UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA; and THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MICHIGAN, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, TENNESSEE, and TEXAS; THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and THE DISTRICT OF COLUMBIA; *ex rel.* KASSIE WESTMORELAND, Plaintiffs, v. AMGEN INC.; INTERNATIONAL NEPHROLOGY NETWORK renamed INTEGRATED NEPHROLOGY NETWORK, a d/b/a of DIALYSIS PURCHASING ALLIANCE, INC.; AMERISOURCEBERGEN SPECIALTY GROUP; ASD HEALTHCARE; and AMERISOURCEBERGEN CORPORATION, Defendants.	**CIVIL ACTION NO.** **06-10972-WGY** **JURY TRIAL DEMANDED**

RELATOR'S FOURTH AMENDED COMPLAINT

NATURE OF THE ACTION

1. This is an action brought on behalf of the United States of America by Plaintiff Kassie Westmoreland (hereafter referred to as "Relator") against Defendants pursuant to the *Qui Tam* provisions of the Civil False Claims Act, 31 U.S.C. §§ 3729-33 ("FCA"), referred to herein as the "*Qui Tam* Action." Pursuant to 31 U.S.C. § 3730(b)(2), this *Qui Tam* Action was brought

in camera and under seal.[1] Relator also continues to pursue on her own behalf her claims that Defendant Amgen retaliated against her in violation of the anti-retaliation provisions of the False Claims Act, 31 U.S.C. § 3730(h) and California law. Those claims have been severed to be adjudicated pursuant to arbitration following disposition of the *Qui Tam* action, at the request of Defendant Amgen.

2. The Relator in this case is a former employee of Defendant Amgen. The allegations of this Complaint arise from the Relator's first-hand knowledge of the unlawful practices of the Defendants with respect to the drug Aranesp® (darbepoetin alfa) (hereafter "Aranesp").[2]

3. As more fully described below, Aranesp is an injectable prescription drug developed and manufactured by Defendant Amgen, which was marketed by all Defendants. Aranesp is approved by the FDA to treat anemia in certain patients – specifically anemia related to the treatment of certain nephrology (kidney) and oncology (cancer) patients.

4. Aranesp is administered to patients in many different inpatient and outpatient settings, including physicians' offices, outpatient clinics, hospitals, and dialysis clinics. Additionally, Aranesp is prescribed to patients for self-injection.

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[1] This action previously included several named Plaintiff States that had intervened in this action by filing their own Multi-State Complaint in Intervention (and amendments thereto). This *Qui Tam* action also included claims brought by Relator on behalf of two states, Georgia and New Mexico, that had not intervened. (Collectively, the claims of States are the "State *Qui Tam* Claims.") Based on this Court's ruling that the State *Qui Tam* claims would be dismissed on various grounds, the Plaintiff States and Relator (for claims respecting Georgia and New Mexico) plan to seek appeal of that part of the Court's ruling. The State *Qui Tam* Claims therefore are not repleaded in this Amended Complaint.

[2] This action originally included as Defendants AmerisourceBergen Corporation and AmerisourceBergen Specialty Group. The Court dismissed those Defendants. Relator does not replead herein with respect to those Defendants, but reserves the right to appeal the Court's dismissal of them from her action.

5. At all times relevant to this case, Aranesp was marketed to medical providers by Defendant Amgen with assistance from Defendant International Nephrology Network renamed Integrated Nephrology Network, a d/b/a of Dialysis Purchasing Alliance, Inc. (hereafter "INN"), a purported group purchasing organization ("GPO") that is a subsidiary of Defendant ASD Healthcare, a distributor who is related to AmerisourceBergen Corporation ("ABC") and AmerisourceBergen Specialty Group ("ABSG").

6. Aranesp is usually purchased directly or indirectly by a medical provider from an entity such as Defendant ASD Healthcare. The medical provider thereafter may seek reimbursement for the drug, often by submission of a claim to federal and state governmental health insurance programs, such as Medicare and Medicaid.

7. As a direct, proximate and foreseeable result of Defendants' fraudulent course of conduct set forth herein and conducted on a national scale, Defendants knowingly caused the submission of thousands of false or fraudulent statements, certifications, and claims to government health insurance programs for the reimbursement of the drug Aranesp from at least September 2002 through at least mid-March 2005, when Relator was actively employed by Defendant Amgen.

8. Moreover, the practices complained of herein are continuing. As detailed below, the Defendants' actions and omissions have caused many years of improper and illegal billings to the United States. For the years 2001-2008, Amgen's aggregate United States revenues from Aranesp total over $11 billion, with approximately $6 billion coming from federal and state health care programs such as Medicare and Medicaid.

9. Defendants' fraudulent conduct has had a dramatic impact on Medicare and the government fisc. Spending for epoetin therapy (of which Aranesp is one) is now the single

largest Medicare drug expenditure ($1.75 billion in 2005) and is the second-largest source of dialysis facility income (approximately 22 percent). Department of Health and Human Services, Office of Inspector General, "Medicare Reimbursement for Existing End-Stage Renal Disease Drugs," OEI-03-04-00120 (Washington: DHHS, OIG, May 2004).

