered drugs. Removing Medicare coverage of either of these products would diminish the profit incentives that Amgen has devised as a part of its highly successful promotion of these products. Therefore, Amgen carefully monitors and calibrates the amount of self-administration that is occurring with each of their injectable drugs. Self-administered product usually is purchased by retail pharmacies for dispensing to patients who receive a prescription from their physician.

42. With Aranesp, Amgen is supporting increasing the market share of product used in the retail setting, because greater retail prescriptions will have a net effect of raising the Average Selling Price ("ASP") that Medicare began to use to set reimbursement of drugs in 2005 and beyond. Amgen does not grant price concessions to retail pharmacies, but gives large discounts to

hospitals and physicians; therefore, higher sales in the retail setting will tend to raise the ASP. To support this strategy, Amgen has offered a significant bonus to all sales representatives who can increase their retail market share during the last half of 2004. Amgen's scheme is aimed at converting retail prescriptions of Procrit to retail prescriptions of Aranesp, thus increasing the ASP for Aranesp, while decreasing the ASP of Procrit. Influencing the ASP of both products in those ways plays into the overall strategy of offering superior financial incentives to providers through the "spread."

43. With regard to Neulasta, there is no competitive situation to differentially influence competing ASP prices. As such, Amgen continued its normal policy of discouraging retail prescriptions where possible for Neulasta, because overall, retail prescriptions of Neulasta are self administered. Self-administration diminishes the profit incentive by the prescribing physician who looses reimbursement for an office visit and, therefore, may decrease the amount of product usage.

44. Enbrel (entanercept) is an arthritis and psoriasis drug marketed jointly by Defendants Wyeth and Amgen. It is administered to patients in many different settings, including physicians' offices, outpatient clinics, hospitals and long term care facilities. Enbrel is derived by introducing human DNA into Chinese hamster ovary cells and creating a genetically engineered protein. Enbrel is a type of protein called a "tumor necrosis factor" (TNF) blocker, and it stops the body from making TNF. People with immune diseases, such as rheumatoid arthritis and psoriasis, have too much TNF in their bodies.

45. Defendants Wyeth and Amgen conspired to market Enbrel for off label purposes through the website www.medscape.com and through an online Continuing Medical Education program. Wyeth's scheme for Enbrel was to increase market share through the covert commercialization of CME programs.

V. FEDERAL LAW PROHIBITS KICKBACKS TO INDUCE PURCHASES OF DRUGS PAID FUNDED BY GOVERNMENT HEALTHCARE PROGRAMS.

46. The Medicare and Medicaid Fraud and Abuse Statute (Statute) was first enacted under the Social Security Act in 1977. The Statute imposes criminal penalties on anyone who, in violation of the Anti-Kickback Provision:

> offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2)(B).

47. Many of the Plaintiff States have enacted analogous laws, cited to and referred to herein.

48. This provision, known as the Anti-Kickback Statute, and the analogous laws of the Plaintiff States applies to Amgen, whose drugs are included on the Medicare and Medicaid formulary, and formularies of other government-funded healthcare programs. Accordingly, the Anti-Kickback Statute and the Plaintiff States' laws prohibited Amgen from engaging in the mere act of offering illegal remuneration, regardless of whether the inducement is ultimately accepted by the buyer of Amgen's drugs. Such inducements cause financial and patient harm because they encourage unnecessary treatments, influence the free exercise of medical judgment by providers, limit patient options and lead to higher payments for medical services by government-funded healthcare programs.

49. The AKS further defines "remuneration" to include "transfers of items or services for free or for other than fair market value." *Id.* § 1320a-7a(i)(6). Perhaps underscoring the breadth of the statutory definition, the HHS OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (1991), broadly define the term "remuneration" as "anything of value in any form whatsoever." *See*

also OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 66 Fed. Reg. 23731, 23734 (May 5, 2003) (AKS addresses the offer or payment of "anything of value"). Accordingly, the exchange of free goods as well as the exchange of money can give rise to violations of the AKS where the intent element is met.

50. Federal and applicable state laws are clear that a prescription drug reimbursement claim is ineligible for reimbursement where the entity submitting the claim was offered and/or accepted a kickback where the kickback was offered with the intent to induce the purchase of the drug. Accordingly, if submitted, such a claim is *false,* as the term is defined by the Federal False Claims Act and the analogous laws of the Plaintiff States.

51. The Patient Protection and Affordable Care Act, Publ. L No. 111-148, 124 Stat. 119 § 6402(f)(1) (2010) ("PPACA"), which became law on March 23, 2010, leaves no doubt that violations of the AKS give rise to a violation of the FCA, by providing: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the False Claims Act]." In other words, pursuant to the PPACA, claims for items or services billed to government-funded healthcare programs (including Medicare) "resulting from" a violation of the anti-kickback statute are "false or fraudulent claims" under the FCA.

52. The PPACA also clarified the intent requirement for the AKS as follows: "a person need not have actual knowledge of this section or specific intent to commit a violation" of the AKS in order to be found guilty of a "willful violation." Accordingly, proof that a Defendant knew of and specifically intended to violate the AKS is not required. Instead, proof that the Defendant intended to perform the actions that violated the AKS is sufficient to establish liability.

53. At all times relevant to this Fourth Amended Complaint, compliance with the Anti-Kickback Statute has been a condition to participation for a health care provider under Medicare.

Moreover, compliance with the AKS is a *condition of payment* for claims made to Medicare for reimbursement for services, including home health services.

54. For example, under 42 U.S.C. § 1395y(a)(1)(A), "nonpayment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury."

55. Kickbacks are, by definition, not "reasonable and necessary for the diagnosis or treatment of illness or injury."

56. Amgen, by and through the acts of offering and paying cash and in kind kickbacks to GPOs, wholesalers and end customers as alleged herein, have caused false claims for Amgen's drugs to be submitted to the Government Plaintiffs. These false claims have been submitted by Amgen's clients, i.e. hospitals, clinics and other medical providers and alleged herein, which accepted Amgen's kickbacks – directly and/or indirectly.

57. The remaining Defendants, which include GPOs and wholesalers, played an integral role in the kickback scheme by accepting kickbacks from Amgen's in the form of rebates, chargebacks and administrative fees and in accord with Amgen's scheme, passing through part of those kickbacks to Amgen's purchaser/clients. This "wholesaler passthrough" schematic devised by Amgen and the remaining Defendants was – as still is - nothing more than sham designed to disguise a thriving kickback scheme through which the Defendants caused providers to submit hundreds of thousands of false reimbursement claims for Amgen drugs to government-funded healthcare programs. In addition, Amgen did not report these discounts afforded to its customers accomplished through the wholesaler passthrough scheme as part of ASP, AWP or best price.

VI. MARKETING AND PROMOTING THE "SPREAD"

58. Up until 2005, reimbursement for prescription drugs by government-funded healthcare programs such as Medicare and Medicaid was based, in whole or part, on the "Average Wholesale Price," or the "AWP." The AWP is not an "average" of "wholesale" or manufacturers' pricing, as the names suggests, but instead is a price that is controlled and set by drug manufacturers, including Amgen.

59. Plaintiff Osiecki became aware, based upon her training and knowledge of Amgen reimbursement policies from 1990 through 2004, that Amgen set the AWP 25% above the list price of Amgen products.

60. In 2005, government-funded healthcare programs such as Medicare and Medicaid went to an ASP-based reimbursement model. Amgen's schemes to manipulate ASP are discussed *infra.*

61. Amgen reported the AWP for its drugs to various pricing compendia, such as the *Red Book* and *First Data Bank*, which in turn published these AWPs in reference books that are used and relied upon by both the public and private sector. Medical providers and other purchasers of Amgen's drugs used the AWP in billing the Medicare and Medicaid programs for Amgen's drugs prescribed and sold throughout the United States.

62. The AWPs reported by Amgen did not represent prices actually paid by any medical provider or other purchaser of Amgen's drugs.

63. Instead, Amgen intentionally inflated the AWP for its drugs so that government-funded healthcare programs would reimburse providers for its drugs far in excess of the price they paid to acquire them.

64. In addition to controlling and setting the price used by the Government Plaintiffs to calculate reimbursement (the AWP), Amgen also set and controlled the acquisition costs paid by medical providers and other purchasers of its drugs through aforementioned direct and indirect marketing and sales schemes (including GPOs and wholesalers). The acquisition costs, i.e. the costs to acquire Amgen's drugs, were far below the AWP-based prices paid by Medicare and Medicaid.

65. Amgen has deeply discounted the acquisition costs for its drugs far below the AWP-based prices paid by Medicare and Medicaid for these same drugs to create "spreads" between the acquisition costs and the AWPs. Included in these lower prices were off-invoice discounts ("OIDs") that Amgen offered to customers to induce purchases of Amgen's products.

66. Amgen sales representatives have carried out the company's scheme by explaining to medical providers and other customers that they could *personally* profit from prescribing Amgen products. For example, Amgen sales representatives have been directed to explain to medical providers that they could generate substantial income by prescribing Aranesp injections.

67. Osiecki has personal knowledge that Amgen accomplished this goal by describing to medical providers the "spread" between (1) the per unit allowable amount reimbursed by Medicare and (2) the lower quantity discount price actually paid by the medical provider to Amgen. Projections made by Amgen to medical providers showed, for instance, that a doctor could obtain a profit from Medicare of over $100 dollars for each 100 mcg Aranesp injection purchased from Amgen.

68. By controlling and inflating the acquisition cost for its drugs paid by it customers and the end payors, such as the Government Plaintiffs through Medicare and Medicaid programs, through discounts and rebates, Amgen has created and manipulated the spreads for drugs sold

directly to medical providers and other customers to the financial detriment of the Government Plaintiffs.

69. The spread created by Amgen constitutes an unlawful kickback.

70. Amgen unlawfully promoted and marketed these "spreads," and the profits to be realized therefrom, to its customers throughout the relevant time period.

71. Amgen's marketing and sales practices have resulted in a perverted "competitive" environment whereby Amgen has sought to continually raise, inflate and fix the AWPs for its drugs, which, in turn, has allowed Amgen to increase the prices paid by its customers in order to continually increase its sales and the profits realized by both Amgen and its customers for Amgen's drugs.

72. This "competitive" environment has had a detrimental effect on the Government Plaintiffs and taxpayers. By "competing" on spreads, Amgen has caused the Government Plaintiffs and taxpayers to pay more for Amgen's drugs than they otherwise would have paid in the absence of Amgen's misconduct. Amgen knows that the profit or "spread" on drug utilization introduces an incentive for physicians and providers to prescribe and use more of the product than they otherwise would, which also increases the costs to the government and other payors.

73. Amgen also knows that several of its drugs compete with other manufacturers' drugs. In some cases, as detailed herein, Amgen manipulated the AWP to create a reimbursement advantage for its drugs. Specifically, Amgen's Kineret competes with Johnson & Johnson Group, Inc.'s Remicade; Neupogen and Neulasta competed against Immunex's Leukine; and Aranesp competes against Procrit, Johnson & Johnson's epoetin alfa product. To assure that its drugs gained market share, Amgen manipulated the AWP for its drugs so that reimbursement rates paid to customers by the Government Plaintiffs would greatly exceed their drug acquisition costs.

74. To carry out its scheme, Amgen has ensured its sales representatives were focused on reimbursement and customer profit motives.

75. Amgen contracts have been purposefully structured so as to provide for increasing discounts based upon increasing dollar purchases of Amgen products. Additional prescriptions of Amgen products caused the price paid by customers to decrease and the "spread" between the acquisition cost and reimbursement from government-funded healthcare programs to increase. By incentivizing greater dollar purchases of Amgen products, providers' profitability increased with greater utilization. Amgen helped customers to understand the economic benefits associated with greater utilization of their products by including providing target patient utilization numbers for each increasing level of product discount. Amgen's marketing scheme caused physicians to make decisions based on patient utilization based upon hitting financial targets, which runs counter to the concept of medical necessity upon which all government reimbursement is based, and encourages product usage for financial gain rather than for medical necessity.

76. By way of example, since Aranesp's launch in October of 2001, the competitive environment between Amgen's Aranesp and Ortho Biotech's Procrit has changed several times. Because of changing government reimbursement levels, and changing contracts responding to both reimbursement changes and competitive contract levels, the "spread" advantage has vacillated back and forth between Aranesp and Procrit over this entire time period.

77. Because Amgen was convinced its competitor Ortho Biotech was marketing Procrit using the spread or profit during the time frames that they had an advantage, Amgen sales representatives were advised to gather any and all evidence that they could, to demonstrate to the federal government that Ortho Biotech was marketing on the spread.

78. Conversely, when the spread advantage was in Amgen's favor, Amgen management cautioned the Amgen sales force that Ortho Biotech would be looking for any evidence that they could find to show the government that Amgen was marketing on the spread.

79. Therefore, when Amgen had the advantage on profit, sales representatives were advised by management to "be smart—use it, but don't leave it." (The "it" being spread marketing tools). On the other hand, when Ortho Biotech had the profit advantage, Amgen representatives had no incentive to market the "spread" and instead shifted to a cost reduction marketing strategy. This dynamic has shifted several times since the launch of Aranesp.

80. An example of the "be smart" philosophy is demonstrated in a PowerPoint slide deck that was presented to Joliet Oncology of Joliet, Illinois, by Amgen's local sales representative, Mike Reinle, and the Amgen Corporate Account Manager, Steve Kolwitz. This presentation was described as a "best practice" to the Great Lakes Region, and Osiecki was asked by her district manager, Lisa Croissant, to use this presentation as a template for a presentation to a high volume account in her territory, Aurora Healthcare. Croissant forwarded the presentation to Osiecki for just that purpose.

81. The Joliet Oncology presentation is of interest in that, at the point in the presentation where it was logical to present the "spread marketing" information, the slide deck paused for discussion/presentation of the "Summary Sheet." The "Summary Sheet" was a blank "income statement" describing the various inputs to the "spread." By providing the information to the attendees verbally, and having them record the inputs, the Amgen personnel were abiding by the "be smart" philosophy—providing the information without direct evidence that they presented it to the physician group. Amgen presenters Reinle and Kolwitz explained that they were concerned that

Ortho Representatives might be able to gain copies of their presentation, so they made sure that the financial data was in the handwriting of the physicians

82. Amgen carried out similar schemes to manipulate the ASP for its drugs beginning in 2005, when ASP became the basis for prescription drug reimbursement claims.

83. Once measure taken by Amgen to increase the ASP for Aranesp so as to increase the spread was a voucher rebate program, launched in mid-2004 in preparation for the switch to an ASP-based reimbursement schematic for government-funded healthcare programs in 2005. Osiecki's manager, Lisa Croissant, circulated a PowerPoint slide show outlining the voucher rebate program styled as a "retail contest." In the slideshow Amgen identifies retail as a "[s]trategically important market segment."

84. Pursuant to the voucher program, Amgen sales representatives were given vouchers for a free month's supply of Aranesp to distribute to targeted physicians to encourage Aranesp prescription writing. In turn physicians were to give these vouchers to their patients. The vouchers came in the form of a special retail label that the physician would affix to his or her Aranesp prescription. The special label "enrolled" the patient so he or she was eligible to receive free Aranesp. The patient would take the prescription affixed with the special label and collect his or her free on month supply of Aranesp at the pharmacy. The free month's supply was offered in the following doses only: 4/100 mcg pre-filled syringes or 2/200 mcg pre-filled syringes.

85. Amgen intended that the free one month supply of Aranesp would lead to refill prescriptions paid at full price thereafter from the retail pharmacies. Subsequent refills would follow the standard prescription refill process and the appropriate cost would be charged to the patient's non-government-funded prescription plan as well as the necessary co-pay.

86. Amgen expressly excluded from the voucher program all patients who participated in Medicare, Medicaid or other federal or state health programs

87. In furtherance of the roll out of the voucher program, Amgen provided sales representatives with retail target lists as well as Aranesp sample kits equal to the number of top retail targets in each representative's territory.

88. Amgen put no limit on the number of patients a physician could enroll in the voucher program.

89. Relator Osiecki's District Manager repeatedly told Osiecki during multiple District Meetings that the purpose of the voucher program was to drive retail sales of Aranesp, with the ultimate goal of increasing Aranesp's ASP, and in turn with the effect increasing the spread for physician customers who were afforded deep discounts below the ASP price. Indeed, Amgen stated that retail sales were of "increasing importance" in 2005.

90. Upon information and belief, for the purpose of artificially inflating the ASP for Aranesp, Amgen purposefully did not take into account the voucher program discounts in calculating ASP or in calculating best price/AMP.

A. HOSPITAL CONTRACTS PURSUANT TO WHICH AMGEN PROMOTED THE "SPREAD" ILLEGALLY GENERATED BY AMGEN.

91. Defendant Amgen has also entered into improper contracts with private and public hospitals. The improper contracts have included various improper inducements, including rebates and discounts, designed to increase Amgen's market share of specific products and to increase its overall sales volume. These inducements have been made to encourage Amgen customers to purchase and prescribe Amgen's drugs over competing drugs or alternative forms of medical care and treatment, rather than to ensure that the most medically appropriate treatment was provided.

92. Moreover, these market share based arrangements supported Amgen's off-label promotional scheme for its drugs because sales representatives promoted to customers that the market share goals required to maximize rebates and off-invoice discounts were attainable if Amgen drugs, in particular Aranesp, were used off-label.

1. The Enhanced Momentum II Hospital Contract.

93. Due to the ongoing competitive marketing of Aranesp and Ortho Biotech's Procrit, Amgen developed the Momentum I hospital contract in 2003 to counter Ortho Biotech's pricing and marketing schemes for Procrit. Due to revised pricing schemes for Procrit and Aranesp, the Enhanced Momentum II Hospital Contract (Momentum II) was developed and took effect for the period of June 1, 2004 through April 30, 2006. Hospitals that were already purchasing Neulasta and Neupogen were automatically enrolled in this program.

94. Under the terms of the contracts, hospitals enrolled in the program receive off-invoice discounts of 25% on their purchases of Aranesp vials and singlejects and 2% on the purchases of Neulasta and Neupogen.

95. Hospital-based dialysis centers receive an off-invoice discount of 11% on all Epogen vials, with the exception of Epogen M20 vials for which an off-invoice discount of 17% is provided. Hospitals without dialysis centers receive a discount of 3% on all Epogen vials.

96. Further, effective October 1, 2004, pursuant to the Momentum II contract, hospitals also receive unreported rebates from Amgen based on the market share of Aranesp and volume of sales of Neulasta and Neupogen.

97. The hospitals receive rebates of up to 21.5% on their total quarterly purchases of Aranesp based on this drug's market share at the hospital. The hospitals also receive rebates of up

to 8% on their quarterly purchases of Neupogen and Neulasta, with the rebate amounts directly tied to Aranesp's market share.

98. To receive the rebate on the purchases of Neulasta and Neupogen, the hospital's net quarterly purchases must equal or exceed 70% of the prior year's same-quarter net purchases.

99. By offering these increased off invoice discounts and rebates based on the market share of Aranesp and continued high purchase volumes of Neulasta and Neupogen, Amgen has improperly induced the hospitals to purchase and prescribe Amgen's drugs over competing drugs or alternative forms of medical care and treatment. The scheme has interfered with the healthcare providers' ability to make unbiased and neutral judgments as to the appropriate medicines to use. As a result, the Government Plaintiffs have been harmed by Amgen's conduct.

2. The Total Oncology Partner Program

100. Amgen also initiated the Total Oncology Partner program ("TOP") with many of the same hospitals that were participants in the Momentum II contract. The TOP program has similarly offered illegal inducements to participant hospitals in the form of rebates in two discrete ways.

101. The TOP program offers rebates to hospitals based on Amgen's increase in product market share at individual hospitals. If Amgen's product market share increases by 1.5 % to 9.49% in a given quarter, the hospital receives a rebate of 21.5% on its Aranesp purchases and a rebate of 2% to 4% on its purchases of Neulasta and Neupogen.

102. If Amgen's quarterly product market share at the hospital is at least 79.5% or the market share increased by 9.5% or more in the quarter, the hospital receives a rebate of 21.5% on Aranesp and a rebate of 7% on the purchases of Neulasta and Neupogen.

103. Further, if the hospital was a partner in both the Momentum II and TOP programs, it is entitled to combine its rebate percentages for its eligible Neulasta and Neupogen purchases.

104. For example, if the hospital achieves the top tier rebate percentage of 7% for Neulasta and Neupogen under Momentum II and the top tier rebate percentage of 8% under the TOP program, the rebate paid by Amgen increases to 15% on the purchases of these drugs.

105. By tying together the two programs and offering increased rebates based on the level of Amgen's market share, this scheme has interfered with the hospitals' ability to make unbiased and neutral professional judgments as to the appropriate medicines to use and purchase for the care of its patients.

106. By offering these increased off invoice discounts and rebates based on the market share of Aranesp and purchase volumes of Neulasta and Neupogen, Amgen has improperly induced the hospitals to prescribe and sell Amgen's drugs over competing drugs or alternative forms of medical care and treatment. As a result, the Government Plaintiffs have been harmed by Amgen's conduct.

3. The Disproportionate Share Program

107. In April 2004, Amgen initiated the Disproportionate Share Program (Dsh). That program is a contractually-based program directed to public hospitals, notably those PHS-eligible public hospitals which have a disproportionate share of indigent patients. The program contains illegal inducements, including high off-invoice discounts designed to attract and retain business from these entities.

108. This two-tier program has been offered to hospitals meeting certain criteria. If the hospital had a 50% market share of Aranesp products for the two months prior to executing a Letter of Commitment (LOC) and its purchases of Neulasta and Neupogen for the quarter prior to executing the LOC was equal to or greater than 70% of its purchases for the prior year's same quarter, it was enrolled in the Dsh Program A. If the hospital met only the Aranesp criteria, it was

enrolled in the Program B Option. The hospital also agreed to waive any discounts, rebates or other incentives it was receiving under any group purchasing organization (GPO) agreement. The Dsh program offered substantially higher off-invoice discounts off of the prevailing Wholesaler Acquisition Price for its in-patient pharmaceutical purchases as opposed to the GPO agreements.

109. If a hospital was to commit to a planned therapeutic exchange from Procrit to Aranesp, Amgen would waive the program enrollment requirements provided that the exchange occurred within sixty (60) days of execution of the Letter of Commitment and the hospital achieved the 50% Aranesp market share level within sixty (60) days of participation in the Dsh program.

110. Hospitals in the Dsh Program A receive discounts of 38.4% to 42.25% on certain Aranesp products, an 8% discount on certain Neupogen products, 10% on certain Neulasta products and 3% on Epogen. The hospital remains eligible for these discounts as long as it meets and maintains a 50% Aranesp market share on a monthly basis, and the hospital's Neupogen and Neulasta purchases during any given calendar quarter are greater than or equal to 70% of the hospital's purchases during the prior year's same calendar quarter.

111. If the hospital enrolls in the Dsh program B option, the hospital receives the Program A discounts on the Aranesp and Epogen products, while the hospital's discounts were reduced to 2% for its Neupogen and Neulasta purchases

112. If a Program A hospital maintains its Aranesp goal but fails to meet the Neulasta/ Neupogen goal in any given quarter, the hospital is transferred to the Program B Discount option. Further, if a Program A hospital fails to maintain its Aranesp market share levels for three (3) consecutive months, regardless of whether it met the Neulasta/Neupogen goals for the quarter preceding the last month of Aranesp noncompliance, it is terminated from the Dsh program and realigned with its prior GPO Agreement under which it was purchasing Amgen products.

113. If a hospital enrolled in the Program B discount plan fails to meet its Aranesp 50% market share goal for three consecutive months, it is terminated from the Dsh program and realigned with its prior GPO Agreement under which it was purchasing Amgen products.

114. The discounts under the Dsh program have been substantially higher than those available under standard GPO agreements. By using a "carrot" (Dsh program discounts) and a "stick" (the removal from the program if the volumes of Amgen product purchases fail to meet the required purchasing tiers), Amgen has been able to increase their market share and revenues by inducing hospitals to achieve and maintain high levels of purchases from Amgen.

115. More importantly, by undercutting the pricing schemes of Ortho Biotech, and waiving pre-enrollment requirements for healthcare providers using Procrit, Amgen induced healthcare providers to switch over to Aranesp as they received substantial price breaks on the various Amgen products.

116. By offering these increased off invoice discounts based on the market share of Aranesp and continued high purchase volumes of Neulasta and Neupogen, Amgen has improperly induced the hospitals to purchase and prescribe Amgen's drugs over competing drugs or alternative forms of medical care and treatment. The scheme has interfered with the healthcare provider's ability to make unbiased and neutral judgments as to the appropriate medicines to use. As a result, the Government Plaintiffs have been harmed by Amgen's conduct.

B. IMPROPER PAYMENTS TO CONSULTANTS TO INFLUENCE HOSPITALS

117. Amgen has retained paid consultants to meet with the appropriate parties at private and public hospitals to persuade hospitals to switch to and/or increase their volume of purchases of Amgen products. In most hospitals, the appropriate parties to speak with would be the director of the pharmacy and other senior medical staff.

118. Amgen has determined that the directors of pharmacy at large academic and institutional hospitals are the key persons to contact because they make the critical decision as to what drugs are put on formulary. Amgen has used its paid consultants to meet with and discuss the clinical and economic advantages of using Amgen products over those of its competitors.

C. IMPROPER USE OF PROFESSIONAL ADVISORY BOARDS TO INFLUENCE HOSPITALS AND OTHERS.

119. Amgen has participated in other activities to induce hospitals, doctors and other healthcare providers to promote the sale of their products and/or switching to its products at substantially discounted prices.

120. Amgen retains so-called Professional Advisory Boards (PABs) that generally consist of doctors who have favorable opinions of Amgen products. The purpose of these boards is to discuss and advocate the use of Amgen products at seminars and other medical professional gatherings. Essentially, PABs were nothing more than another marketing arm of Amgen and by appearances a legitimate way to funnel money to top Amgen prescribers to maintain brand loyalty.

121. The PAB presentations are directed to medical professionals who are ambivalent about the use of Amgen products and/or who strongly prefer products of Amgen's competitors, including, but not limited to, Ortho Biotech's Procrit.

122. The PAB members extol the benefits of Amgen products and relate anecdotes of their successes with Aranesp and other Amgen pharmaceuticals. Their efforts are geared toward convincing their audience to either increase their use of Amgen product or to switch over from the use of the competing products.

123. All of the seminar attendees receive a stipend from Amgen and PAB members receive a fee and partial reimbursement of their expenses from Amgen. The payment of the fees creates an inherent conflict of interest and leads to biased opinions of PAB members, as their

presentations have favored Amgen over its competitors, yet seminar attendees were not made aware of the financial dealings between the speakers and Amgen

124. Similarly, Amgen has had a Pharmacy Advisory Board (PhAB), whose purpose was to advise pharmacists, particularly those at hospitals and other large institutions, as to the economic and clinical benefits of using Amgen products. Directors of pharmacies at large hospitals were the key contact persons, from Amgen's perspective, as they generally controlled what drugs went on formulary.

D. IMPROPER USE OF UNRESTRICTED EDUCATIONAL GRANTS TO INFLUENCE HOSPITALS AND OTHERS

125. In an effort to increase its volume of sales with existing customers, namely hospitals, Amgen has made what were known as unrestricted educational grants to various physicians, hospitals and other institutions. These grants would often be in the form of a sponsorship of a seminar or meeting held at existing or potential customer facilities. The sponsored speaker(s) would discuss disease processes and stages and further discuss how Amgen products were clinically and economically beneficial in the treatment of these diseases.

126. Although Amgen has stated in letters and other materials related to grants of this nature that there was no expectation of any quid pro quo, there was an implicit understanding that the grantee would increase its purchases of Amgen product and/or its speakers would advocate the use of the defendant's products to other attendees at the seminar.

127. These grants are illegal inducements to the hospitals to change or switch their prescribing and billing habits in order to create financial incentives for greater Amgen product use.

E. IMPROPER USE OF PATIENT EDUCATION GRANTS TO INFLUENCE HOSPITALS AND OTHERS

128. In addition to the unregistered education grants, Amgen has also supplied Patient Education Grants ("PEGs") to customers.

129. These grants have been made to various hospitals for the purchase of various education materials and other supplies a hospital needed to create a patient education center. These materials have consisted, in part, of books and research materials on cancer and the various treatments.

130. In exchange for providing funds for these centers or rooms, the hospitals have been expected to increase or maintain its purchase of Amgen pharmaceutical products. This exchange has been an implicit understanding as Amgen has been careful not to state its expectations in any correspondence related to these grants.

131. These grants are illegal inducements to the hospitals to change or switch their prescribing and billing habits in order to create financial incentives for greater Amgen product use.

VII. AMGEN'S OFF-LABEL MARKETING

132. At all times relevant to this action, Amgen has maintained sales and sales support field forces throughout the United States.

133. For fifteen (15) years, Jill Osiecki worked in the Wisconsin and Illinois region as a professional sales representative ("PSR"). During that time, she marketed Epogen, Aranesp, Neupogen and Neulasta.

A. FDA REQUIREMENTS FOR DRUG ADVERTISING AND LABELING INFORMATION

134. The pharmaceutical industry is highly regulated by the Food and Drug Administration ("FDA").

135. Pursuant to the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, the FDA strictly regulates the content of consumer and physician based advertising, direct to physician product promotion, and drug labeling information used by pharmaceutical companies in promoting and selling FDA-approved prescription drugs.

136. Under 21 C.F.R. § 202.1(k)(2), any brochures, handouts, slide shows or other such promotional materials aimed at physicians are deemed to be "product labeling" and is regulated as such.

137. Under relevant FDA regulations, product labeling must be pre-approved by the FDA and conform to very exacting requirements concerning, *inter alia*, drug interactions, indicated uses and claims concerning competing products. *See* 21 C.F.R. § 201.57.

138. All claims made in any labeling material must be truthful, cannot be misleading and must represent a fair balance of the information presented.

139. Any presentations, promotions or marketing to physicians for products for use other than that approved for labeling purposes by the FDA is considered "off label" marketing and, thus, is prohibited by FDA regulations.

140. Any failure to fairly and accurately represent the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. *See* 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n); 21 C.F.R. § 201.57.

141. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading violate the Food Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated hereunder. Such violations exist where promotional and marketing materials and presentations for an FDA approved drug:

- Minimize, understate or misrepresent the risks, contra-indications and complications associated with that drug;

- Overstate or misrepresent the risks, contra-indications and complications associated with any competing drugs;
- Reference "off label" uses of the drug for which it was not an approved indication by the FDA, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated;
- Make comparative claims about the drug that have not been demonstrated by substantial evidence, such as comparisons with competing drugs and/or drug indications of patient usage, warnings and safety claims including side effects, physician preference, or
- Are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

B. AMGEN'S OFF-LABEL MARKETING SCHEMES

142. Amgen currently markets Epogen, Aranesp, Neupogen, Enbrel, Kineret, and Neulasta. The FDA has approved each of these medications only for the treatment of specific medical conditions.

143. To expand the market penetration of these drugs, Amgen has engaged in a pattern of marketing each of these medications for "off-label" uses not approved by the FDA. Osiecki, as a member of the Oncology Business Unit, is intimately familiar with current and recent "off-label" promotional schemes involving Aranesp and Neulasta.

144. To effectuate its off-label marketing program Amgen has engaged in a scheme to make unsubstantiated representations as to the efficacy of some of its medications.

145. Amgen's off-label promotion is also an integral part of the aforementioned scheme to promote products based upon profit or "spread." Off-label usage of Aranesp and Neulasta increases the dollar volume of purchased Amgen products, thereby increasing both discounts and profits to customers.

146. All of Amgen's "off-label" promotional activities have constituted false and fraudulent statements as a matter of law under the Food, Drug, and Cosmetics Act, 21 U.S.C.

section 331(a) and (b), 352(a) and (f) and regulations promulgated by the FDA to implement that Act.

147. Amgen knew and intended for its "off-label" promotional campaign to increase the submission of prescriptions for Aranesp and Neulasta, and for uses for which the drugs had not been FDA approved, including those prescriptions reimbursed by Medicare and Medicaid programs.

148. Absent Amgen's unapproved, illegal off-label marketing and its false statements concerning those medications, physicians would not have been led to believe it was medically prudent or necessary to write so many prescriptions for Aranesp and Neulasta.

149. Amgen's off-label marketing programs have been extremely successful leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

1. Aranesp, Generally

150. On or about September 17, 2001, the FDA approved Aranesp for use in the United States for the treatment of anemia associated with chronic renal failure ("CRF"), both in patients on dialysis and those not on dialysis. On or about July 17, 2002, the FDA approved the drug for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies ("CIA").

151. Aranesp's FDA-approved dosing regimens are disease-specific, with a recommended starting dose in renal failure patients of .45mcg/kg body weight injected on a weekly basis. For patients with chemotherapy induced anemia, the recommended starting dose is 2.25 mcg/kg administered as a weekly subcutaneous injection. The only FDA-approved dosage for Aranesp for CIA was once weekly, up until March 23, 2006, when the FDA approved once every 3 week dosing for Aranesp for CIA only.

152. Off-label promotional activities with Aranesp have occurred and been encouraged by Amgen management from the original approval date, contrary to the purported "company policy" not to engage in off-label promotion.

153. The various Aranesp off-label promotional schemes engaged in by Amgen include:

- Promotion of various off-label dosing schemes, including once every two weeks (Q2W), once every 3 weeks (Q3W) and monthly dosing in oncology patients. Also, Q2W and once per month dosing in renal patients;
- Promotion of use of Aranesp in the Anemia of Cancer (AOC), also referred to as the Anemia of Malignancy; and,
- Promotion of the use of Aranesp in Myelodysplastic Syndrome, or MDS.

154. Amgen's support for promotion of these off-label indications has included training materials and presentations on both a national and regional level, provision of a "proof source" book with abstracts and posters, representative "personal selling binders" composed of FDA approved literature commingled with personally selected, and sometimes personally produced, selling materials, and non-branded discussion aides to discuss a non-indicated disease state (AOC).

155. Additional support has included the activities of the Government Economic Managers who were actively lobbying Medicare Carriers and Fiscal Intermediaries to cover the various off-label indications and schemes, as physicians would not prescribe medications that would not be reimbursed.

i. Off-label Marketing of Aranesp for Anemia of Cancer

156. During 2003 and 2004, Aranesp was at a competitive disadvantage in the area of insurance coverage to Procrit®, the more established and well-known anemia product marketed by Johnson and Johnson by and through its subsidiary, Ortho Biotech. Procrit® was covered by Medicare and Medicaid for a number of uses that those programs did not cover for Aranesp. To utilize the spread marketing strategy, coverage of Aranesp by Medicare, Medicaid and other third

party payors was a key competitive factor because any use of a drug that was ineligible for reimbursement would greatly reduce the profitability of that drug for physicians.

157. The pricing contracts for the purchase of Aranesp or Procrit were structured on a market share basis so that customers had to purchase a minimum dollar figure of the contracted product to achieve and/or maximize price concessions, which had the net effect of precluding purchase of the competitive product. Amgen sought to prevent Aranesp-loyal customers from purchasing Procrit® for use for conditions that Medicare and Medicaid covered for Procrit® but would not be covered for Aranesp.