10. By their actions, the Defendants have violated several laws, including without limitation, the FCA and the Medicare and Medicaid Patient Protection Act (also known as the Anti-Kickback Statute).

11. The purpose of these unlawful activities was to encourage sales of, and to gain market share for, Aranesp over its competitor drug Procrit® (marketed by Johnson & Johnson) (hereafter "Procrit"), and to switch patients from Procrit and/or the drug Epogen® (hereafter "Epogen" also manufactured by Defendant Amgen) to Aranesp.

12. Among other misconduct, Defendants conspired to encourage medical providers to purchase Aranesp based on representations of the profits that the providers could realize from submission of inflated Aranesp-related claims to Medicare. Defendants encouraged medical providers to overstate the amount of Aranesp administered so that the provider could achieve greater amounts of reimbursement from Medicare and/or Medicaid, thereby making Aranesp more attractive than competitive drugs.

13. As is explained by way of example in this Complaint, Defendants' actions involved, among others, concerted efforts to encourage medical providers throughout the United States to (a) base their clinical decisions on misinformation, such as Defendants' presentation of the purported overfill of Aranesp versus its competitors and/or "special" incentives offered to Aranesp purchasers who contracted with INN, (b) to overdose patients with Aranesp overfill, that was, in some cases, prescribed by the physician and, in any event, medically unnecessary;

and (c) to submit overstated claims relating to Aranesp overfill that was not administered to patients.

14. This misconduct was based on collusion and conspiracy among the Defendants to target medical providers who could provide lucrative business for Defendants through the purchase of Aranesp, as well as medical providers who could influence other providers to contract with Defendants for Aranesp.

15. In addition to causing damage to programs such as Medicare, Defendants' actions have also put patient safety and health at risk. The population of patients for whom Aranesp is indicated is especially vulnerable. Though Amgen was aware of issues earlier, 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 most serious warning available on a drug's label. The 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.

16. 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.

17. One of Amgen's responses to the black box warnings appears to have been to treat them as humorous. A script for a July 2007 meeting of Amgen's Nephrology Business Unit from the files of Amgen Vice President of Sales Leslie Mirani included a joke about "black box

warnings," following up on the FDA's February 2007 warning about potential harm from Aranesp.

Two recent studies provide further evidence of harm or potential harm:

(a) A study published online on October 30, 2009 by the New England Journal of Medicine, raised fresh safety concerns with Aranesp. The study led by Dr. Marc Pfeffer, a heart specialist at Brigham and Women's Hospital in Boston, involved 4,038 patients with Type 2 diabetes, kidney problems and moderate anemia. As of that date, it was the largest ever study of any ESA drug and the first to compare Aranesp to placebo. The study examined the use of Aranesp in the prevention of heart attacks, heart failure, strokes or the need for dialysis. The study found that not only was Aranesp ineffective in these applications, Aranesp nearly doubled the risk of stroke in people with diabetes and chronic kidney problems who are not yet sick enough to need dialysis; and

(b) A second study, published on November 10, 2009 in the Journal of the National Cancer Institute, was led by Dr. Dawn Hershman of New York-Presbyterian Hospital/Columbia University. That study tracked the use of ESAs such as Aranesp in more than 55,000 cancer patients over a decade. The study found the use of ESAs more than doubled the patient's risk of developing blood clots in the lungs or legs while not reducing the need for blood transfusions (the original purpose of ESAs when first approved in 1989).

18. Information about Defendants' illegal conduct is detailed further in the paragraphs below.

JURISDICTION AND VENUE

19. This Court has jurisdiction over this action under the False Claims Act ("FCA") causes of action pursuant to 28 U.S.C. §§ 1331, 1345, and 31 U.S.C. §§ 3732(a), 3730.

20. Venue is appropriate as to the Defendants in that the Defendants can be found, reside and/or transact business in this judicial district, and/or acts proscribed by 31 U.S.C. § 3729 have been committed by the Defendants in this judicial district. Therefore, venue is proper within the meaning of 28 U.S.C. § 1391(b) and (c), and 31 U.S.C. § 3732(a).

21. The Relator's action is not based upon the disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [General] Accounting Office report, hearing, audit, or investigation, or from the news media. At the time the original complaint was filed, there was no such disclosure, and in any event, as discussed below, this action is based on Relator's direct and independent knowledge as an employee (now former) of Defendant Amgen, not on any such disclosure. Furthermore, as discussed and demonstrated in Relator's Complaint and amendments and prior proceedings before the Court, Relator is an "original source" of the information upon which her action is based: she has direct and independent knowledge of the information on which the action is based; and she voluntarily provided her information to the government in 2006, before filing her Complaint, and has made several subsequent disclosures prior to amending her Complaint. *See generally* 31 U.S.C. § 3730(e)(4). Her complaint and any amendments were properly served on each sovereign named.

THE PARTIES

22. The real party in interest to the FCA Q*ui Tam* claims herein is the sovereign government of the United States of America. The United States of America has filed with this

Court a Notice of Not Intervening at this Time (but is continuing its investigation and filed a Statement of Interest relating to Defendants' Motion asking the Court to clarify or reconsider its ruling on Count I as to Medicare).