158. Among the off-label uses for Procrit® that was covered by Medicare was the "Anemia of Chronic Disease." According to Osiecki's customers, as well as competitive information provided to Amgen by their sales force, the billing code for Anemia of Chronic Disease was promoted by Ortho Biotech as a catch-all for circumstances that would not be otherwise covered by Medicare. Many customers did not want to purchase two anemia products, and simply continued to purchase Procrit® as their only anemia product because of its comparably more attractive insurance coverage.

159. To gain market share from Procrit, beginning in 2003, Relator Osiecki learned of a new strategy to promote Aranesp off-label for a use known in Amgen vernacular as "Anemia of Cancer."

160. According to Amgen-taught continuing medical education seminars, the disease of cancer causes anemia by producing an "anemia-inducing substance." This substance makes anemia very prevalent in many types of cancer regardless of whether cancer patients undergo chemotherapy, and causes the correction of anemia in cancer patients to be more difficult than in other types of patients.

161. In the intense competitive environment fostered by Amgen upper management, Amgen Sales and Marketing were expected to capture greater than 50% of the market share for Aranesp, relative to Procrit. Achieving 50% of the market share was the personal goal of Amgen CEO, Kevin Sharer. To attain that goal, Amgen had to overcome the reimbursement advantage held by Procrit.

162. Notably, Procrit® has been marketed for chemotherapy-induced anemia since 1993. Over the course of its product life, many studies had been done on Procrit® in non-chemotherapy treatment settings. In previously documented studies among anemic cancer patients in the absence of chemotherapy, Procrit® was proven to not be effective as Procrit® patients did worse than the placebo patients. In a review in the Journal of the American Medical Association by Dr. Charles Bennett, (JAMA, February 27, 2008-Volume 299, No. 8), it is noted that in 2003, two trials were published that demonstrated poorer survival for patients treated with Procrit® and chemotherapy or radiation therapy. In November of 2003, Johnson and Johnson halted the remaining four trials of Procrit which it was funding for the purpose of expanding the FDA's approved uses of Procrit in cancer patients. J&J stopped the studies because of the incidence of unexpected levels of blood clotting when compared to placebo, as addressed in the New York Times article dated November 27, 2003, *Drug Company Halts Trials of Procrit®.*

163. Amgen marketing did not want to try to simply replicate the coverage of Procrit® by attempting to gain Medicare coverage of Anemia of Chronic Disease because of the potential competitive factors mentioned above. Hence, the apparent issues demonstrated by clinical data of Procrit used to treat anemia of cancer provided Amgen with an opportunity to gain market share from Procrit, albeit for an untested, off-label use.

164. Medicare, Medicaid and other government-funded healthcare programs cover drugs for FDA-approved indications. Obtaining a FDA indication, however, is a long and expensive process. Therefore, it was explained to Osiecki and her fellow sales representatives by Amgen management at a National Sales Meeting that Amgen had launched a campaign to procure Medicare coverage for Anemia of Cancer pursuant to the Rockefeller-Levin bill, which expanded Medicare coverage of anticancer therapies. Pursuant to that statute, which was part of the Omnibus Reconciliation Act of 1993 (OBRA 93), Medicare allows for coverage of off-label uses of anticancer chemotherapeutic regimens if they are "supported by" a citation in at least one of the following compendia: American Hospital Formulary Service Drug Information (AHFS DI) or United States Pharmacopoeia Drug Information (USPDI) or are supported by peer-reviewed articles in certain journals outlined by Medicare. The law governing Medicare reimbursement of prescription drugs also allows for coverage of off-label uses under the same circumstances, i.e., medically accepted indications.

165. However, "supported by" does not mean that Medicare will pay for an off-label use simply because it appears in one of the aforementioned compendia. Rather, CMS will only pay for medically accepted indications, which are uses that are *supported by* the compendia; accordingly, Medicare has the discretion afforded by the statutory schematic to determine whether the medical study or studies that form the basis for purported compendia "support" are sufficient to deem the off-label use reasonable and necessary.

166. Despite the aforementioned statutes that allows for coverage of off-label uses in certain limited circumstances, drug manufacturers are and have been at all times relevant to this complaint legally prohibited from proactively marketing off-label uses of their drugs.

167. In November 2003, Amgen invited customers from "Oncology of Wisconsin" ("OOW") to visit Amgen's headquarters in what was an all-expense paid promotional event titled, "Day at Amgen." Amgen paid for travel from Milwaukee, Wisconsin to Amgen headquarters in Thousand Oaks, California as well as incidental expenses.

168. According to Dudley Blank, RPh, the Pharmacy Director for OOW who attended this meeting, Amgen discussed early scientific and marketing data regarding Anemia of Cancer with the OOW physicians, pharmacists, and research and business management during the course of the "Day at Amgen." Blank reported that Amgen estimated that the Anemia of Cancer market was three times as large as the market for CIA. Accordingly, Amgen endeavored to convince insurers – primarily government-funded health care plans - to cover only Aranesp for Anemia of Cancer and, therefore, gain a huge competitive advantage over Procrit, regardless of the illegality if such conduct and the risk to patients from promoting Aranesp for this unproven and untested use.

169. Blank's estimation of the size of the Anemia of Cancer market is confirmed by Amgen sales representative John Hendricks's email to the Osiecki, Osiecki's manager Lisa Croissant and Amgen Corporate Accounts Manager Steve Kolwitz dated September 3, 2003. The email discussed an "updated version of [Hendrick's] discount / rebate analysis... for Oncology Alliance." Attached was a spreadsheet setting forth Hendrick's projections for Aranesp and Neulasta business. The projected Aranesp purchase for Oncology Alliance for the year amounted to $5,000,0000; however, Hendricks emphasized that "[t]he anemia of cancer reimbursement has the potential of adding $1,500,000 to $2,000,000 of Procrit business to our Aranesp base."

170. On November 16, 2003, the results of a small pilot study conducted by Amgen were published in abstract form for the American Society of Hematology ("ASH") meeting, which occurred in December of that year. The study was authored by Charu, and it was titled "Abstract

1816 Every 2-Week (Q2W) Dosing of Darbepoetin Alpha in Patients with Anemia of Cancer (AOC): Interim Analysis of a Randomized Controlled Study." Amgen marketing explained that they expected that the stronger bioactivity of Aranesp relative to Procrit® would convey a greater effect.

171. The Charu abstract became the cornerstone of Amgen's AOC marketing campaign, and it became the illegitimate "support" for the AOC listing in the USPDI, as is alleged *infra*, and in turn the basis for Medicare coverage of Aranesp for Anemia of Cancer. Specifically, Amgen approached the publishers of USPDI to request inclusion of Anemia of Cancer as a recommended use. The publishers of USPDI agreed to include Anemia of Cancer on or about November 2003. As a *quid pro quo*, Amgen purchased hundreds of thousands of copies of the reprint of the USPDI Compendium listing for distribution to approximately 8,000 U.S. Oncologists. Amgen's improper conduct that resulted in obtaining the medically bogus Anemia of Cancer listing in the USPDI is described *infra*.

172. On the heels of the USPDI's listing of AOC as a "supported" Aranesp off-label use, Amgen Sales and Marketing formally rolled out the new promotional program for Anemia of Cancer at Amgen's National Sales meeting in December 2003. Amgen's sales nationwide strategy to gain off-label prescriptions in the AOC market was laid out in the meeting preparation binder disseminated to the oncology sales force prior to the meeting. The aim of the program was to initiate a discussion to inform physicians of Anemia of Cancer as a disease state and, then, "in response to unsolicited questions," to offer information on the use of Aranesp in treating Anemia of Cancer. While in printed materials Amgen phrased the marketing as a reactive, in reality, Amgen made clear to sales representatives that they were expected to proactively market Aranesp for AOC.

173. Despite USPDI deeming Aranesp "accepted" for Anemia of Cancer (despite lacking legitimate medical support for this listing), Medicare did not automatically cover this off-label use. USPDI acceptance was only the first prong of the two prong effort to gain Medicare coverage of Aranesp for AOC. The second prong involved Amgen influencing Local Medicare Carriers to cover Aranesp for Anemia of Cancer.

174. If physicians asked about insurance coverage for Aranesp prescribed to treat Anemia of Cancer, Amgen sales representatives, including Relator Osiecki, were directed to ask the physicians to write to the local medical review board for Medicare and request coverage of Anemia of Cancer. Amgen sales representatives were directed to explain that Medicare would agree to cover off-label uses when requested by local physicians. Representatives were trained in the provisions of the Rockefeller-Levin legislation that allowed for Medicare reimbursement of off-label uses of Oncology drugs.

175. Amgen provided sales representatives with contact information for the state representatives and the advisory committee members for each Medicare Carrier to distribute to oncologists who agreed to write a supporting letter. They have been provided with extra copies of the USPDI so that the physicians could refer to the USPDI Compendium entry addressing Anemia of Cancer in preparing their letter to the Medical Director and enclose the entry therewith. They have also been given prototype letters of request to provide to oncologists to expedite and facilitate the submission of letters of request.

176. In fact, Amgen representatives and GEMs were actively involved in developing "advocacy" campaigns among Oncologists to prompt them to request additional; coverage from Medicare for AOC, among other off-label uses including Anemia of MDS, discussed *infra*.

177. All representatives who have succeeded in having a letter written to the Carrier Medical Director had their "accomplishment" announced to their district via voicemail and passed to the Regional Director for a message of commendation. Representatives were asked to get copies of letters sent by their physicians to the Medical Directors so that they could be used to support a positive achievement in the representatives' performance review.

178. Amgen bestowed an additional responsibility upon those representatives who called on CAC (Carrier Advisory Committee) members – to solicit their CAC members to support Medicare reimbursement for Anemia of Cancer with the local Carrier Medical Director.

179. Relator Osiecki and her partner, John Hendricks, were assigned to CAC member William Mattheus, MD, a physician associated with Oncology of Wisconsin (whose name was later changed to Oncology Alliance). John Hendricks arranged for his personal friend, Dudley Blank, RPh to request Dr. Mattheus to write a letter in favor of coverage of Anemia of Cancer for Aranesp. According to Hendricks and Blank, Dr. Mattheus did, in fact, write a letter of request to the Medical Director at Wisconsin Physicians Services, the Carrier for Wisconsin, Minnesota, Iowa and Michigan.

180. According to Hendricks, Blank informed Dr. Mattheus and the Oncology Alliance Management Committee of the additional profit that could be expected by their practice if Medicare allowed coverage for Anemia of Cancer. According to Blank, the additional annual profit could be in excess of $1 million dollars for the practice.

181. Amgen representatives were constantly informed via voicemail and email of the progress in attaining Medicare coverage for Anemia of Cancer by the various Medicare Carriers. Amgen Government Economics Managers (GEM) actively called Medical Directors for the various Medicare Carriers, as well as all CAC members. Updates were required of each representative,

GEM, and each District Manager on progress made with all Medical Directors, CAC members and any local physicians who agreed to write letters of request for coverage. Amgen provided reports on a weekly basis via email in the form of a grid that contained the Carrier status information for the entire nation. GEMs were required to maintain and update this data on a continual basis. GEMs also reported to the District Managers for each state affected by their assigned Fiscal Intermediary.

182. WPS, a prominent Medicare Carrier in Osiecki's territory, changed their coverage guidelines to include coverage for Anemia of Cancer in 2005. Unfortunately for Amgen, Procrit and Aranesp were treated equally in the new WPS coverage guidelines. Nonetheless, Amgen was generally pleased because Procrit's® reimbursement advantage had been eliminated.

183. Osiecki made consensual recordings at several meetings that evidence this scheme to influence improperly Medicare coverage of Aranesp for Anemia of Cancer, including a District Meeting in Minneapolis during the early part of 2005. At this meeting, Lisa Dunn, the GEM assigned to Wisconsin and WPS, reported on the progress of obtaining reimbursement coverage for Aranesp in AOC. In giving her report, GEM Dunn stated: "I hope no one is taping this" and then proceeded to boast to the district meeting participants about the Minnesota CAC member to whom she had provided a $10,000 grant.

184. The unrestricted educational grant was given to a pet project of the CAC member. GEM Dunn conveyed her belief that she had gained his cooperation in supporting Amgen's reimbursement goals in exchange for providing this substantial unrestricted grant.

185. At the same meeting, representatives were asked to report their most successful sales promotional tool. According to Executive Professional Representative Hendricks, his most useful tool was the newly-revised WPS Coverage Guidelines (although use of guidelines, as an unapproved Amgen-approved marketing document, was in violation of the law) because it

specifically mentioned the anemia of malignancy as a covered use for Aranesp. He used the Medicare Coverage Document as his sales tool to demonstrate to physicians that Aranesp prescribed for Anemia of Cancer was now eligible for reimbursement. Other representatives agreed that they were also using the coverage document, called the LCD (Local Coverage Decision).

186. Copies of the LCD were generally shared among the representatives, via fax and via email. Osiecki and others also learned how obtain copies of the document from the WPS website. Osiecki was thanked by her District Manager, Lisa Croissant, for sharing this piece of helpful information. Another professional Sales Representative in Osiecki's district, Jim Adair, was appointed as the district reimbursement expert. Representatives were directed to Adair for clarification of policies and for copies of updated documents. Adair was assigned to maintain current records of the LCDs for the district and to provide them as requested.

187. By 2005, Medicare Carriers had uniformly changed their guidelines to cover Aranesp when prescribed for Anemia of Cancer. Most carriers had also included Procrit® in the updated usage guidelines so that reimbursement parity between Aranesp and Procrit® was almost universal across all of the states. At the mid-year national sales meeting Osiecki attended in San Diego, CA, the Vice President of Oncology Marketing, Cynthia Schwalm, congratulated the sales force as a whole on the attainment of universal Medicare coverage for Anemia of Cancer.

188. Once Amgen procured Medicare coverage for AOC, Amgen provided representatives with the Medicare LCDs to use in "educating" their customers on the changes in reimbursement. This "education" was a key to expanding usage of Aranesp in the AOC market.

189. An example of Amgen's management-endorsed AOC marketing message was circulated by Iowa team Manager Julie Brown to the Amgen "Management Team," (i.e. other Amgen District Managers, including Lisa Croissant) on January 15, 2004. The messaging directed

the sales representative to "show the USPDI laminate" and then to deliver the following proactive pitch: "Doctor I have great news to share with your regarding a new indication with Aranesp for anemia associated with malignancy. As you can see the dose is [sic] 200 mcq q 2wks for anemia of malignancy....This compendia listing is based on a study done by Dr. Charu that was just presented at ASH."

190. Croissant passed this message along to Osiecki's team on the same day, with the message, "in case you are interested in how the Iowa team is crafting/presenting their message. FYI, lc." If Amgen did not expect sales representatives to proactively market Aranesp for AOC, they would not be circulating such proactive marketing messages to the field.

191. In addition to the December 2003 Sales Meeting preparation binder, Amgen provided other sales training materials and marketing materials that supported the AOC off-label marketing campaign. For example, soon after the roll out of the AOC marketing campaign, sales representatives were given an Aranesp Audio Training CD titled *Hematology Hotline, OBU Semester 1, 2004.* This training CD provided detailed information about how to market Aranesp for AOC using the Charu data presented at ASH; how to promote Aranesp 200 mcg Q2W for CIA patients using the Schwartzberg study and Aranesp 300 mcg Q3W dosing using the Reardon Abstract and poster presented at ASH in 2003.

192. The addition of the Anemia of Cancer as a covered off-label indication for Aranesp, and the achievement of reimbursement parity for Aranesp on a nationwide basis allowed Amgen to enhance the success of their marketing the spread schemes. Expanded Medicare coverage continued to be a potent selling tool in all contract negotiations.

193. Amgen used promotion by its sales force and GEMs to exploit the loophole for off-label reimbursement provided by the Rockefeller-Levin statute and the Medicare reimbursement

regulations. The Rockefeller-Levin statute was intended to allow currently diagnosed cancer patients to benefit from peer reviewed published clinical trials describing successful use of anti-cancer medications for uses that might not yet be FDA-approved, rather than requiring the lengthy wait for FDA-approval for this category of patients for whom time was of the essence.

194. While the intent of the statute was to inspire hope for a cure for cancer to currently-diagnosed cancer patients, Amgen endeavored to exploit this law to increase dramatically sales of a non-curative, supportive therapy. In sum, Amgen illegally used personal promotion of an off-label use, purchased influence with the USPDI, and substituted a small pilot clinical trial which was published only in abstract form for the intended peer reviewed clinical trial.

195. Amgen garnered the cooperation of the physician community in seeking LCDs covering Aranesp for AOC because of the enormous profits that physicians could gain with expanded usage of the anemia products.

196. The megablockbuster Aranesp sales for 2003 through 2006, no doubt largely fueled by off-label promotion and off-label claims paid by government-funded healthcare programs are as follows:

2003	2004	2005	2006
1.5B	2.47B	3.27B	4.12B

197. During 2005 and 2006, Amgen's sales of Aranesp increased by $1.65 billion, largely on increased usage of Aranesp in the expanded reimbursement environment. Medicare covers approximately half of all cancer patients in the U.S. With Medicare reimbursements being substantially higher than the actual sales price of Aranesp, Medicare paid approximately $825 million more than would have been required absent the illegal off-label promotion of Aranesp.

198. The inherent danger to patients when pharmaceutical companies engage in short cuts to circumvent the FDA-approval process and simply market their drugs off-label without the time and expense required to obtain FDA-approval became clear with regard to Aranesp in January 2007.

199. On January 25, 2007, Amgen announced the results of a large scale, placebo-controlled trial of Aranesp in the Anemia of Cancer. Amgen's apparent purpose in conducting this study was to substantiate Aranesp's safety and efficacy in the off-label AOC use and for the purpose of applying for an FDA indication for the Anemia of Cancer.

200. This trial was a Phase 3, double blind placebo controlled trial, which is the gold standard for all drug trials. In addition, this trial involved a sufficient number of participant patients to confirm statistically a difference between the treatment and the control groups with regard to outcomes.

201. Amgen was forced to reveal that the results of the trial showed that Aranesp was ineffective in treating AOC. Even worse, however, the trial showed a ***statistically significant increase in the rate of death of patients treated with Aranesp relative to placebo when used to treat anemia of cancer.***

202. This trial – which Amgen irresponsibly failed to conduct prior to launching its off-label AOC marketing campaign for its megablockbuster drug - also proved that for years while Amgen's profits were increasing dramatically due to Aranesp sales derived from AOC prescriptions that Amgen's marketing caused to be written, the lives of patients with cancer were placed in even more grave danger than that posed by the disease itself. Amgen's own study further proved that the results of the small pilot study Amgen used to petition for USPDI acceptance of Anemia of Cancer to support the off-label promotional activities that led to Medicare coverage were bogus and that

Medicare would not have covered any Anemia of Cancer prescriptions had the truth about Aranesp's danger to patients been known.

203. In response, in 2007, the FDA posted an alert on MedWatch, its safety information and adverse-event reporting program. The alert identified the study and flagged the increased risk of death and the product's ineffectiveness in reducing red blood cell transfusions and adds that it failed to reduce fatigue as well. Then, beginning on or about March 9, 2007, the FDA issued a series of black box warnings for Aranesp when used in kidney and cancer patients. The Black Box warning is the most serious warning available on a drug's label.

204. The first black box warned of increased risk of death, of serious cardiovascular or thromboembolic events, and more rapid tumor progressions. The new warnings cautioned physicians to administer the lowest dose possible in order to bring red blood cell counts to the lowest level necessary to avoid blood transfusions.

205. On July 30, 2007, CMS issued a National Coverage Decision that trumped all LCDs allowing for coverage of Aranesp when prescribed for AOC, due to the dangers of the drug that were just coming to light. Further, CMS imposed strict rules on dosing and length of treatment, among other things, even when the drug was prescribed on-label.

206. In March 2008, the black box was expanded among other things to clarify that Aranesp, when used for cancer patients, should only be used on label, i.e., for chemotherapy-induced anemia.

207. Concerns that, rather than helping patients, Aranesp can increase the risk of tumor growth and shorten survival in patients with cancer, and increase the risk of heart attack, heart failure, stroke, and blood clots in other patients, led the FDA to impose a Risk Evaluation and Mitigation Strategy on Amgen for Aranesp in February 2010.

208. On March 3, 2007, Relator Osiecki spoke to a former customer, Julie Groninger, RN at a local oncology fundraiser titled, "The Lombardi Award of Excellence." Groninger was in charge of purchasing oncology products for a local oncology practice, Medical Consultants, Inc. Osiecki inquired if Groninger had seen any of her former colleagues at Amgen lately, and Groninger reported that Amgen sales representative Hendricks had made several visits since the announcement regarding the Anemia of Cancer clinical trial.

209. Osiecki asked how Amgen was handling this news about Aranesp, and Groninger stated that she had been told by Amgen that the negative trial was flawed in that the FDA had required Amgen to include "end stage" cancer patients, *i.e.*, the sickest of all oncology patients. She further stated that Amgen had told her that Medicare had not yet changed its coverage guidelines and was still paying for Aranesp in Anemia of Cancer. Therefore, according to Hendricks, Medical Consultants could continue to use the product for Anemia of Cancer. According to this account, Amgen flagrantly disregarded the safety issues that were found in the large placebo-controlled trial, and continued its off-label promotion of Anemia of Cancer, despite the higher death rates shown in Amgen's own phase 3 clinical trial.

210. By engaging in the illegal off-label promotion of Anemia of Cancer with the intent of gaining Medicare coverage in the absence of an FDA indication, Amgen profited greatly at the expense of patients who were treated with an unsafe and unproven medical therapy. Amgen has also profited at the expense of the Government Plaintiffs through government-funded healthcare programs. Amgen has even profited by the off-label use of Procrit® in Anemia of Cancer, as Amgen sells the raw material to Ortho Biotech for sale as Procrit® and is then paid a royalty for each vial of Procrit® sold.

ii. Amgen's Improper Efforts to Procure Coverage for AOC

211. Because Amgen knew that the off-label uses for which it was promoting its drugs were not eligible for reimbursement under government-funded health care programs, including Medicaid, Medicare, Medicare Part D, Tri-Care/CHAMPUS, ChampVA and others as described herein, in furtherance of its "spread" and off-label marketing programs, Amgen engaged in an active campaign to: A) Gain compendia "support" for use of Aranesp for Anemia of Cancer when such "support" was not medically warranted and B) target providers that purchase and prescribe Amgen drugs to lobby for reimbursement of off-label uses of Amgen products to the Center for Medicare and Medicaid Services and local Medicare Carriers.

212. The general restrictions on reimbursement of prescription drugs by government-funded healthcare programs is set forth *supra.* However, Congress has provided that local Medicare Medical Directors can approve reimbursement of off-label uses where the product can be shown to be safe and effective by independent, peer reviewed literature.

213. A drug company's promotion of an off-label use of a prescription drug violates FDA promotional regulations and it also constitutes misbranding. The use of personal promotion to influence Medicare Carriers and Fiscal Intermediaries to expand coverage to include off-label indications bestowed a huge financial benefit on Amgen by allowing the company to avoid the lengthy and incredibly costly process of seeking approval of new uses.

214. By convincing customers to lobby for government reimbursement, Amgen is aware that physicians will be unencumbered by the financial constraints of lack of reimbursement, and be free to increase prescriptions for the unapproved use. An example of this promotional scheme occurred in November and December of 2003 regarding the product Aranesp and the unapproved indication of Anemia of Cancer. During that time, Amgen pursued a strategy whereby they applied

for inclusion of the Anemia of Cancer indication by USPDI (a division of Thomson Micromedex). Despite the lack of any published clinical trials on Aranesp use on Anemia of Cancer, USPDI designated Anemia of Cancer as "accepted" in November of 2003. On December 6, 2003, a single abstract (author Charu, et al) was presented at the American Society of Hematology ("ASH"), and published in the ASH journal, Blood. On December 9-12, Amgen representatives participated in a National Sales Meeting at La Mirage in Las Vegas, Nevada. In preparation for the National Sales Meeting and at the meeting itself, Amgen representatives were educated in Anemia of Cancer and the Charu data. Representatives were required to be "certified" in the presentation of the Charu data, and were provided copies of the Charu ASH poster and abstract for inclusion in their "proof source" book. They were also provided with a "non-branded disease state" detail piece that discussed the incidence and features of Anemia of Cancer. Amgen directed its sales force to use this educational sales piece proactively with customers

215. Amgen representatives were instructed to use the non-branded Anemia of Cancer detail piece to initiate a discussion of the Anemia of Cancer disease state with the customer and, when presented with an "unsolicited question" from the customer regarding the use of Aranesp in Anemia of Cancer (absolutely an expected question), to use the Charu data to demonstrate the effectiveness and benefits of Aranesp in this patient population. Representatives were also instructed to inform physicians that Aranesp was compendium listed for Anemia of Cancer, to provide copies of the USP-DI compendium listing and to ask the physician to contact the local Medicare Medical Director to ask for Medicare coverage of Aranesp. Representatives were provided with contact information for their respective Medicare Medical Directors so that they could facilitate physicians in making such requests to Medicare. By 2005, most Medicare contractors had begun to provide coverage for Anemia of Cancer.

216. By expanding the reimbursement coverage for Aranesp in this way, the market for this class of drugs increased dramatically. A conservative estimate indicates a potential one-third increase in usage of the product. Because the market for this drug class results in annual U.S. sales exceeding $3 billion dollars, most of which is covered by Medicare and Government payment programs, this increase in coverage will result in significant additional expenditures by Medicare, based upon a very small threshold of proof.

217. Relator Osiecki is in possession of documents that she received in conjunction with the National Sales meeting in Las Vegas, including the Sales Training binder, the Semester "Playbook" (marketing instructions), the Proof-Source book, and memos from sales members referring to their plans to promote usage of Aranesp in Anemia of Cancer. Relator Osiecki also possesses documents such as a "Talking Points" memo, which explains how to assist physicians to request coverage of Anemia of Cancer by their local Medicare Medical Directors.

218. Defendants have marketed Aranesp -- and Enbrel and other Amgen drugs - in ways that compromised physicians' independent medical judgment and threatened patient safety through use of kickbacks and off-label promotion.

iii. Off-label Promotion for MDS

219. Myelodysplastic Syndromes (MDS), also known as pre-leukemia or "smoldering" leukemia, encompass a group of disorders in which the bone marrow does not produce enough blood cells. MDS causes abnormal blood counts or poorly functioning blood cells. Approximately 90% of the time, patients with MDS present with anemia.

220. As of 2005, approximately 21,000 new cases of MDS were diagnosed each year in the United States. MDS is most prevalent patients over the age of 60.

221. MDS can turn into a fast-growing cancer of bone marrow cells called *acute myeloid leukemia.* This happens in about 1 out of 3 people with MDS. Now that doctors have learned more about MDS, it is considered to be a form of cancer.

222. As of 2005, there were no recombinant erythropoietic products approved by the FDA for the treatment of anemia in MDS patients. The lack of on-label treatment for anemia of MDS rendered it ripe for off-label promotion for Aranesp to gain additional market share over Procrit.

223. Amgen's marketing of Aranesp for anemia of MDA commenced almost immediately following the FDA's approval of Aranesp for CIA. For example, below is an email exchange between Osiecki and her former District Manager Julie Brown on June 13 and 14, 2002:

> Julie, I called professional services and they stated that there are no published trials in MDS, only EPO, as below. While we don't really have anything to offer Dr. Blake, I am going to talk to Bryan Tucker at Aurora today, and among other topics, I will propose an Aranesp MDS trial with Dr. Hanson as the PI. Dr. Hanson expressed a great deal of interest in MDS research at our meeting yesterday. There may be an opportunity for other Aurora practices in the Metro Region and in the Central and North regions (Tom O's area) to participate. We'll see how this idea goes over. I have called Professional Services, and they are getting me a name for Dr. Hanson or Bryan Tucker to call. MDS is a good market opportunity, because the treatment course is prolonged, and the doses are higher. It is off-label however, so we would have to provide drug for the study. The quicker we get data on this disease state, the quicker the reimbursement issues will be overcome.
>
> Jill
>
> -----Original Message-----
> **From:** Brown, Julie
> **Sent:** Thursday, June 13, 2002 2:28 PM
> **To:** Osiecki, Jill
> **Cc:** Burgeson, Kelly
> **Subject:** FW: Anemia Intelligence Weekly
>
> Hi Jill,
> Regarding your question on MDS. There is a reference below on an artical [sic] that may be helpful with your physician wanting to use Aranesp in this patient

type. He may or may not have seen this but I think it would be a great follow up with him. Hope it's helpful.

224. Amgen management and GEMs worked diligently to further the Anemia of MDS marketing efforts for Aranesp. For example, on July 8, 2003, Osiecki's manager Lisa Croissant had the following exchange via email with GEM Lisa Dunn:

From: Dunn, Lisa
Sent: Tuesday, July 08, 2003 9:37 AM
To: Croissant, Lisa
Cc: Donovan, Timothy; Andes, Eugene; Dunn, Lisa
Subject: MDS Follow-up

Hi Lisa,

In follow-up to our meeting in Minneapolis about WPS coverage of MDS, thanks to you and your team for the time and attention.
Congratulations to your team!
The success of your selling efforts is clearly demonstrated by the voice of physicians who want to use Aranesp wherever they use EPO.

Since our meeting I have exchanged additional information with Gene Andes, Medical Affairs.
First and most important your message has been heard!
It is my understanding that a MDS has been brought to the attention of the decision makers to look at priorities and get a dialogue going.

Regarding Anemia of Cancer in the Compendia, it sounds like July would be the earliest time frame, and it may happen later.
Once listed, it will take time for pull-through activities and coverage.

In the mean time, I would like to suggest the following process to your team members who have physicians who are vocalizing their desire to use Aranesp in MDS:

•Refer physicians to Professional Services for information on MDS and Aranesp
•Refer physicians to WPS' EPO/Aranesp LMRP for guidelines on the use of EPO in MDS
•Encourage the physician to contact Kathleen Brooks, WPS Carrier Medical Director in Minnesota and the CMD involved in writing the EPO/Aranesp LMRP
•If the physicians choose to contact Dr. Brooks, they should be prepared to share the following:
•Who they are, and their expertise in treating MDS patients
•That their MDS patients are responding to EPO within the guidelines of the LMRP

•The reasons Aranesp would be advantageous over Procrit in these patients
•Ask Dr. Brooks if they can use Aranesp in these patients, and get reimbursed
•If so, what is the process

The following cautions should be kept in mind:
•Use this process sparingly, and
•with a high level of confidence that the physicians will interact appropriately with the CMD
•Avoid jeopardizing our likelihood of Anemia of Cancer

If the physicians follow the above process ask them to let you know the following:
•who did they contact
•when
•what did they share
•what was the response
This information will be very helpful in understanding this process and for use in future inquires.

I would also suggest that for those PSRs who do have physicians with whom they plan to share these suggestions that we have a live conversation first to talk about the process and agree that the physician is appropriate for sharing this information. At that time I can share contact information for the CMD.

Finally, I am planning to work with John Hughes to meet with Dr. Londer. I am also interested in visiting a couple of the hematologists who have aggregates of MDS patients that they want to treat with Aranesp. It would be helpful prior to those visits to have the names of the physicians so that we can internally investigate their involvement in Amgen trials and if they are an Amgen investigator, or do they want to be. Our goal in these meetings would be to understand what criteria they are using for diagnosis, what doses they are seeing, and how this compares to the WPS guidelines for EPO in MDS.

After your review of these suggestions, let's talk live about next steps.

225. On July 18, 2003, Croissant shared the foregoing information with her Wisconsin team, including Osiecki.

226. Lisa Dunn routinely communicated with Lisa Croissant and Osiecki's team concerning LCDs for coverage of Aranesp in MDS, as well as other off-label uses (including AOC) and off-label dosing regimens. For example, on July 30, 2004, Dunn circulated "MDS Talking Points" for use in discussions with physicians regarding MDS coverage.

227. Similarly, on March 10, 2005, Lisa Dunn circulated to the members of Osiecki's District revised WPS guidelines that provided for coverage of MDS effective as of January 1, 2005. The revised guidelines also provided for coverage of AOC.

228. Dunn's email contained her "suggest[ion]" that "you and your team use these documents as 'bag pieces' to review with customers rather than as 'leave behinds'. And, encourage providers to access the LCD and coding guidelines on the WPS website at http://wpsic.com/medicare/policies/wisconsin/inj23.shtml[.]"

229. In addition, Amgen's Director of Medical Affairs Lyndah Dreiling, MD, authored a slide deck titled "Treatment of Anemia in Myelodysplastic Syndrome" in or about August 2003 for use in conjunction with a journal club. This slide show was still in circulation as of January 30, 2004, when Croissant circulated it to her team via an email containing the acknowledgement that "MDS has been a topic of conversation across our customer base." Regional Manager Tom Kennedy provided the slideshow to Croissant.

230. Moreover, Osiecki was present for multiple District, Regional and National Meetings where promotion of Aranesp for anemia in MDS patients was discussed. For example, during the March 9, 2005 District Meeting in Minneapolis, Minnesota, Osiecki's team discussed at length which study each team member was using to promote Aranesp for MDS (the favored study was a study by Patton titled *Effectiveness of darbepoetin alfa 200 mcg every 2 weeks (Q2W) for the treatment of anemia in myelodysplastic syndrome (MDS)*, which purported to establish efficacy of Aranesp when used for anemia of MDS when dosed at 200 mcg Q2W, as well as what dosage should be promoted for this off-label use. The team discussed these fundamental issues due to the paucity of data on Aranesp use and efficacy in anemia of MDS at that time. The March 9, 2005

meeting was one of the multiple consensual recordings Osiecki made in furtherance of her cooperation with the federal government investigation into the allegations made in this complaint.

231. Amgen provided sales tools including study abstracts to sales representatives to use during sales calls to proactively promote Aranesp for MDS. These studies included the Patton study discussed *supra* as well as studies authored by Mannone and Diluth. Another study in use in 2003 was titled *Initial experience with darbepoetin alfa in patients with myelodysplastic syndrome (MDS)*, authored by Vinh et al, which purported to provide "real world" experience of use of Aranesp for MDS. These studies were among other off-label MDS materials Amgen provided to sales representatives in the Oncology Proof Source book.

232. Similarly, on January 26, 2005, Amgen circulated a "MDS Educational White Paper" to all Corporate Accounts and Oncology sales teams purportedly to provide "background information on this disease state." The white paper concluded that "Aranesp," due to its prolonged half life, may pose an attractive therapeutic alternative in a population where patients potentially require longer treatment periods and office visits are often burdensome, due to advanced age and comorbidities." As with other Amgen corporate communications marked for background use only, Osiecki understood that this statement was pure lip service solely to create the appearance of compliance with statutory prohibitions on off-label promotion.