23. Accordingly, at this time, Relator is pursuing her cause of action on behalf of the United States on the FCA *Qui Tam* claims set forth herein. *See, e.g.*, 31 U.S.C. § 3730(c) (3).

24. Relator Kassie Westmoreland is a citizen of the United States of America. She is a resident of California, and a former employee of Defendant Amgen. She brings this *Qui Tam* action based upon direct, independent, and unique information obtained during the period of her active employment at Amgen from September 2002 to mid-March 2005, at which time she went on temporary disability leave as a result of Amgen's unlawful retaliation against her as detailed *infra*.

25. Defendant Amgen Inc. ("Amgen"), a Fortune 500 company, is a publicly-traded diversified, human therapeutics company in the biotechnology industry. It conducts business throughout the United States (including Massachusetts) and in many other countries. Its principal place of business is Thousand Oaks, California. Amgen is traded on the NASDAQ under the symbol "AMGN." Amgen engages in the discovery, development, manufacture, and delivery of biotherapeutics (*e.g.*, prescription drugs) for various medical needs. The company provides products for the treatment of various human ailments, including anemia, arthritis, psoriasis, cancer treatment side effects, and side effects of dialysis. Amgen was the original developer of the drug Aranesp® (darbepoetin alfa) ("Aranesp") approved by the United States Food and Drug Administration in 2001 for the treatment of anemia associated with chronic renal failure (both in patients on dialysis and those not on dialysis) and in 2002 for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies.

26. Defendant International Nephrology Network ("INN") was formed in September 2003 and operated as one of several d/b/as of International Physicians Networks ("IPN") (other d/b/as used by IPN included International Oncology Network and International Rheumatology Network). In 2002, AmerisourceBergen Corporation ("ABC") acquired a 20% ownership interest in IPN; in April 2003, ABC acquired an additional 40% interest in IPN; and in January-April 2004 ABC acquired the final 40% of IPN, thus making IPN a wholly owned subsidiary of ABC. INN operated as a d/b/a of IPN until April 2008, at which time that d/b/a was withdrawn, and INN was renamed Integrated Nephrology Network and was registered as a d/b/a of Dialysis Purchasing Alliance, Inc. In this Complaint, INN shall be referred to as INN regardless of which name it was doing business as or under at what point in time. Since at least 2004, INN has operated as a business unit of ABSG. INN, whose principal place of business is in Frisco, Texas, is purportedly a "group purchasing organization" ("GPO") that focuses on nephrology practices and physicians. Amgen started doing business with INN in 2003. INN does business throughout the United States, including in the Commonwealth of Massachusetts.

27. Defendant ASD Healthcare a/k/a ASD Specialty Healthcare, Inc. ("ASD" or "ASD Healthcare"), is a pharmaceutical distributor operated by ABSG, whose ultimate parent is ABC. Its principal place of business is Frisco, Texas. ASD Healthcare distributes drugs throughout the United States, including the Commonwealth of Massachusetts, and is the preferred distributor for INN.

FEDERAL AND STATE LAWS AND REGULATIONS

A. The Anti-Kickback Laws of the United States and the States

28. The Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that the

remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and can result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of the federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The Anti-Kickback Statute was enacted in 1972 "to provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost of the Medicare and Medicaid programs." H.R. Rep. No. 92-231, 92d Cong., 1st Sess. 108 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

29. In 1977, Congress amended the Anti-Kickback Statute to prohibit receiving or paying "any remuneration" to induce referrals and increased the crime's severity from a misdemeanor to a felony with a penalty of $25,000 and/or five years in jail. *See* Social Security Amendment of 1972, Pub. L. No. 92-603, 241(b) and (c); 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the Anti-Kickback Statute was to combat fraud and abuse in medical settings that "cheats taxpayers who must ultimately bear the financial burden of misuse of funds . . . diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services . . . [and] erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs." H.R. Rep. No. 95-393, pt. 2, at 37, reprinted in 1977 U.S.C.C.A.N. 3039, 3047.[3]

[3] Through the amendments Congress sought to "give a clear, loud signal to the thieves and the crooks and the abusers that we [Congress] mean to call a halt to their exploitation of the public

30. In 1987, Congress again strengthened the Anti-Kickback Statute to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

31. The Anti-Kickback Statute prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in part by a federal health care program, which includes any State health program or health program funded in part by the federal government. 42 U.S.C. §§ 1320a-7b(b), 1320a-7b(f).

32. The statute provides, in pertinent part:

> (b) Illegal remunerations
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> * * *
>
> (2) Whoever knowingly and willfully 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 –
>
> (A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Federal health care program, or
>
> (B) 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,
>
> Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

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and the public purse." 123 Cong. Rec. S31767 (daily ed. Sept 30, 1997) (statement of Sen. Talmadge).

42 U.S.C. § 1320a-7b(b).

33. In addition to criminal penalties, a violation of the Anti-Kickback Statute can also subject the perpetrator to exclusion from participation in federal health care programs (42 U.S.C. § 1320a-7(b)(7)), civil monetary penalties of $50,000 per violation (42 U.S.C. § 1320a-7a(a)(7)), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose, 42 U.S.C. § 1320a-7a(a).