233. That same month, Amgen announced to its Corporate, Nephrology and Oncology business Units that it had increased its funding to, *inter alia,* two foundation-sponsored patient support programs designed to ensure access for patients in need of co-pay assistance for prescription drug for anemia. The programs were open to all qualified patients regardless of their insurance plan. According to Amgen's internal announcement, "[o]ne of the programs is for Anemia of Chronic Disease so patients with anemia due to AOC, MDS, CRF or other disease states, may be

able to receive assistance as well." Amgen sales representatives were instructed in the announcement that they "may tell the physician that there are several independent foundations that provide co-pay assistance for their underinsured patients. You may also say that Amgen donates to these foundations. Other than that, please refer them to the Reimbursement Connection."

234. MDS marketing continued to gain momentum in 2005 when on July 6, 2005, Amgen announced interim data from a Phase 2 study evaluating the use of 500 mcg of Aranesp Q3W to treat anemia in patients with MDS. The data was presented at the 17th International Symposium of the Multinational Association of Supportive Care in Cancer (MASCC) in Geneva. (Abstract #02-007). Amgen announced that the interim results were encouraging in that MDS patients who had never been treated for their anemia responded to Aranesp and those who had prior erythropoietic therapy continued to respond.

235. A few months later, on October 27, 2005, this interim study data became the subject of a discussion among Lisa Croissant, Jill Osiecki's team members and Julie Nelson during the October 27, 2005 National Amgen Meeting held at the Sheraton Hotel in San Diego, California.

236. During this discussion, in the presence of Osiecki, Nelson gave a sample detail for MDS at the instruction of Lisa Croissant. Further, Nelson explained that Amgen planned to have the final data by the ASCO meeting and that this Phase 2 study was the only study as of that date establishing the dosing at 500 mcg Q3W for anemia of MDS. This discussion reveals Amgen's improper use not only of off-label Aranesp studies, but interim study results.

237. Amgen also paid physician speakers to promote Aranesp for MDS. Osiecki recalls that Amgen representative Dan Jedloe organized several off label speaker programs on MDS in Osiecki's district.

238. Finally, sales representatives, including Osiecki and her partner John Hendricks, included MDS marketing as a component of their business plans to grow Aranesp market share. These business plans were presented to and endorsed by Croissant.

239. Off-label promotion of Aranesp for MDS occurred on a nationwide basis and caused the submission of thousands of false claims to Medicare, Medicaid and other government-funded healthcare programs for reimbursement for Aranesp prescribed to treat anemia of MDS.

iv. Off-label Promotion of Extended Dosing

240. In violation of federal laws prohibiting marketing of drugs off-label, Amgen marketed Aranesp off-label in higher than approved doses on a less frequent basis than as approved by the FDA, as follows: once every other week ("Q2W"), once every three weeks ("Q3W")[1] and once monthly dosing.

241. Despite the package insert's direction that Aranesp dosing for CIA should vary with a patient's weight, Amgen rolled out a fixed dose extended dosing marketing campaign as follows: 200 mcq Q2W and 300 mcq Q3W. This marketing practice raised potential safety concerns because Amgen does not manufacture a time release formulation of Aranesp. Accordingly, Amgen was promoting the unproven and untested protocol that patients should be administered greater than FDA-approved volumes of the drug all at once on the hypothesis that this approach would control patients' anemia for longer periods of time.

242. The off-label extended dosing campaign was endorsed and encouraged by senior Amgen management. Amgen trained sales representatives how to promote off-label extended

[1] The FDA approved Q3W dosing of Aranesp in the treatment of CIA only on March 23, 2006. Therefore all of Amgen's marketing for Aranesp Q3W in CIA prior to that date and all marketing of Q3W in CRF patients was and was off-label and caused false Aranesp claims to be submitted to government-funded healthcare programs such as Medicare and Medicaid. In addition, Q2W dosing was off-label at all relevant times for CIA patients.

dosing regimens in training materials such as the Aranesp Playbook and during District, Regional and National meetings.

243. Marketing Aranesp in extended doses allowed Amgen to differentiate its product from Procrit, which was FDA-approved to be administered either 3 times weekly or once weekly in CIA patients. The extended dosing campaign was premised upon the fact that Aranesp has a nearly three fold longer half life than Procrit.

244. Financial "return to practice" was a key motivating factor for physicians to prescribe Aranesp over competitor Procrit. To capitalize on this profit motive, Aranesp sales representatives, including Osiecki, were trained to promote to customers that providers could maximize profit by prescribing Aranesp at higher than approved doses on a less frequent basis. Indeed, Amgen launched the extended dosing campaign in part because Aranesp prescribed at a labeled dose and frequency was not as financially attractive as Procrit when used once weekly, but when administered in extended doses, Aranesp became the more financially attractive anemia treatment.

245. Amgen's off-label dosing campaign touted the financial benefit of reduced administrative time for customers and increased comfort for patients. Specifically, Amgen advocated to customers that less frequent injections saves staff and physicians time, allowing them to see more patients. Amgen marketed extending dosing as more desirable for patients due to fewer needle sticks and the convenience of reduced office trips. Q3W was particularly "efficient" for physicians and patients because dosing once every three weeks allowed for synchronizing Aranesp anemia therapy with common chemotherapy regimens. Indeed, as alleged *infra*, Amgen marketing tools, training materials and business plans often referred to synchronizing Aranesp treatment to chemotherapy.

246. As part of the extended dosing marketing scheme, sales representatives were trained to point physicians to abstracts of articles from authors such as Charu (Q2W for AOC); Glaspy (Q2W), Thames (Q2W), Boccia (Q3W) and Schwartzberg (Q2W) that purported to demonstrate Aranesp's safety and effectiveness when administered off-label in extended doses.

247. In fact, the majority of the abstracts of efficacy studies Amgen provided to its oncology sales representatives studied Aranesp dosed on a Q2W or Q3W basis. Accordingly, when a customer was uncertain about the efficacy of Aranesp, the sales representatives were trained to lead with "Schwartzberg," "Glaspy," the "MUE data" or the "Head to Head" data. These were studies that compared Procrit Q-weekly to Aranesp Q2W.

248. Schwartzberg, Glaspy, Thames and Boccia were also frequently paid to give promotional lectures about Aranesp off-label dosing regimens, based upon their study findings. Osiecki was present for numerous promotional lectures where the speakers promoted off-label dosing regimens, including a presentation by Thames.

249. Sales representatives were also provided with extended dosing promotional materials in their Proof Source books. While all off-label Proof Source Book materials were marked for reactive use only, in truth, Amgen uniformly instructed sales representatives such as Osiecki to proactively use those materials for the purpose of increasing market share. Notably, no studies with on label dosing schemes were provided to sales representatives as proof sources nor were any on-label studies provided for training purposes or reviewed during National, Regional or District meetings. Instead, they were strictly cited in the package insert and were available from the medical information department upon request. All clinical data support given to sales representatives involved data on off-label dosing. This is telling that Amgen never intended to promote Aranesp at a dosage consistent with its FDA-approval.

250. Another way sales representatives promoted extending dosing was to create Aranesp dosing protocols for their customers; or, Amgen representatives would use off-label Aranesp dosing protocols adopted by other Oncology practices in the region as a promotional tool during sales calls to demonstrate general acceptance of off-label dosing regimens. These protocols invariably recommended commencing Aranesp therapy at Q2W dosing and oftentimes also promoted Q3W dosing as well. This practice was done with the knowledge of and encouragement by Amgen management.

251. Examples of these off-label dosing protocols in circulation in Osiecki's territory and apparently other territories include: Southwest Regional Cancer Center Patient Candidate and Usage Guidelines for Aranesp (Q2W protocol); UCLA Oncology Medical Center Guidelines (Q2W and Q3W protocol) and the Oncology Alliance Aranesp Clinical Pathway (Q2W protocol).

252. As further evidence of this extended dosing scheme, in late 2003, Amgen divided the oncology-based sales representatives into 2 teams, the Red and White team. In Osiecki's territory, the red team was directed to "lead with Aranesp (Head to Head Study, A of C)," followed by Neulasta messaging. The White Team was directed to lead with Neulasta, "followed by Aranesp (Head to Head Study and Q3W dosing. This direct instruction by Amgen marketing to market Aranesp off-label for Q3W (as well as for AOC) was disseminated to Osiecki's sale team by her District Manager, Lisa Croissant, in an email dated December 3, 2003.

253. Amgen instituted the Red and White team designations, and accompanying brand messaging, on a nationwide basis.

254. For example, on January 13, 2004, Amgen District Manager Julie Brown circulated to the Amgen Management Team Aranesp "a template" for the new red and white team brand messaging developed by the Iowa District.

255. Q2W marketing was launched in October 2002, however, as evidenced by the Iowa brand messaging, Q2W marketing continued to be prolific in 2004. The proactive Aranesp Messaging for Q2W was as follows for physicians who were not using Aranesp in their practices: "1. Lead with Schwartzberg: Doctor I am here today to talk to you about saving your chemotherapy induced anemia patients a significant amount of time by utilizing Aranesp 200 mcg q 2 weeks."

256. The messaging went on to cite to a study which shows that the average amount of time affected for anemia treatment was 2 hours, hence, "If I could prove to you that Aranesp 200 mcq q 2 wk is clinically equivalent to Procrit and it would decrease the number of times your patients have to come in for an injection by 6 visits, costs less for you to purchase, and costs your patients less in co pays, would you chose Aranesp 1st for your CIA patients...[?]"

257. If the doctor responded "Yes" to this question, sales representatives were directed to pitch the Schwartzberg study data, which purports to prove Aranesp Q2W is clinically equivalent to Procrit 40,000 q per week in CIA, as proof of the efficacy of Aranesp 200 mcg Q2W dosing in treating CIA. This email exchange demonstrates not only the off-label marketing scheme, but Amgen management's endorsement thereof.

258. Moreover, "Flexible dosing...100 mcq QW, 200 mcg Q2W and 300 mcg Q3W"; "less frequent dosing than Epoetin alfa [Procrit]"; "Aranesp delivers equal efficacy with flexible dosing as compared to Epoetin alfa"; and, "synchronize Aranesp to chemotherapy treatments [i.e. 300 mcg Q3W]," were routinely included in PowerPoint sales presentations to Amgen customers in Plaintiff Osiecki's territory, including a May 6, 2004 PowerPoint presentation to Joilet Oncology Hematology Associates and an August 12, 2004 presentation to Aurora Healthcare.

259. Such customer presentations also incorporated the sales pitches outlined above that extended dosing conferred significant patient benefits (less frequent injections, improved quality of

life) and financial benefit to the customer (reduced administrative time for nursing, billing and pharmacy staff due to less frequent injections; reduced cost to acquire Aranesp).

260. Amgen also created posters containing "clinical" data that touted Aranesp's efficacy in extended dosing regimens to support its off-label marketing efforts. Sales representatives, including Osiecki, were provided with these posters to use during sales calls with physicians.

261. For example, Amgen presented data derived from the 300 patient Schwartzberg phase II study at the annual American Society of Oncology ("ASCO") conference in 2004. The Schwartzberg study was a head to head study comparing the efficacy and safety of Aranesp 200 mcg Q2W to Procrit 40,000 u QW in the treatment of CIA. Amgen touted the study as concluding that that Aranesp Q2W had a similar efficacy and safety profile as Procrit Q2W in terms of hematopoietic response, mean change in Hb from baseline to EOTP, reduction in RBC transfusions and the ability to achieve and maintain NCCN-recommended HB target range. Amgen presented this data at ASCO using a poster to highlight the efficacy and safety of Aranesp Q2W. Notably, one of the authors of the Schwartzberg study was an Amgen employee.

262. The only head to head trials of Procrit and Aranesp funded by Amgen studied 200 mcg Q2W as the only Aranesp dose.

263. Following the conference, Amgen provided sales representatives with a letter-sized version of the ASCO poster for use during sales calls with physicians to promote Aranesp Q2W. In or about June 9, 2004, sales representatives were also provided with training materials on the data presented at ASCO. While the training materials were couched in terms of responding to unsolicited physician questions about Aranesp Q2W, sales representatives knew and understood this data was to be used proactively to gain market share for Aranesp.

264. Monthly dosing was a principal part of Amgen's marketing for CRF patients. Osiecki recalls Oncology representatives, when pitching Aranesp to Hospital Pharmacists, would bring in nephrology counterparts to deliver the monthly dosing marketing message for a hospital's CRF patients. Generally, Amgen promoted monthly dosing for CRF patients receiving outpatient treatment and Q3W in smaller doses for nephrology inpatients. Aranesp has never been proven safe or effective when prescribed once per month or Q3W for CRF patients.

265. In the course of her employment, Osiecki became aware that Amgen nephrology representatives were using data from a monthly dosing Aranesp study to further the promotion of Aranesp for monthly dosing during sales calls with physicians. Because Amgen used the same strategies to promote Aranesp in nephrology as it did in oncology, Osiecki believes nephrology representatives were provided with posters of this study akin to that described above for Q2W to promote Aranesp off-label for monthly dosing during sales calls.

266. Moreover, Amgen's monthly dosing marketing of Aranesp was discussed by Osiecki's team during the March 9, 2005 District Meeting held in Minneapolis. Specifically, during this meeting, there was a discussion about obtaining a monthly dosing CRF packet from their nephrology counterparts.

2. Neulasta

267. Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

268. The FDA-approved dosing is 6 mg administered as a subcutaneous injection to be given twenty-four (24) hours after chemotherapy.

269. Neulasta was tested as an equivalent to Amgen's already-approved Neupogen, which has been marketed since 1991 but requires daily injections and is similarly indicated.

270. Also, Neupogen therapy has been evaluated by the American Society of Clinical Oncology (ASCO), which has developed "evidence based guidelines" for the usage of the broad class of Hematopoetic Growth Factors (also known as Growth Factors or GF). These guidelines have been established, reviewed and revised over the past ten (10) years based upon the vast quantity of available published literature on this class of drugs. The peer-reviewed guidelines recommend using GF's in the first cycle of chemotherapy only when the risk of febrile neutropenia is $\geq$ 40%. The phase 3 clinical trial supporting the approval of Neulasta was conducted in a chemotherapy regimen with a published incidence of 38% febrile neutropenia. The Package Insert for Neulasta (under "Clinical Studies" heading) states, "in the absence of growth factor support, similar chemotherapy regimens have been reported to result in a 100% incidence of severe neutropenia (absolute neutrophil count [ANC] $< 0.5 \times 10^9$/L) with a mean duration of 5-7 days, and a 30% to 40% incidence of febrile neutropenia."

271. Amgen launched a promotional campaign to encourage physicians to prescribe first cycle use of Neulasta in chemotherapy regimens with an incidence (or risk) of febrile neutropenia of 20% or greater. To support this activity, sales representatives have been provided a single abstract (not a peer-reviewed published trial) that purports to show a significant reduction in febrile neutropenia in breast cancer patients receiving an unconventional chemotherapy regimen. Based upon that trial, representatives have been directed to imply that all regimens of chemotherapy with an incidence of febrile neutropenia of 20% or greater should receive Neulasta in the first cycle. Because Medicare has no restrictions on reimbursement for Neulasta, physicians can prescribe Neulasta in this fashion contrary to the published ASCO Guidelines. Further, physicians are

provided a financial incentive to increase prescriptions of Neulasta by Amgen's contracting and "spread marketing" schemes.

272. A single Neulasta injection costs $2,502 (Wholesaler Acquisition Price) with contractual discounts from 20% (hospital) to 26% (clinic) and a Medicare reimbursement rate set at $2,507 (Hospital) and $2,596 (Physician office). Therefore, typical physician profit, or "spread," on a single Neulasta injection is approximately $500. This profit is obtained through a simple subcutaneous injection that takes a nurse approximately 5 minutes to administer.

273. Over time, a 20% threshold of febrile neutropenia as compared to a 40% threshold could more than double the utilization of Neulasta, thereby doubling the costs of treatment to the federal government. Amgen sales goals increased by 40% in the second half of 2004 in anticipation of this large increase in utilization.

3. ***Enbrel***

274. Enbrel is FDA-approved for moderate to severe rheumatoid arthritis, moderate to severe juvenile idiopathic arthritis, ankylosing spondylistis (AS), psoriatic arthritis, and chronic moderate to severe plaque psoriasis.

275. On November 2, 1998, the FDA first approved Enbrel for the treatment of moderate to severe active rheumatoid arthritis. Since then, the label has been changed twenty-one (21) times to reflect the FDA's approval of the disease states identified above.

276. In 2005, Enbrel sales rose to $2.6 billion in the United States, a 35% increase from 2004.

277. Medscape, WebMD, and Defendants Amgen and Wyeth have engaged in various illegal activities including financial inducements designed to promote the use and purchase of Enbrel, including for off label purchases.

278. From as early as 2003, Amgen and Wyeth have coordinated efforts to market Enbrel beyond its approved indications. For example, Amgen's Helen Jordan has served as co-leader of the Enbrel Product Strategy Teams and has worked closely on coordinating the Enbrel marketing strategy with Wyeth.

279. Tamika Roy was a member of the Amgen marketing team for Enbrel, and she was familiar with the web-based marketing campaign conducted through the website www.medscape.com.

280. Among other off label uses, Amgen and Wyeth's marketing campaign has targeted patients with mild psoriasis, although Enbrel was only approved for use with patients suffering from moderate to severe psoriasis.

281. Amgen's Tamika Roy acknowledged in early 2004 that the Enbrel team had been successful because Medscape had allowed it to influence Medscape's editorial content in exchange for commercial sponsorship of a promotional Resource Center site for Enbrel. Amgen's Director of Marketing for Aranesp, Ray Chow, admired the Enbrel team's success with Medscape and sought to duplicate the results with Amgen's Aranesp.