34. Concern about improper drug marketing practices prompted the Inspector General of the Department of Health and Human Services the ("HHS OIG") to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the Anti-Kickback Statute. *See* Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 29, 1994).

35. In May 2003, the HHS OIG published further guidance on marketing practices which may constitute kickbacks known as the "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23731 (May 5, 2003) (the "OIG Guidelines"). The Guidelines address, *inter alia*, the conflicts which may arise when a pharmaceutical manufacturer provides educational or research funding to "entities in a position to make or influence referrals." *Id.* As a general rule, educational grants should be made without conditions or restrictions, otherwise the arrangement becomes a forbidden *quid pro quo* relationship:

> Manufacturers should take steps to ensure that neither they, nor their representatives, are using these activities to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence the content of the program.

Id. § II (b)(2).

36. The Anti-Kickback Statute not only prohibits outright bribes and rebate schemes, but also prohibits any payment or other remuneration by a drug company to a physician or other person which has as one of its purposes the inducement of the physician to write prescriptions for the company's pharmaceutical products or the inducement of the physician to influence or recommend the prescribing of the product.

37. Compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under a Government Health Care Program, including Medicare and the state Medicaid programs. Moreover, compliance with the Anti-Kickback Statute is a *condition of payment* for drug claims administered by physicians for which Medicare or Medicaid reimbursement is sought.

38. 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."

39. The Second Circuit has held that, "[s]ince § 1395y(a)(1)(A) expressly prohibits payment if a provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision." *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 701 (2d Cir. 2001).

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

41. Federal law makes clear that violation of the Anti-Kickback Statute can support false claims liability.

B. The False Claims Act

42. The FCA, 31 U.S.C. § 3729(a)(1)(A), makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

43. The FCA, 31 U.S.C. § 3729(a)(1)(B), makes "knowingly" making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

44. The FCA, 31 U.S.C. § 3729(a)(1)(C)), makes any person, who conspires to commit a violation of the FCA, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

45. The FCA defines a "claim" to include any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 U.S.C. § 3729(b)(2).

46. The FCA, 31 U.S.C. § 3729(b)(1) provides that "(1) the terms 'knowing' and 'knowingly' – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii)

acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud."

47. The FCA, 31 U.S.C. § 3729(b)(4) provides that "(4) the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

48. Furthermore, the FCA, 31 U.S.C. § 3730(h), provides relief to employees who have been retaliated against in their employment because of lawful acts done by the employee in furtherance of efforts to stop one or more violations of the FCA. Such retaliation may include discharge, demotion, suspension, threats, harassment or any other type of discrimination in the terms and conditions of employment. The employee is entitled to all relief necessary to make that employee whole, including reinstatement, two times back pay, interest on the back pay, and compensation for any special damages, including litigation costs and reasonable attorney's fees.

C. Group Purchasing Organizations

49. Group purchasing organizations (GPOs) are buying consortiums or associations of hospitals, clinics, doctors, and healthcare organizations that are designed to leverage the aggregate purchasing power of members and thereby increase their ability to negotiate contract terms with various suppliers of drugs, medical devices and other goods and services. GPOs negotiate such acquisitions, but do not typically purchase anything from the suppliers. Once a contract is in place, the member hospitals and healthcare organizations can make purchases under it. *See, e.g.*, Department of Health and Human Services Office of Inspector General ("OIG") Report: "Review of Revenue from Vendors at Three Group Purchasing Organizations and Their Members," (A-05-03-00074) (Jan. 19, 2005).

50. The term "group purchasing organization" is defined at 21 CFR § 203.3 as follows:

> § 203.3 Definitions.
>
> (o) *Group purchasing organization* means any entity established, maintained, and operated for the purchase of prescription drugs for distribution exclusively to its members with such membership consisting solely of hospitals and health care entities bound by written contract with the entity.

GPOs act as agents for their members, but they may be compensated through "administrative" or "service" fees from the vendors or suppliers. These fees are paid by the vendors or suppliers to the GPO in exchange for administrative services and the ability to sell through the GPO to its members. *See* OIG Report, *supra*. Typically, the fees are calculated as a small percentage, generally less than 3%, of the revenue generated under the GPO contract. *Id.*

51. The Anti-Kickback Statute provides certain exemptions (known as "safe harbors") to exclude certain conduct from its ambit, *as long as* the involved parties have complied with all the conditions of the safe harbor. One such safe harbor involves GPO administrative fees.

52. Regulations promulgated by the HHS OIG limit this "safe harbor" by imposing standards for the written agreement between the GPO and its members. *See* 42 C.F.R. § 1001.952(j). A GPO may invoke the "safe harbor" if:

> (1) The GPO's written agreement with each individual or entity purchasing items or services states either (a) that the vendor will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by the vendor; or (b) the specific amount or, if not known, the maximum amount the GPO will be paid by each vendor expressed either as a fixed sum or a fixed percentage of the value of the purchases by the members of the group;

> and
>
> (2) The GPO must disclose to the entities who are health care providers in writing at least annually the amount received from each vendor with respect to purchases made by or on behalf of the entity.