282. Medscape has promoted its Resource Centers to Amgen and Wyeth as a means of persuading doctors to prescribe Enbrel. Medscape stated that an online Resource Center "allows Medscape to create brand relationships by teaching physicians at key teachable moments." Medscape promised that its Resource Center would "drive physicians to Amgen's online destinations and resources" by creating "links to Amgen's other supported Medscape programs." Medscape's Resource Center has provided Amgen and Wyeth with branded product positioning and off label marketing information that other sites could not provide.

283. Medscape's Resource Centers have featured quarterly expert columns, authored by leading doctors in the field, without regard for Amgen's influence upon those doctors. Amgen and Wyeth have found Medscape to be an effective way of marketing Enbrel for off label uses.

284. For example, Defendant Wyeth sales representatives promoted Enbrel for the off label use of treatment of neurological spine pain to Dr. Don Olson, a pediatric neurologist based in Palo Alto, California.

285. In March 2004, Medscape's Director for Strategic Accounts, Pam Peters, Ph.D., made an Internet marketing proposal to Amgen's Associate Marketing Director of Aranesp, Matt Skelton, Amgen's Senior Marketing Manager for Aranesp, Brian Bennett, and to Amgen's Ray Chow. The proposal was modeled after Medscape's Resource Center for Enbrel.

286. Payments to Medscape from Amgen and Wyeth to market Enbrel and Aranesp via Medscape's Resource Centers constitute unlawful kickbacks to promote the drugs off label, in violation of federal law.

C. Off-Label Prescriptions of Amgen's Drugs Were Not Eligible for Reimbursement By Government-Funded Healthcare Programs.

1. Medicaid

287. Though Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Controlling federal statutes and regulations restrict the drugs and drug uses for which the federal government will pay through its funding of state Medicaid programs.

288. The Medicaid program includes individualized provisions, by statute and regulation, concerning reimbursement for prescription drugs, drug utilization review, eligibility of various drugs for federal financial participation ("FPP"), price controls on prescription drugs and drug manufacturer rebate agreements.

289. According to the Social Security Act, the Plaintiff states are entitled to FFP for

reimbursement of pharmacies for a "covered outpatient drug." 42 U.S.C.A. §1396r-8. The definition of "covered outpatient drug" is limited to drugs used for medically accepted indications. 42 U.S.C.A. 1396(k)(3). A medically accepted indication is defined as any use approved by the FDA or supported by any of the three specific compendia. *Id.* (k)(6). The compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information and the Drugdex Information System. *Id.* at (g)(1)(b)(i).

290. For example, under the Florida Medicaid Program, the determination of whether a drug is eligible for reimbursement and prescribed for a purpose that is covered by Medicaid is governed by 42 U.S.C. 1396r-8, Chapter 465 F.S. and the Florida Medicaid Prescribed Drug Services Provider Handbook.

291. Under 42 U.S.C. 1396r-8, state Medicaid programs may exclude or otherwise restrict coverage of outpatient prescription drugs. Pursuant to the Florida Medicaid Prescribed Drug Services Coverage, Limitations, and Reimbursement Handbook, to be reimbursed by Medicaid, a drug must be medically necessary and prescribed for medically accepted indications and dosages found in **(A)** the drug's labeling ("labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article), **(B)** American Hospital Formulary Service Drug Information, **(C)** United States Pharmacopeia-Drug Information ("USPDI") or the **(D)** DRUGDEX Information System.

292. Whether the use of a drug meets federal regulation's criteria for coverage is material Medicaid's decision to reimburse for prescription. Consequently, Medicaid (as well as Medicare and other government-funded healthcare programs as set forth *infra*) would have denied reimbursement for claims made for prescriptions of Amgen's drugs if it had been known the purpose for which the drug had been prescribed failed to meet coverage criteria.

293. Use of Amgen's Epogen, Aranesp, Neupogen, Enbrel, Kineret, Kepiance and Neulasta, for example, for the medical conditions and in the dosages alleged herein are not supported by the compendia as medically safe and effective, and therefore should not have been covered by the Medicaid programs. To the extent an off-label use of an Amgen drug at issue in this Fourth Amended Complaint is listed in any of the above-referenced compendia, the listing and studies cited therein do not legally justify coverage of any such off-label use. In other words, the listings fail to legally "support" any such off-label use as is required by the Social Security Act.

294. Nonetheless, Amgen recklessly has promoted its drugs for unauthorized, untested and unproven uses through the unlawful methods alleged in this Fourth Amended Complaint.

2. Medicare and Other Government Funded Healthcare Programs

295. In addition to Medicaid, the federal government covers in whole or in part the cost of prescription drugs under several other health care programs, including but not limited to Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, the Federal Employees Compensation Act Program, 5 U.S.C. § 8101 *et seq.*, the Bureau of Prisons, State Legal Immigrant Assistance Grants and the Indian Health Service, the Department of Defense, the Department of Labor, and the Public Health Service Entities.

296. Legal restrictions on the coverage of off-label drug use by these programs mirrors the restrictions on coverage under the Medicaid program. See, eg., TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

297. For example, Medicare generally does not cover off-label uses of drugs except when certain criteria is met when off-label uses are supported by the 3 medical compendia cited

supra.

298. Similarly, the VA and CHAMPUS/Tri-care programs operate in substantially similar ways to the Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

299. Amgen expected and intended its unlawful off-label promotional efforts to cause claims for reimbursement for off-label uses of its drugs to be submitted to Medicaid, Medicare, Medicare Part D and other government-funded healthcare programs throughout the country. The intended and foreseeable effect Amgen's avaricious scheme was that these programs would fund the cost of treatment with Amgen's drugs through its reimbursement claims system and accordingly, that Amgen's promotional efforts would directly and substantially increase its drug revenue stream at the expense of, inter alia, Medicare and Medicaid.

300. The Government Plaintiffs were unaware of the unlawful manner in which Amgen promoted its drugs throughout the United States. Amgen knew or should have known federal regulations governing prescription drug reimbursement under government-funded healthcare programs.

301. Under the Federal False Claims Act, it is unlawful for any "person," as defined by those statutes, to submit a false or fraudulent claim to the United States government, and/or to cause false claims to be submitted. As alleged supra, soliciting, receiving, offering or paying any kickback, bribe or rebate in connection with a claim submitted to the United States Government also renders a claim false as that term is defined by the Federal False Claims Act.

302. The Federal False Claims Act provides for penalties of up to $11,000.00 for each violation of the Act.

303. In summary, throughout the country, Amgen aggressively and intentionally

marketed its drugs for non-indicated uses and non-medically necessary uses as described herein. By and through this and other conduct, Amgen caused hundreds of thousands of prescription reimbursement claims for Amgen drugs prescribed for medically unnecessary and non-indicated uses to be submitted to and paid by the Medicaid/Medicare programs for reimbursement. However, the prescription drug reimbursement claims for off-label uses of Amgen's drugs that Amgen caused to be submitted to the Government Plaintiffs as a direct result of its unlawfully off-label promotion campaign were not eligible for reimbursement from Medicare, Medicaid, the VA or CHAMPUS/Tricare, Medicare Part D and other government-funded healthcare plans described *infra* for the reasons set forth *supra.*

304. Amgen engaged in its national off-label marketing campaign with the knowledge that the majority of prescriptions written as a result thereof would be reimbursed by government-funded health programs such as Medicare and Medicaid, as well as with the knowledge that such prescriptions were for non-medically accepted indications and non-medically necessary uses that the fall outside the coverage of such programs.

VIII. PROVISION OF FREE GOODS AND DRUG SAMPLES

305. Defendant Amgen has also provided free goods, drug samples and non-billed units of its drugs (collectively "free goods and drug samples") to medical providers and other purchasers with the knowledge and expectation that medical providers and other purchasers, as recipients of such free goods and samples, would bill government-funded healthcare programs for the free goods and samples were administered to induce the providers and other purchasers thereof to prescribe and sell Amgen's drugs over competing drugs or alternative forms of medical care and treatment.

306. Apart from the use of free goods and drug samples as a "*quid pro quo*" incentive or inducement, Amgen is known to have been using free goods and drug samples as a method of

providing hidden price concessions or reductions in the acquisition costs of its drugs. Amgen representatives have provided such free goods and drug samples with the knowledge and expectation that the free goods would be billed by Amgen's customers to Medicare and Medicaid.

307. Amgen's offers of free goods and drug samples has included not only free shipments of drugs and drug samples, but also free product bundled with other products, as well as other arrangements to provide credit or to forego payment for product already delivered.

308. Amgen has used the provision of free goods and drug samples as another form of improper incentive or inducement to cause medical providers and other purchasers to prescribe and sell Amgen's drugs.

309. The Government Plaintiffs have been harmed by Amgen's conduct in providing free goods and drug samples as an inducement in at least two (2) ways: (1) by paying for the costs of the free goods and drug samples unlawfully billed; and, (2) by otherwise paying the inflated AWPs and ASPs for Amgen's drugs as a result of Amgen's use of free goods and drug samples as an improper "quid pro quo" incentive to promote the sale of its drugs.

IX. PROMOTION THROUGH OTHER UNLAWFUL FINANCIAL INDUCEMENTS

310. These financial inducements include the provision of trips, consulting opportunities, speaking engagements, gifts, meals and other cash payments.

311. Amgen has provided such incentives and inducements in order to promote the sale of and/or switching to its drugs at artificially inflated prices.

312. Amgen has provided such incentives as part of its overall scheme to market the "spread" on Amgen products to customers who were not at the time purchasing and billing Amgen products. Amgen has paid customers familiar with the profit or "spread" on Amgen products versus

competing products to influence other customers who were not familiar with the profit or spread to use and bill for Amgen products.

313. For example, Relator Osiecki has personal knowledge that such activities took place in July and August of 2004, involving two Amgen customers, the Newland Clinic of Southfield, Michigan, and Oncology Alliance of Milwaukee, WI.

A. NEWLAND CLINIC AND ONCOLOGY ALLIANCE

314. The Newland Clinic ("NC") is an eight (8) physician practice specializing in Hematology Oncology and Infectious Disease. NC annually purchased approximately $500,000.00 of Amgen products, principally Neupogen and Neulasta. NC was not a purchaser of Amgen's anemia product, Aranesp. However, NC annually used approximately $3 million dollars of Aranesp's competitor, Procrit®. Thus, NC was a prize prospect for conversion to Amgen products. NC used a large quantity of Amgen's Neulasta, but it mostly provided the product through prescriptions that patients would have filled at a local retail pharmacy. Thus, it was not frequently billing for the product out of its office.

315. In the opinion of Amgen's acting District Manager, NC did not understand the financial incentives associated with Neulasta use and the follow-on financial benefits of switching to Aranesp under the bundled clinic contract that Amgen was offering to NC. The District Manager devised a promotional scheme whereby she paid for consultation services by another Amgen customer, Oncology Alliance ("OA") of Milwaukee, WI, who annually purchased approximately $13 million dollars of Amgen Products to "educate" the Newland Clinic regarding the profitability of utilizing Amgen products.

316. In late July of 2004, Amgen paid for a consultation visit by Mike Korosic, the practice manager and COO of Oncology Alliance, to visit and educate NC as to the financial aspects

of its business. According to the Amgen District Manager, Lisa Croissant, one key objective of the visit by Mike Korosic was to convince NC that it should bring its Neulasta prescriptions back into the clinic to realize the approximately $500 – plus profit margin that it could realize with each Neulasta injection.

317. As described by Lisa Croissant, once NC was prescribing and billing for significant quantities of Neulasta, a significant profit incentive would exist for switching its $3 million dollars of Procrit® to Amgen's Aranesp. NC was invited to visit OA at its offices in Wisconsin to consult with other members of the OA staff, especially its pharmacist, Dudley Bank, who is a member of the Amgen Speaking Faculty. Dudley Blank is noted within the Amgen organization for his presentation of "Contract Analysis," demonstrating greater profitability with Amgen's Aranesp than Ortho Biotech's Procrit®. For the OA practice, Dudley Blank estimates that usage of Aranesp yields annual profits of $7 million dollars as compared to $6 million dollars for the usage of Procrit®. Relator Osiecki has witnessed the presentation by Dudley Blank.

318. Amgen paid for the expenses, including air travel of three out of four attendees from NC. In addition, three attendees from NC were paid presentation fees by Amgen, despite the fact that the program agenda made no mention of presentations by these individuals. In addition, OA was compensated for three speaking fees to provide its financial consultations to NC. Together, all six speaking fees were paid as "Clinical Roundtable" presentations, which are supposed to be clinical in nature, not financial. However, the primary objective of the program with NC was to demonstrate the financial incentives in using Amgen products. The speaking fees constitute illegal inducements for NC to change or switch its prescribing and billing habits in order to create financial incentives for greater Amgen product use.

319. In addition, the speaking fees to Oncology Alliance compensate it for clinical presentations it did not provide. As such, the fees constitute illegal kickbacks provided for ongoing aggressive use of Amgen products.

320. Relator Osiecki has had extensive conversations with the Amgen employees involved in the Newland Clinic/Oncology Alliance consultation meetings. She is in possession of the memo setting forth the meeting agenda prepared by Oncology Alliance customer Dudley Blank. Osiecki has a record of the "Contract Analysis" presentation of Dudley Blank as it was presented to the Minneapolis District Meeting on October 6th and 7th at the Pfister Hotel in Milwaukee, WI.

X. WHOLESALER DISTRIBUTION CHANNEL REBATES AND DISCOUNTS

321. Defendants OSI, ABC, ABSG, Cardinal Health SPD and OTN are pharmaceutical wholesalers that entered into contracts with Amgen to purchase various pharmaceutical products for the "list price" of the drug.

322. Amgen also contracts with intermediaries who negotiate pricing contracts on behalf of large groups of independent customers, group purchasing organizations (hereinafter GPOs) or physician practice management organizations (hereinafter PPMOs). A GPO or PPMO, when it conducts legitimate business, is a group of doctors, clinics, hospitals or other health care providers, organized for many purposes, including the ability to make large volume purchases of supplier products at substantial discounts.

323. Defendants ION and NOA are two of the GPOs with which Amgen has contracted. In reality, ION and NOA are not independent GPOs, and instead function as de facto marketing arms for Amgen. Amgen counts on ION's and NOA's *appearance* of complete independence such that customers/members would see them as neutral and objective about the benefits of Amgen's products as compared to competitors.

324. The "list price" of Amgen' drugs is lower than the average wholesale price (AWP) as reported by Amgen to such pricing compendia as the Red Book and First Data Bank. These compendia then publish the AWPs in reference books used and relied on by the private and public sectors.

325. For example, the list price for a 100 mcg vial of Aranesp is twenty five percent (25%) less than the AWP provided by Amgen for that product.

326. The wholesaler, in turns, sells the product to its own customers at the contractual rate agreed upon by the manufacturer and its customers. This rate includes an off-invoice discount, resulting in the wholesaler selling the product for less than the amount it paid Amgen for the product. The wholesaler thereby incurs a loss on these transactions.

327. In order to recoup its losses, the wholesaler sends Amgen a charge back, advising the manufacturer how much of the various Amgen products, including but not limited to Aranesp, it sold, to whom the products were sold and at what price.

328. Amgen then reimburses the wholesaler plus an additional 2% or other agreed-upon charge back amount. This payment is consideration for the wholesaler passing on the discount to its customers and for reporting its purchases. Both of these elements are part of the wholesaler service agreements entered into between Amgen and the various wholesalers.

329. The wholesaler also receives a cash discount for prompt payment to Amgen (2% if paid within 30 days). Thus, in practice, the wholesaler receives a total discount of 4% or higher off of the list price, combining the chargeback rebate and prompt payment discount.

330. The wholesaler, in turn, passes on a significant portion of the reimbursement received from Amgen in the form of a prompt payment discount offered to its own customers. This prompt payment discount, of up to 2.5 % or more, is actually a discount from Amgen, with the

wholesaler acting as the conduit through which the discount passes. This discount further reduces the actual price paid by the wholesaler's customers for Amgen's products.

331. These discounts are not reported to the government, they are not included in the calculation of AWP or ASP and they are not included in the best price calculations.

332. Again, contrary to the independence of a legitimate GPO and a pharmaceutical company, Amgen worked and continues to work closely with the GPOs and PPMOs to develop special discount programs to offer to its GPOs' or PPMOs' customers, including but not limited to discounts for helping the GPO or PPMO meet its purchase targets.

333. GPO and/or PPMO employees and sales representatives actively promote Amgen's discount contracts and the profit margin of Amgen and other company's products to the member clinics. Amgen is aware of this promotion of the profit margin, and has cautioned Amgen representatives not to make joint sales calls with the channel representatives.

334. The combination of the contracted GPO and/or PPMO and their associated wholesalers are referred to as "the distribution channel." Each wholesaler has a GPO and PPMO with which it is allied and to which unreported discounts are passed through to the GPO or PPMO.

335. For example, in the first half of 2005, Amgen encouraged the development of a rebate/discount program through Cardinal Health (the wholesaler) and NOA (the GPO). Under this program, NOA customers would receive an additional 2% discount on its purchase of Aranesp and Neulasta and an additional 1% discount on purchases of Neupogen. The discount would be on purchases made through Cardinal Health SPD.

336. The 2% additional discount offered by NOA for purchases made through Cardinal Health SPD served as an inducement for NOA's customers to purchase Amgen products from

Cardinal. NOA had terminated its prior contract with OTN as the wholesaler through which a similar discount program had been in effect.

337. Although non-NOA accounts could also be offered these additional discounts for purchases made through Cardinal Health SPD, Amgen representatives were directed not to be proactive in offering this rebate program. Further, representatives were directed to have NOA sign up any new accounts to be eligible for the rebate, not Amgen employees.