53. Parties to a GPO arrangement cannot obtain safe harbor protection by entering into a contract that complies with the written agreement requirement of a safe harbor and appears, on paper, to meet all of the other safe harbor requirements, but that does not reflect the actual arrangement between the parties. *See generally* 42 C.F.R. § 414.802 (fees must be "bona fide" to be excluded from Average Sales Price calculations).

54. Administrative or service fees charged by GPOs and paid to them by vendors are also material to Medicare's calculation of the ASP at which a covered drug is reimbursed.

55. Beginning on January 1, 2005, Medicare Part B reimbursement for Aranesp in the physician clinic setting was based on a new formula calculated as "average selling price" ("ASP") plus six percent – *i.e.*, ASP + 6%. The regulations governing ASP were promulgated in 2004. *See* 42 C.F.R. § 414.800. In calculating ASP, a manufacturer such as Amgen must deduct "price concessions," but "*bona fide* service fees" (emphasis added) are not considered a concession. *See* 42 C.F.R. § 414.804(a)(2).

> 'Bona fide service fees' means fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

See 42 C.F.R. § 414.802.

56. When a manufacturer submits its ASP-required information to CMS (which it is required to do on a quarterly basis), the manufacturer's CEO, CFO, or Authorizing Official must certify that "the reported Average Sales Prices were calculated accurately and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that the information contained in this submission may be used for Medicare reimbursement purposes." 42 C.F.R. § 414.805 and Form Addendum B.

GOVERNMENT HEALTH INSURANCE PROGRAMS

57. The Health Insurance for the Aged and Disabled Program, popularly known as the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.*, (hereinafter "Medicare"), is a health insurance program administered by the Government of the United States that is funded by taxpayer revenue. Medicare is overseen by the United States Department of Health and Human Services through its Center for Medicare and Medicaid Services ("CMS").

58. Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age, and for certain others that qualify under the terms and conditions of the Medicare Program.

59. Payments made under the Medicare Program include payment for certain prescription drugs used during treatment at an appropriate medical facility and otherwise, as well as certain injectable drugs and drugs used in conjunction with the treatment of patients with cancer and chronic kidney disease.

60. Pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003, effective January 1, 2006, Medicare Part D took effect, extending prescription drug coverage to all Medicare eligible persons who choose to participate in Part D.

61. Reimbursement for Medicare claims is made by the United States through CMS which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS.

62. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services.

63. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to, among others, financially needy individuals that qualify for Medicaid. The States directly pay providers, with the States obtaining the federal share of the payment from accounts which draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994).

64. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMPUS pays for, among other items and services, prescription drugs for its beneficiaries.

65. The federal government, through its Departments of Defense and Veterans Affairs, maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise. In addition, under the Public Health Service Act, the Section 340B Drug Pricing Program, and the Veterans Health Care Act of 1992, the federal government directly or indirectly provides funds to certain other federal agencies and to state and local facilities and programs, including to non-profit disproportionate share hospitals ("DSH"). *See generally* 38 U.S.C. § 8126.

66. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries. (Together these programs described in paragraphs 57-66, and any other government funded healthcare programs, shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs").

67. Reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. The most basic requirement for reimbursement eligibility under Medicare, Medicaid and other Government Health Care Programs is that the service provided must be reasonable and medically necessary. *See*, *e.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396, *et seq.*; 42 C.F.R. § 410.50. Medical providers are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. *See id.*

68. Each of the Government Health Care Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute and with other federal laws governing the provision of health care services in

the United States. That agreement represents an ongoing obligation, and the provider must notify the government of any change in information or certifications provided.

69. In other words, if a provider tells CMS or its agent that it provided goods or services in violation of the Anti-Kickback Statute, that were not medically unnecessary, that were performed solely for the profit of the provider, and/or that violated another relevant law, CMS will not pay the claim.

70. CMS will also not pay a claim relating to reimbursement for goods or services that were not actually provided.

71. Physicians and hospitals enter into Provider Agreements with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which the hospitals and physicians may not seek reimbursement from Federal Health Care Programs, the provider must sign the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Form CMS-855A (for institutional providers); Form CMS-855I (for physicians and non-physician practitioners), (effective 2001). (Attached as Exhibits I & J)

72. The "Certification Statement" that the medical provider must sign also contains the following provisions and requirements *inter alia*, for "initial *and continuous* enrollment in the Medicare program," and instructs that by signing the Certification Statement, the provider "agree[s] to adhere to all of the requirements listed therein." (Emphasis added.)

73. Further, it states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to *meeting and maintaining* the Medicare requirements stated below." (Emphasis added).

74. By signing the "Certification Statement," the provider certifies, *inter alia,* to the following:

> 1. I have read the contents of this application, and the information contained herein is true, correct, and complete. *If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare [program] immediately*.
> . . .
>
> 3. I have read and understand the Penalties for Falsifying Information…I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application *or contained in any communication supplying information to Medicare* …may be punished by criminal, civil or administrative penalties, including but not limited to the denial or revocation of Medicare billing privileges, and/or imposition of fines, civil damages, and/or imprisonment. (Emphasis added).
> . . .
> 8. I *will not knowingly present or cause to be presented a* false or fraudulent claim for payment by Medicare, and *will not* submit claims with deliberate ignorance or reckless disregard of their truth or falsity. (Emphasis added).

75. The certifications made by the medical provider in the Provider Agreement, which are mandatory for Medicare enrollment, expressly create a continuing duty to comply with the conditions of participation in and payment by the Medicare program. In particular:

(a) Prior to signing the Agreement, the provider is advised of the criminal, civil, and administrative penalties "for deliberately furnishing false information in this application *to gain or maintain enrollment* in the Medicare program." Section 14 (emphasis added); and

(b) Among those penalties are criminal sanctions for fraud, concealment and any trick, scheme or device or scheme to defraud, any false or

fraudulent statement or representation or any false writing or document, violations of the FCA, civil penalties for billing for a medical or other item or services that the provider knows or should know was not provided as claimed. *Id.* "Remedies include compensatory and punitive damages, restitution, and recovery of the amount of the unjust profit." *Id.*

76. When a provider submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the Anti-Kickback Statue.

THE RELATOR

77. Relator Kassie Westmoreland is a registered pharmacist with a Bachelor of Science in Pharmacy and Biology and a Master of Business Administration. She currently lives in California.

78. In September 2002, she took a position with Defendant Amgen as a professional sales representative. At the time, Amgen had its sales and marketing staff organized into separate groups focused on specific drugs or "brands" that Amgen produced. One such drug was Aranesp, and when Relator joined Amgen, she was assigned to be a "Professional Sales Representative" ("PSR") in the Aranesp sales group.

79. Amgen's sales and marketing of Aranesp were coordinated and overseen from Amgen's corporate headquarters in Thousand Oaks, California. Amgen employed numerous PSRs like Relator throughout the United States to market Aranesp, and each PSR had his/her own geographical area and/or physician practice area.

80. Relator was Amgen's Aranesp PSR for the State of Oregon and Southwest Washington. In that capacity she called on nephrology (kidney) practices, hospitals, long term care facilities, and multi-specialty clinics. In her territory, there was another PSR who only called on dialysis centers, and four other Amgen PSRs who marketed Aranesp to oncology practices in the territory as well as a Hospital System Manager who called on nephrology and oncology customers, at teaching institutions including Oregon Health and Science University, and the Portland Veterans Administration Hospital.

81. Although Relator lived in Oregon at that time, she nevertheless had extensive contacts with other Aranesp PSRs from around the country through training seminars and Aranesp sales staff meetings, which included quarterly, semi-annual, and annual meetings. She also had weekly phone contact with other district PSRs and district managers as well as other PSRs around the country. Relator also had extensive contacts with upper-level Aranesp sales managers and directors through these seminars and staff meetings, as well as countless telephone conferences and e-mails.

82. Relator worked as an Aranesp PSR from approximately September 2002 to March 2004. She witnessed firsthand and heard about promotion of "overfill" by Defendant Amgen and medical providers billing for Aranesp "overfill." Defendant Amgen's promotion of "overfill" and billing for "overfill" is discussed more fully below.

83. In March 2004, Relator left the Aranesp sales force and took a promotion to be a product manager for Aranesp in Amgen's home office in Thousand Oaks, California. As a Product Manager for Aranesp, Relator focused more broadly on marketing and advertising of the drug, as opposed to direct sales.

84. As part of Relator's new position in Amgen's marketing department, Relator was assigned responsibility for managing Amgen's relationship with Defendant INN, which Relator had been informed was an independent entity (and qualified as a GPO) that focused on nephrology practices and physicians. Defendant Amgen's relationship with Defendants INN and its related entity ASD Healthcare is discussed more fully below.

85. As detailed below, while in the employ of Defendant Amgen, Relator personally observed Defendants' unlawful practices, and participated in and was privy to meetings, conversations, and other internal communications, including at the management and headquarters levels of the company. Among other things, in the regular course of her employment, Relator had access to e-mail and internal documents and data which describe, document, and reflect the conduct discussed herein. Relator also had many interactions with managers, employees, sales representatives, physicians, hospital representatives, and other third parties relating to Defendants' business practices on a national level.

ANEMIA PRODUCTS MANUFACTURED BY AMGEN

86. Defendant Amgen manufactures three anemia products, as detailed herein: Aranesp; Procrit; and Epogen.

A. Aranesp (Darbepoetin Alfa)

87. Aranesp (darbepoetin alfa) is an injectable prescription drug developed and manufactured by Defendant Amgen that is indicated to treat certain forms of anemia, namely those associated with chronic kidney disease and chemotherapy induced anemia in the treatment of certain nephrology and oncology patients. Patients with kidney disease and/or cancer often have decreased levels of red blood cells, which are essential to transporting oxygen throughout

the body. The absence and/or decreased levels of red blood cells can cause anemia in such patients.