338. The other defendant wholesalers and GPOs, with the encouragement and knowledge of Amgen, have entered into similar contracts through which discounts have been passed through to the end users of various Amgen products.

339. Amgen evaluates the "performance" of various GPO and PPMO organizations by the degree to which they "promote" Amgen contracts. The most favored PPMOs offer additional discounts on Amgen products to the end user, passing a greater proportion of their fees to the customer. In return, Amgen partners with these PPMOs to offer additional discounts to their members. Ultimately, the best PPMOs offer the highest pass-through discounts, and help increase the profit margins of the clinics.

340. Amgen does not normally provide this type of discount to individual customers and has actively steered customers away from making direct purchases from Amgen. Individual customers are encouraged to purchase directly through the wholesaler/GPO distribution channel and are referred to wholesalers or the GPOs to make their purchases in order to receive the wholesaler discount. This policy is reflected in the Cardinal Health SPD/NOA rebate program.

341. Amgen also encourages individual customers to ask the wholesaler for a prompt payment discount and/or to negotiate a higher pass-through discount if the customer has asked Amgen to lower its prices. To ensure that customers receive the highest discounted prices possible,

Amgen encourages the wholesalers to pass along the discounts received from the manufacturer to its customers.

342. ION and NOA are two of the GPOs through which Amgen offers a 2% discount to the GPOs' customers. An additional discount of 2% is offered to the larger purchasers from ION.

343. Amgen pays ION and NOA (and other Amgen GPOs) two to three percent (2-3%) of total group sales as an "administrative fee." This fee is paid in return for the GPO's promotion of Amgen's contract price and for the GPO providing Amgen with sales data for each of its member customers. Amgen already purchases data on outlet sales from IMS Health (an industry sales data clearinghouse) and from wholesalers via their charge back reports.

344. In practice, the GPOs pass a large portion of the "administrative fee" on to the member practices either directly or through their wholesaler "prime vendors." Amgen representatives have been advised that its internal sources have confirmed that customers receive additional discounts as much as five percent (5%) through this channel via the wholesaler pass-through mechanism. Amgen's internal sources also confirm that the Amgen "channel" discounts exceed those of its competitors, including but not limited to Johnson and Johnson's Ortho Biotech division.

345. Through these discount schemes, Amgen is able to offer its customers illegal inducements to purchase its products rather than those of its competitors. These discount schemes are in violation of the Anti-Kickback Act that is triggered when the manufacturer induces drug purchases by deeply discounting a drug off of an artificially high AWP.

346. These same schemes continued when ASP became the benchmark for reimbursement for prescription drugs by government-funded healthcare programs.

347. The discounts and charge backs (rebates) provided by Amgen are prohibited by the Anti-Kickback Act as manufacturers are prohibited from offering or paying "any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly" to induce the purchase of goods or services payable by the federal government. 42 U.S.C. Section 1320a-7(b)(2).

348. By providing the discounts and reimbursements to the wholesalers and GPOs and encouraging that the discounts are passed through to the ultimate purchaser, Amgen has illegally paid these entities substantial remuneration for the purchase of its products, including but not limited to Aranesp. These wholesaler pass-through discounts (including chargebacks, administrative fees and other discounts) were in reality price concession given by Amgen to end customers that should have been included in the calculation of best price. However, Amgen used this sham GPO/wholesaler purchase mechanism to disguise these price concessions to avoid including them as part of the calculation for AWP and ASP. All claims Amgen and the remaining Defendants caused to be submitted for reimbursement for Amgen drugs that were reimbursed based upon Amgen's falsified AWP and ASP were false as that term is defined in the Federal False Claims Act and the analogous laws of the Plaintiff States. Further, these disguised price concessions constituted kickbacks paid by Amgen, acting in conspiracy with the remaining Defendants, for the purpose of increasing prescriptions of Amgen drugs ultimately paid for in whole or in part by government-funded healthcare programs.

349. Government purchasers are not offered GPO discounts or prompt payment discounts by the wholesalers. Amgen does not pay administrative fees for the reporting of government sales, and there is no channel discount available for federal government program customers, even when they purchase through the same wholesaler as other GPO customers. None of the prompt payment discounts or charge back fees are passed through to most of the federal program participants.

350. Amgen pays administrative fees to hospital GPOs as well as clinic GPOs. Hospitals can earn as much as 3.5-4% "cost minus" pass-through discounts from their GPO partner wholesaler. Hospitals that qualify for both government purchase discounts and GPO discounts receive pass-through discounts only on the GPO purchases, not on the government program purchases. The GPO and wholesaler pass-through discounts are not reported to the government for the purposes of calculating the AWP (up until 2005), ASP (2005 and beyond) or "Best Price."

351. By offering these unreported discounts to its customers, Amgen's and the other defendants' customers are able to submit claims for reimbursement to the applicable federal and/or state entities greatly exceeding the best price available for the pharmaceutical products, as well as the actual price paid by the claimant. All claims based on purchases induced by Defendants' discount schemes violate the AKS, the federal False Claims Act and the False Claims Acts of the Plaintiff States set forth herein. As a result of these practices, the federal and state governments have been damaged in substantial amounts of monies.

XI. AMGEN'S UNLAWFUL REPORTING OF BEST PRICE

352. Amgen was required under the Medicaid Rebate Act, 42 U.S.C. § 1396r-8, to report these discounts provided to GPOs and wholesalers and the discounts funneled through GPOS and wholesalers to end customers as "best prices" for calculating Amgen's rebates to the Plaintiff States. However, Amgen concealed these discounts, omitting these discounts from the Centers for Medicare and Medicaid Services ("CMS"), which relies on truthful reporting of best price information to accurately calculate rebates owed to the States. Amgen has knowingly, deliberately and purposefully concealed the discounted prices because if it had reported the true discounted prices, Amgen would have had to pay far greater rebates to the States.

353. Amgen's conduct has damaged the Medicaid program by way of sophisticated and complicated contractual arrangements, which set forth rebates terms with private sector purchasers (many of which are multi-tiered agreements depending on purchasing volume), that have the net effect of causing State Medicaid programs to pay more for Amgen drugs than purchasers in the private sector. The contractual arrangements include the Momentum I and II programs and the TOP Program.

A. THE MEDICAID REBATE PROGRAM

354. In 1990, Congress enacted the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, as part of the Omnibus Budget Reconciliation Act of 1990. The Medicaid Rebate Program, also known as the Medicaid Rebate Act and the Medicaid Rebate Statute, is "a cost-savings measure" that Congress passed "(i)n response to increasing Medicaid expenditures for prescription drugs (and) requires drug companies to pay rebates to states on their Medicaid purchases." *Pharmaceutical Research & Mfrs. Of America v. Walsh,* 538 U.S. 644, 649 (2003).

355. Pursuant to the Medicaid Rebate Act, participating manufacturers who want their drugs covered by Medicaid must contract with the federal government in a manner that is consistent with Congressional intent in passing the Medicaid Rebate Act.

356. Drug manufacturers must enter into a Rebate Agreement with the Secretary of HHS in order for federal matching funds to be made available for that manufacturer's covered outpatient drugs, 42 U.S.C. § 1396r-8(a) (1). Each participating manufacturer must sign, indicating agreement and compliance with all provisions therein, including that "The Rebate Agreement shall be construed in accordance with federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme."

357. The Rebate Agreement provides that the Secretary enters the agreement "on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent they have in force an Individual State Agreement)." Upon entering a Rebate Agreement with the Secretary, the manufacturer must pay a quarterly rebate directly to each participating State based on all of the manufacturer's drugs purchased by that State pursuant to its Medicaid plan during that quarter.

358. For single source or innovator multiple source drugs, the basic rebate due on each unit paid for under the State plan is calculated as the greater of either (a) a flat 15.1% off of the average manufacturers' price (AMP) or (b) the difference between the AMP and the "best price," or the lowest price available from the manufacturer during the previous quarter rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or non-excluded government entity. 42 U.S.C. § 1396r-8(c) (1), (2).

359. "The term 'average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." 42 U.S.C. § 1396r-8(k) (1).

360. The best price, or lowest price charged must take into account cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates, excluding the rebate paid to the States under the Medicaid Rebate Program. The best price is determined without regard to special packaging, labeling, or identifiers on the dosage form, product or package. And, the best price does not take into account prices that are merely nominal in amount. 42 U.S.C. § 1396r-8(c) (1).

361. Nominally-priced discounts are intended for not-for-profit, charitable entities and for researchers using the drugs for experimental or non-standard purposes. *See* S. Rep. 102-28 (I), Developments in Aging: 1990-Volume 1, 102nd Cong., 1st Sess. 1991 (March 22, 1991), 1991 WL 52579 (Leg. Hist.). Such discounts are not intended for marketing purposes. The Rebate Agreement defines "nominal price" as "any price less than 10% of the AMP in the same quarter for which the AMP is computed." Rebate Agreement at I. Definitions, (s).

362. Any rebate amounts received by the State must be offset against the State's Medicaid expenditures in that quarter for purposes of calculating the matching federal financial participation. 42 U.S.C. § 1396r-8(b) (1) (B).

363. Drug manufacturers are required under the Medicaid Rebate Statute and Rebate Agreement to calculate and report their AMPs and best prices to the Secretary on a quarterly basis. 42 U.S.C. § 1396r-8(b) (3) (A) (i); Rebate Agreement at § II (e). Any information provided by a manufacturer or wholesaler under the rebate statute is confidential and "shall not be disclosed by the Secretary...or a State agency...except as the Secretary determines to be necessary to carry out this section." 42 U.S.C. § 1396r-8(b) (3) (D); Rebate Agreement at § VII.

364. States are required to report their total Medicaid drug utilization to each manufacturer and the Secretary sixty (60) days after the end of the rebate quarter. 42 U.S.C. § 1396r-8(b) (2) (A). Using the manufacturer pricing data, CMS computes the unit rebate amount ("URA") "to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due." Rebate Agreement at § I (dd). Using the Medicaid drug utilization data, manufacturers calculate and pay the States the rebates they believe are due and owing to each State.

365. The Government Plaintiffs have relied and continue to rely upon the benefits conferred by the Medicaid Rebate program and on Amgen's performance of its obligations imposed by Rebate Agreements to ensure that the Medicaid Program reimburses payors (e.g., pharmacies) based on the actual Best Price available for Amgen's drugs.

B. AMGEN'S FALSE AND FRAUDULENT REPORTING OF AMP AND BEST PRICE.

366. As alleged in this Fourth Amended Complaint, at all times relevant hereto, Amgen has been entrenched in a battle for market share for its drugs including Epogen, Aranesp, Neupogen, Enbrel, Kineret, Neulasta and Sensipar. To beat the competition, Amgen has employed illegal marketing strategies and promotional schemes to induce hospitals, clinics and doctors to prescribe Amgen's drugs over other competitors. These marketing strategies have been rolled out to the public in the form of programs providing for off-invoice price discounts, as has been alleged in detailed herein.

367. At the heart of Amgen's marketing programs has been its promotional scheme known as "Marketing the Spread."

368. Amgen's illegal programs have included the Enhanced Momentum II Programs and the TOP programs described below and the misuse of Physician Practice Management Groups ("PPMs").

369. During her employment with Amgen from 1990 through 2005, Plaintiff Osiecki learned first hand that Amgen had devised, drafted and entered into improper contracts with private and public hospitals and/or clinics. The improper contracts included various improper inducements, including rebates and discounts, designed to increase Amgen's market share of specific products and to increase its overall volume of sales at the expense of the taxpayers. These inducements were devised by Amgen to encourage its customers to increase prescriptions of Amgen's drugs over

competing drugs or alternative forms of medical care and treatment, not to ensure that the most medically appropriate treatment was provided.

370. Specifically, Plaintiff Osiecki has first hand knowledge gained while employed by Amgen as a PSR, that the complained of unlawful marketing and pricing schemes as set forth in detail below are national in scope.

371. The complained of unlawful schemes are evidenced in contractual agreements entered into between Amgen and the following hospitals and clinics, of which Plaintiff Osiecki has first hand knowledge:

HOSPITAL	CLINIC
Evanston Hospital George Carro, RPh, MS Evanston, IL	Glen Morton Medical Center Chicago and Morton Grove, Illinois
Glenbrook Hospital Amanda Niemi, PharmD Glenview, IL	Hematology Oncology Associates of Illinois Leon H. Dragon, MD Highland Park, IL
Highland Park Hospital Gary Gehrke, PharmD Highland Park, IL	Hematology Oncology Associates of Illinois Ira A. Oliff, MD Skokie, IL
Holy Family Medical Center Mala Singh, PharmD, MS Des Plaines, IL	Block Medical Center Keith I. Block, MD Evanston, IL
Lake Forest Hospital Gregg Helm, PharmD Lake Forest, IL	Deerpath Medical Oncology/Hematology Rohit R. Shah, MD Ira J. Piel, MD Lake Forest, IL
Lutheran General Hospital Bonnie Bachenheimer, PharmD Park Ridge, IL	Oncology Specialists, SC Rossini Parayno, PharmD Park Ridge, IL
North Suburban Medical Consultants Leonard A. Kosova, MD Niles, IL	North Shore Oncology Hematology Associates, Ltd Peter Muhlbach- Business Manager Barrington, IL Libertyville, IL
Condell Medical Center Kati Kwasiborski, RPh Libertyville, IL	Midwestern Regional Medical Center Cancer Treatment Centers of America Robert E. Musick, RPH
Rush North Shore Medical center	Oncology Hematology Associates of

Carol Heunisch, PharmD Skokie, IL	Northern Illinois, Ltd Naren Kapadia, MD Nilesh D. Mehta, MD Gurnee, IL
St. Francis Hospital Susan Pahl, RPh Evanston, IL	Progressive Care, SC Mark E. Singer- Chief Operating Officer Chicago, IL
Resurrection Medical Center Joseph R. Gera, RPh Chicago, IL	
Swedish Covenant Hospital Chicago, IL Cancer Center- K. Joseph Philip, MD- Chief of Oncology Department Inpatient Hospital Pharmacy- Ramesh V. Patel, PharmD Rush University Medical Center The Rush Cancer Institute Matthew A. Kemper, PharmD Chicago, IL	
John H. Stroger, Jr Hospital of Cook County Pamela L. Sperl, PharmD Chicago, IL	
MacNeal Health Network William Pong, PharmD Berwyn, IL	
Louis A. Weiss Memorial Hospital Chicago, IL	
Jesse Brown VA Medical Center Richard J. Rooney, PharmD Chicago, IL	
University of Chicago Abdul S. Manasrah, MS- Finance Manager Chicago, IL	
University of Illinois Divyesh Mehta, MD- Chief Oncology John Gargas- Pharmacy Andrew Donneley, Pharm D- Pharmacy Chicago, IL	
University of Wisconsin-Madison Hospital Madison, Wisconsin	

1. ***The Enhanced Momentum II Hospital Contract.***

372. As set forth above, under the terms of Amgen's Momentum II contracts, hospitals clients receive off-invoice discounts of 25% on their purchases of Aranesp vials and singlejects and 2% off the purchases of Neulasta and Neupogen. Hospital-based dialysis centers receive off-invoice discounts of 11% on all Epogen vials, with the exception of Epogen M20 vials for which an off-invoice discount of 17% is provided. Hospitals without dialysis centers receive discounts of 3% on all Epogen vials.

373. Further, effective October 1, 2004, pursuant to Amgen's Momentum II contract, hospitals also receive unreported rebates from Amgen based on the market share of Aranesp and volume of sales of Neulasta and Neupogen. Additional rebates on Neupogen and Neulasta based upon Aranesp's market share constitute illegal bundling of products, intended to increase the incentive to purchase Aranesp without further reducing the price of Aranesp. In other words, Amgen has used the discounts on Neupogen and Neulasta to provide additional rebates tied to Aranesp purchases which Amgen has not calculated as Aranesp discounts.

374. Amgen has regularly monitored and reported customers' "red to white" ratio as a way for representatives and management to measure the economic power of the bundled discounts. The larger a customer's purchase of "white" blood growth factors such as Neupogen and Neulasta relative to the "red" blood growth factors, Aranesp and Procrit®, the more significant the customer's additional bundled discounts would be and the greater the bundled incentive would become as compared to unbundled discount offerings by Amgen's competitor, Johnson and Johnson, sellers of Procrit®.

375. The hospitals received rebates of up to 21.5% on its total quarterly purchases of Aranesp based on the drug's market share at the hospital. The hospitals also receive rebates of up to

8% on its quarterly purchases of Neupogen and Neulasta, with the rebate amounts directly tied to Aranesp's market share.

376. To receive the rebate on the purchases of Neulasta and Neupogen, a hospital's net quarterly purchases must be equal to or greater than 70% of the prior year's same-quarter net purchases.

377. By offering these increased off invoice discounts and rebates based on the market share of Aranesp and continued high purchase volumes of Neulasta and Neupogen, Amgen has improperly induced the hospitals to prescribe and sell Amgen's drugs over competing drugs or alternative forms of medical care and treatment. The scheme interfered with the healthcare provider's ability to make unbiased and neutral judgments as to the appropriate medicines to use.

378. Amgen has known that the rebates provided to private purchasers through its Momentum II hospital contracts must be reported to CMS pursuant to the Medicaid rebate Act and Amgen's Rebate Agreement with CMS. Yet, Amgen has purposefully failed to report the cumulative result of the rebates associated with the Momentum II contracts as required under the Medicaid Rebate Act. Amgen has knowingly and deliberately concealed these discounts for the purposes of Best Price and AMP, and has knowingly failed to account for the steep discounts offered under the Momentum II hospital contracts in calculating its quarterly report of AMP or best price to CMS.