88. Aranesp is an erythropoeisis-stimulating agent (ESA) that purportedly stimulates or boosts the production of red blood cells, with the goal of lowering the risk of anemia.

89. Treatment of anemia is a vital and integral part of the medical care of nephrology and cancer patients, given that anemia can undermine the efficacy of a medical treatment plan, and/or it can lead to severe health consequences for the patient, including death.

90. Aranesp was to be prescribed to increase red blood cell counts, specifically to increase hemoglobin levels, so as to avoid the need for blood transfusions in patients experiencing kidney failure or chemotherapy induced anemia.

91. 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 (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.

92. Safety and efficacy have *not* been established in other conditions and Aranesp is not approved for other uses, or in dosages different from those approved in the label. The dosage of Aranesp varies somewhat according to the patient's weight and condition, but a typical dosage would be 25-40 mcg for a weekly injection, or 60 mcg for an injection every two weeks for pre-dialysis patients.

93. Pharmacists submit claims for Aranesp using the several National Drug Code ("NDC") numbers for Aranesp depending on the dosage; these NDCs are attached in Exhibit A**.** Medical providers who administer Aranesp on an outpatient basis use procedure codes shown on Exhibit A.

94. Since its introduction to the prescription drug marketplace in 2001, United States sales of Aranesp have been substantial. According to Amgen's public filings, aggregate (2001-2008) United States revenues for Aranesp have totaled over $*11 billion* during those years.

95. Moreover, since the drug was first introduced, Aranesp sales in the United States have increased steadily and dramatically year-after-year until the FDA began issuing black box warnings in 2007: from $27 million in its first year, 2001; to $285 million in 2002; to $980 million in 2003; to $1.533 billion in 2004; to $2.104 billion in 2005; to $2.79 billion in 2006; to $2.154 billion in 2007; and $1.65 billion through 2008.

96. Of these revenues, approximately $6 billion is from Government Health Care Programs: over $372 million from Medicaid and at least $5.6 billion from Medicare and other Government Health Insurance Programs.

97. Relator was employed at Amgen during the period of tremendous revenue growth for Aranesp (2002-2006 and before the first black box warning was issued).

98. On or about March 9, 2007, the FDA issued a black box warning for Aranesp, the most serious warning available for a drug's label, warning of increased risk for death, of serious cardiovascular or thromboembolic events, and more rapid tumor progressions. The new warning 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. The black box warning described the results of six clinical studies which demonstrated that survival was shorter and tumors progressed faster when used to achieve hemoglobin levels of 12 grams per deciliter ("g/dL") of blood or greater in cancer patients.

99. On or about November 8, 2007, the FDA approved revisions to prior black box warnings, which expanded the labeling changes made in March 2007, to provide specific dosing

information. The revised black box warning stated that dosing should be individualized to "achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL." For kidney patients, the revised warning read that: "patients experienced greater risks for death and serious cardiovascular events when administered ESAs to target higher versus lower hemoglobin levels." For cancer patients, the new warnings emphasized that Aranesp could cause tumor growth and shorten survival among patients with advanced breast, head and neck lymphoid tumors, and non-small cell lung tumors.

100. On or about March 7, 2008, the FDA mandated new black box warnings for Aranesp relating to two clinical studies that concluded there was increased risk of death and faster tumor growth when administered to target a hemoglobin level of 12 g/dL in cancer patients not receiving chemotherapy or radiation therapy. This revised black box warning clarified that Aranesp should only be used in cancer patients with anemia specifically caused by chemotherapy, not for other causes of anemia. Amgen also issued a "Dear Healthcare Provider Letter" to medical providers advising of the revised Aranesp labeling. The Aranesp label, as approved by the FDA on or about November 19, 2008, is attached as Exhibit B.

101. As of February 6, 2010, the FDA approved a Risk Evaluation and Mitigation Strategy ("REMS") for Aranesp. The FDA required Amgen to develop a risk management program because studies have shown that 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, including patients with chronic kidney failure. Aranesp's REMS requires Amgen to provide a Medication Guide explaining the risks and benefits of Aranesp to all patients receiving Aranesp. Amgen is also required to develop and publicize a program for healthcare professionals who prescribe ESAs like Aranesp to patients with cancer,

called ESA APPRISE. Amgen must ensure that only providers who have completed this program can prescribe or dispense ESAs to patients with cancer.

B. Procrit and Epogen (Epoetin Alfa)

102. Prior to becoming the Fortune 500 company that it currently is, Amgen was a fledgling biotech company struggling to finance the development of its drugs. One such drug under development was "epoetin alfa" ("EPO") – an ESA drug that would treat anemia in certain patients by stimulating the production of red blood cells.

103. In 1985, Amgen contracted with a subsidiary of Johnson & Johnson, Ortho Pharmaceutical Corporation ("J&J" or "Ortho") for financial and technical assistance in completing the development of, and FDA approval for, EPO. Among other things, Amgen and J&J agreed that Amgen would have exclusive rights to market EPO in the United States for use with dialysis patients; and J&J would have exclusive rights to market EPO for all other uses in the United States, including non-dialysis kidney patients. J&J also would have exclusive rights to market EPO outside of the United States (excepting China and Japan) for all uses. Amgen would market EPO under the name "Epogen," and J&J would market EPO under the name "Procrit." (J&J markets EPO under the name Procrit in the United States; but J&J markets EPO under different names internationally.)