379. As Amgen has well known and sought to avoid, had Amgen truthfully reported these prices, it would have affected the best price calculations and Amgen would have been legally obligated to pay the Medicaid program and other government-funded health care programs much greater rebates.

380. Amgen has knowingly failed to disclose these discounts and has knowingly failed to account for the steep discounts offered under the Momentum II hospital contracts in calculating its quarterly report of AMP or best price to CMS.

2. *The Total Oncology Partner Program*

381. The Total Oncology Partner ("TOP") program has similarly offered illegal inducements to participant hospitals in the form of rebates in two discrete ways.

382. As alleged above, the TOP program provides for rebates to private hospitals based on the increase in product market share of Amgen's products at individual hospitals. Specifically, when Amgen's product market share increases by 1.5 % to 9.49% in a given quarter, the hospital is given a rebate of 21.5% on its Aranesp purchases and a rebate of 2% to 4% on its purchases of Neulasta and Neupogen.

383. If Amgen's quarterly product market share at the hospital is at least 79.5% or the market share increases by 9.5% or more in the quarter, the hospital receives a rebate of 21.5% on Aranesp and a rebate of 7% on the purchases of Neulasta and Neupogen.

384. Further, if the hospital is a partner in both the Momentum II and TOP programs, it is entitled to combine its rebate percentages for its eligible Neulasta and Neupogen purchases. By tying together these two programs and offering increased rebates based on the level of Amgen's market share, this scheme interfered with the hospitals' ability to make unbiased and neutral professional judgments as to the appropriate medicines to purchase and use for the care of its patients.

385. Amgen has known that the rebates provided to private purchasers through its TOP contracts must be reported to CMS pursuant to the Medicaid Rebate Act and Amgen's Rebate Agreement with CMS. Yet, Amgen has purposefully failed to report the cumulative result of the

rebates associated with the TOP program as required under the Medicaid Rebate Act. Amgen has knowingly and deliberately concealed these discounts for the purposes of Best Price and AMP and has knowingly failed to account for the steep discounts offered under the TOP program in calculating its quarterly report of AMP or best price to CMS.

386. Had Amgen truthfully reported these prices, it would have affected the best price calculations and Amgen would have paid much greater rebates to the Medicaid program. In addition, had Amgen truthfully reported its drug prices, Amgen would have effectively eliminated the "spread" it relied upon so heavily to induce purchases of its drugs over competitors.

C. AMGEN'S IMPROPER USE OF UNRESTRICTED EDUCATIONAL GRANTS AND PATIENT EDUCATION GRANTS TO INFLUENCE HOSPITALS AND OTHERS, AS WELL AS TO DISGUISE PRICE REBATES THAT AMGEN INTENTIONALLY FAILED TO REPORT.

387. In an effort to increase its volume of sales with existing customers, namely, hospitals, Amgen has made what are known as unrestricted educational grants to various physicians, hospitals, and other institutions. These grants have often been in the form of a sponsorship of a seminar or meeting held at existing or potential customer facilities. The sponsored speaker(s) would discuss disease processes and stages and further discuss how Amgen products were clinically and economically beneficial in the treatment of these diseases.

388. Although Amgen has stated in letters and other materials related to grants of this nature that there was no expectation of any *quid pro quo*, there has been an implicit understanding that the grantee would increase its purchases of Amgen products and/or its speakers would advocate the use of the Amgen products to other attendees at the seminar.

389. For example, in January 2005, Amgen was asked to make such a grant to Rush University Medical Center for its 5th Annual Rush Review. Various seminars were planned to discuss synopses of the latest clinically relevant research. Amgen provided a grant in the amount of

$10,000 in support of this seminar. In return, there was an unspoken expectation that the hospital would increase its purchases of Amgen products and/or speakers at the seminar would comment favorably on Amgen products, including Aranesp.

390. These grants are illegal inducements to hospitals to change or switch their prescribing and billing habits in order to create financial incentives for greater Amgen product use.

391. In addition to the unregistered education grants, Amgen has also supplied what are known as Patient Education Grants ("PEGs").

392. These grants have been made to various hospitals for the purchase of various education materials and other supplies as needed to create a patient education center. These materials have consisted, in part, of books and research materials on cancer and the various treatments.

393. In exchange for providing funds for these centers or rooms, the hospitals were expected to increase or maintain their purchase of Amgen pharmaceutical products. The exchange has been an implicit understanding between Amgen and the recipient hospitals, as Amgen has been careful not to state its expectations in any correspondence related to these grants.

394. For example, in 2005, the University of Illinois Medical Center received a PEG in the amount of $5,000.00 from Amgen to establish such a center.

395. These grants are illegal inducements to the hospitals to change or switch their prescribing and billing habits in order to create financial incentives for greater Amgen product use.

D. AMGEN KNOWINGLY UTILIZED PHYSICIAN PRACTICE MANAGEMENT ORGANIZATIONS TO EVADE BEST PRICE REPORTING REQUIREMENTS.

396. Pursuant to a scheme separate from that implemented through the hospital & clinic contracts, but in a similar fashion, Amgen has entered into purchase contracts with for-profit physician-owned clinics to provide discounts and rebates tied to the purchase of Aranesp, Neupogen

and Neulasta. Plaintiff Osiecki, as an Amgen Professional Sales Representative (or PSR), was responsible for presenting these contracts to physician clinics, gaining signatures from the appropriate clinic personnel, and monitoring and communicating the status of discounts and rebates to the contracted customers.

397. The physician clinics would purchase Amgen products at a discounted price, administer the product to patients, and then submit Amgen drug reimbursement claims to the patient and/or the insurer, Medicare and Medicaid for the administered Amgen drug and an administration fee, and sometimes for a clinic visit as well.

398. Physician clinic agreements have been offered either directly to a clinic, or through a Physician Practice Management organization (PPM), to which Amgen has also internally referred as a "Buying Group." The PPM contracts have generally been the same as those offered directly to clinics; however, the PPM contracts have offered additional features such as add-on discounts, which Amgen funded through various payments from Amgen to the PPM groups. These groups have included International Oncology Network (ION), National Oncology Alliance (NOA) and other small or regional PPM groups. Amgen has funded these added discounts *via* cash discounts, administration fees, data collection fees and chargebacks.

399. Working through the PPM contracts, Amgen could offer physician practices discounts that amounted to as much as 6-8% *in addition to* the prevailing Amgen APC contract.

400. Amgen has worked with a PPM partner and an approved wholesaler. Each PPM has generally utilized a selected or contracted wholesaler. Plaintiff Osiecki questioned the need and rationale for contracting through PPMs, including involvement of wholesalers. Specifically, Plaintiff Osieki questioned Amgen's Corporate Accounts Director Anthony Carraeo as to why Amgen preferred to work through the more expensive route of distributing the drugs at issue

through wholesalers and PPMs rather than discounting and selling directly to the customers. Amgen's Carraeo explained that the discounts provided through the PPM/wholesaler distribution route would not be counted toward calculating government "Best Price" and, therefore, the extra cost was warranted. This discussion took place sometime in 1998.

401. The PPM/wholesaler distribution scheme has worked as follows:

a. Amgen sold products to the wholesaler at the Wholesaler Acquisition Price ("WAP"), which was the list price for the drug. Terms for the purchase are 2% 30, net 60, referred to as the "cash discount."

b. The wholesaler sold the drug to the PPM member physician clinic at the off-invoice discount price (APC customers received 10% off invoice discount for Aranesp and 5% off invoice for Neupogen and Neulasta.) The wholesaler then reported the customer purchase back to Amgen.

c. The wholesaler received a cash discount of 2% 30, net 60 days from Amgen, and a 2-3% "chargeback" for reporting the sale of the product to the contracted customer to Amgen. Amgen also credited the wholesaler with the off-invoice discount that was passed on to the customer. In this way, the wholesaler was made whole for the "off-invoice" discount, and reaped 4-5% discounts in the form of cash discounts and "chargeback" fees.

d. The wholesalers used their combined cash discount and chargeback fees to offer additional cash discounts to clinic customers. Clinic customers who paid with a bank transfer or within 10 days could reap 3.75% cash discounts.

e. The PPM group would also receive an administration fee of 2% of the total purchases of contracted Amgen products. Amgen would then offer discounts of up to an additional 4% for purchases made by the PPM contracted customers. These rebates were paid directly by the

PPM and, thus, did not come directly from Amgen, although the money to pay the rebates came from Amgen through contractual agreement with the PPM.

f. Amgen preferred to use this distributor marketing channel because it could incentivize its clinic customers with several percentage points of additional discount that was passed through other channel partners. Because these additional rebates and discounts were not paid directly by Amgen, but through a third party, these discounts have not been reported by Amgen to CMS for the purposes of calculating best price. The discounts have been closely monitored and dictated by Amgen, and used in Amgen promotion of its products. Amgen made it known to customers that these were additional discounts credited to purchase of Amgen products through the wholesalers and PPM groups.

g. In this fashion, Amgen has provided discounts of up to 7.75% on its product purchases that Amgen excluded from its calculation of Best Price.

h. When the discounts were provided to the customer, Amgen told the customer that they were responsible for reporting all discounts in accordance with applicable state and federal laws. However, this method was not used to calculate Best Price.

402. As set forth above, Amgen has knowingly utilized PPMs to cover up its multi-tiered rebate schemes and to avoid reporting the same to CMS in violation of the Medicaid Rebate Act's Best Price requirements.

XII. FEDERAL HEALTHCARE PROGRAMS DAMAGED BY DEFENDANTS' FRAUDULENT AND ILLEGAL PRACTICES

A. MEDICAID AND MEDICARE

1. The Medicaid Program

403. Title XIX of the Social Security Act is a program that provides medical assistance for certain individuals and families with low incomes and resources. The program, known as

Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children. Among the health benefits funded primarily by Medicaid, up until January 1, 2006, was funding for the prescription drug needs of the Program's beneficiaries.

404. At all times relevant to the Complaint, in most states, Medicaid was an open-ended, federal-state matching program. The federal government contributes a fixed percentage of each state's Medicaid costs each year; however, the exact percentage the federal government contributes varies each year according to a formula that takes into account each state's per capita income relative to the national per capita income. The percentage of state contribution to the funding of prescription drug purchases and all other covered Medicaid health benefits has typically amounted to at least 40% at all times relevant to the Complaint.

405. Although Medicaid is administered on a state by state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §1396b(i)(10), 1396r-8(k)(3). "Covered outpatient drugs" are drugs that are used for a "medically accepted indication." *Id.* §1396r-8(k)(3).

406. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or use of which is supported by one of the drug compendia identified in the Medicaid statute. *Id.* §1396r-8(k)(6).

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2. *The Medicare, Medicare Part B and Medicare Part D Programs*

407. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. The health insurance provided to beneficiaries of the Medicare insurance program is paid in whole or in part by the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals sixty-five (65) and over. Payments made under the Medicare Program include payment for certain prescription drugs used during treatment at an appropriate medical faculty and otherwise, as well as certain injectable drugs and drugs used in conjunction with the treatment of patients with cancer and chronic kidney disease.

408. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created new outpatient prescription drug coverage under Medicare ("Medicare Part D").

409. Medicare Part D went into effect on January 1, 2006. The Program is administered by the United States Department of Health and Human Services, Centers for Medicare and Medicaid ("CMS"). For "dual eligibles," defined as individuals who received prescription drug coverage under Medicaid in addition to Medicare coverage for other health care in 2005, enrollment in Medicare Part D was compulsory. Such beneficiaries were automatically switched to Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

410. Coverage of prescription drugs under Medicare Part D is subject to the same regulations as coverage under the Medicaid Program described above.

411. Some of Amgen drugs at issue in this Fourth Amended Complaint, including Aranesp and Neupogen, are covered by Medicare Part B in addition to Medicare Part D, depending where and how the drugs are administered.

412. The Medicare Modernization Act (MMA), Section 1847A of the Social Security Act (SSA), changed reimbursement for Medicare Part B drugs from 95% of average wholesale price (AWP) to 106% of ASP net of volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than Medicaid rebates).

413. Medicare reimbursement is based on the lesser of this allowable amount or actual charges, as follows:

- Physician offices are reimbursed for 80% of the allowable amount
- The patient or patient's secondary insurer is responsible for the remaining 20% coinsurance

414. Since January 2005, Medicare Part B has been paying for most covered drugs using a reimbursement methodology based on ASPs. Section 1847A(c) of the Social Security Act, as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, defines an ASP as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program.

415. A manufacturer's ASP must be calculated by the manufacturer every calendar quarter and submitted to CMS within thirty (30) days of the close of the quarter. Each report must be certified by one of the following: the manufacturer's Chief Executive Officer (CEO); the manufacturer's Chief Financial Officer (CFO); an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

416. Manufacturers report ASPs by national drug codes (NDC), which are 11-digit identifiers that indicate the manufacturer, product dosage form, and package size of the drug. Manufacturers must provide CMS with the ASP and volume of sales for each NDC on a quarterly basis, with submissions due 30 days after the close of each quarter.

417. Because Medicare Part B reimbursement for outpatient drugs is based on HCPCS codes rather than NDCs and more than one NDC may meet the definition of a particular HCPCS code, CMS has developed a file that "crosswalks" manufacturers' NDCs to HCPCS codes. CMS uses information in this crosswalk file to calculate volume-weighted ASPs for covered HCPCS codes.

418. Just as it has manipulated the AMP/best price for its drugs under the Medicaid Rebate Act, Amgen has manipulated the ASP for its drugs reimbursed under Medicare Part B for its financial gain.

B. OTHER FEDERALLY FUNDED HEALTH CARE PROGRAMS

419. In addition to Medicaid, Medicare and Medicare Part D, the federal government reimburses a portion of the cost of prescription drugs under several other health care programs, including but not limited to the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), the Indian Health Service and CHAMP VA, as alleged below. These programs operate in similar ways to the Medicare and Medicaid programs. For example, the VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicare

and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

1. The Railroad Retirement Medicare Program

420. The Railroad Retirement Medicare program is authorized by the railroad retirement act of 1974, at U.S.C.A. §231 *et seq.* It is administered through the United States Railroad Retirement Board, "RRB," and furnishes Medicare coverage to retired railroad employees.

2. Federal Employee Health Benefit Plans

421. The Federal Employees Health Benefits Program ("FEHBP") is administered by the United States Office of Personnel Management ("OPM") pursuant to 5 U.S.C.A §8901 *et seq.* and provides health care coverage to federal employees, retirees and their dependants and survivors.

3. Tri-Care

422. The Tri-Care program, formerly, CHAMPUS, is administered by the United States Department of Defense through its component in agency, CHAMPUS, under the authority of 10 U.S.C.A. §§1701-1106. It is a health care program that provides for care in civilian facilities for members of the uniformed services and their dependents. Pursuant to 38 U.S.C.A. §8126, and the regulations based there on, drugs furnished by drug manufacturers to the Department of Defense must be furnished at the best price.

423. Upon information and belief and base their own relators a ledge that the United States also furnishes funds which several states used to pay for such drugs pursuant to the State Legal Immigrant assistance Grants, 8 U.S.C.A. §1255a; 45 C.F.R. §402.10.

4. The Veterans Administration

424. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") is a comprehensive health care program in which the VA shares the cost of

covered health care services and supplies with eligible beneficiaries. The program is administered by Health Administration Center and our offices are located in Denver, Colorado. In general the CHAMPVA program covers most health care services and supplies that are medically and psychologically necessary.

425. Due to the similarity between CHAMPVA and the Department of Defense ("DoD") Tri-Care program the two are often mistaken for each other. CHAMPVA is a Department of Veterans Affairs program whereas Tri-Care is a regionally managed health care program for active duty and retired members of the uniformed services, their families and survivors. In some cases a veterans may look to be eligible for both/either program on paper. However, military retirees, or the spouse of a veteran who was killed in action, are and will always be Tri-Care beneficiaries.

426. Pursuant to 38 U.S.C.A. §8126, and the regulations based thereon, and contracts the Veterans Administration had with manufacturers, drugs furnished to the Veterans' Administration by drug manufacturers must be furnished at the best price.

427. The VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

5. Indian Health Service

428. The Indian health service is responsible for providing comprehensive health services to more than 1,400,000 Americans. It is administered by the department of health and human services pursuant to 42 U.S.C.A. 2002 *et seq.* The statute authorizes the Secretary to enter into contracts with independent providers to furnish health services to Native Americans whenever the Secretary determines that independent providers can better meet the population's need. Pursuant to

38 U.S.C.A. §8126, and the regulations based thereon, drugs furnished to the Indian Health Service by drug manufacturers must be furnished at the best price.

6. State Legal Immigrant Assistance Grants

429. Relator is informed and believes and based thereon alleges that the United State also furnishes funds which several States use to pay for such drugs pursuant to State Legal Immigrant Assistance Grants, 8 U.S.C.A §1255A; 45 C.F.R. §402.10.

C. THE GOVERNMENT HEALTH PROGRAMS WERE DAMAGED

430. During the time relevant to this Complaint, many of the off-label uses of Amgen's drugs promoted by Amgen as alleged herein were not eligible for reimbursement under Medicaid, Medicare and the other government healthcare programs because such off-label uses were neither listed in the labeling approved by the FDA nor otherwise supported as safe and effective by any of the drug compendia specified by the federal regulation

431. Additionally, because Amgen's unlawful marketing efforts have been designed to generate overutilization of their drugs in situations which the drugs either were not proven safe or effective or were not medically necessary for treatment of patients' specific medical conditions, Amgen has caused health care providers to submit claims for reimbursement to Medicaid, Medicare and the other government health programs that were unwarranted and not covered and therefore false.