104. When Amgen made its deal with J&J, EPO was primarily used to treat anemia in dialysis patients, which under the agreement would be Amgen's market. Thereafter, EPO was approved for many other uses, however, including the treatment of anemia suffered by cancer patients.

105. This oncology market for EPO was (and is) substantial indeed, but under the agreement this market belonged to J&J, selling EPO as the cancer drug Procrit. Moreover, when

EPO was used outside of dialysis (*e.g.*, in a patient with chronic kidney disease who was not yet on dialysis), Amgen owed J&J a royalty of between 5-10%.

106. Given this lucrative (but contractually barred) oncology anemia market, Amgen developed Aranesp, which was approved in 2001, as a new anemia drug that Amgen could market for use with oncology patients and non-dialysis kidney patients, without violating its agreement with J&J.

107. Since then, Amgen has aggressively and successfully marketed Aranesp as an alternative to Procrit, in an effort to increase sales and market share of Aranesp and to recapture the lost Procrit market.

108. Amgen also has marketed Aranesp as an alternative to its own drug Epogen, which as of 2003 was Amgen's best-selling drug with gross sales totaling $2.4 billion.

109. Amgen's cannibalization of its own Epogen sales laid the groundwork for Amgen to replace Epogen with Aranesp in anticipation of patent expiration issues and reimbursement changes that could make Aranesp more profitable for Amgen than Epogen.

110. Amgen, through its subsidiary Amgen Manufacturing, Limited (also previously known as Amgen Puerto Rico or "APR") manufactures Epogen and Procrit, as well as Aranesp. Amgen is responsible for the labeling of Aranesp and the other drugs it manufactures.

111. The FDA's black box warnings and 2010 guidance regarding Aranesp, referred to *supra*, also applied to Epogen and Procrit.

AMGEN'S NATIONAL FRAUD SCHEME TO OFFER OVERFILL IN ARANESP AS AN INDUCEMENT

A. The Use and Dosing of Aranesp

112. Aranesp is distributed by Amgen in single dose vials and single dose pre-filled syringes ("PFS") containing liquid solution with a predetermined concentration of the drug.

113. Vials may be used for administration of Aranesp by medical professionals while PFS packaging could be used by some medical professionals in their offices or by patients to administer their own medication on an outpatient basis.

114. Not all patients require the same level (strength) of Aranesp solution. For example, oncology patients typically require a higher dose of Aranesp than do nephrology patients. In order to accommodate the different clinical uses for Aranesp, Amgen distributes the drug in vials or syringes that contain different amounts of the drug – *e.g.*, 25 mcg (micrograms), 40 mcg, 60 mcg, 100 mcg, 150 mcg, 200 mcg, 300 mcg, or 500 mcg.

115. For each patient, the volume of liquid solution of Aranesp to be administered to the patient is roughly the same – usually 1.0 ml (milliliter) for the vials or 0.3-0.6 ml for the PFS packaging – but the amount of Aranesp administered to the patient (*i.e.*, the total micrograms of medicine) varies depending on the drug concentration within that liquid.

B. Aranesp Overfill

116. Although single-dose vials of Aranesp contemplate that a 1.0 ml injection will be administered to the patient, the actual volume of liquid solution in the vial *exceeds* 1.0 ml. This excess is known as "overfill."

117. According to the United States Pharmacopeia (the "USP"), injectable drug vials may include a "slight excess" beyond the label volume in order to permit withdrawal and administration of the labeled volume.

118. For the entire time that Aranesp has been on the market the USP has recommended overfill *up to* 10%. Thus, for a labeled fill volume of 1 ml, the USP contemplates overfill of no more than 0.1 for a total volume of 1.1 ml.

119. Although the USP statement is styled as a recommendation, overfill should be limited to the minimum amount necessary to obtain the prescribed dose of a drug to avoid, for example, overdosing patients. Overfill should not be administered to a patient, and doing so would result in misdosing.

120. As Amgen Northeast Regional Sales Director Mark Papineau explained in deposition testimony, "Overfill is the contents in the vial … that go above and beyond what is on the label that is the normal process for biologics in order for the average person to be able to get out whatever is on the label."

121. The overfill amounts contained in Amgen's ESA products, Aranesp and Epoetin Alfa (Epogen and Procrit), and the changes to the Epoetin Alfa overfill amounts, were issues of importance at the highest level within Amgen. By example, an e-mail dated January 6, 2006 from Edwin Mar, Senior Manager of Medical Information, to Helen Torley, Vice President and General Manager of Nephrology, and Leslie Mirani, Vice President of Sales, states: "In regards to your request to provide EPOGEN overfill historical information to [CEO] Kevin Sharer, these are the information I have available so far regarding EPOGEN 1.0 mL vial fill volumes."

122. The e-mail goes on to provide the overfill amounts for Epogen from 1993 through January 2006 as follows: (1993-Q4/2002) – 1.168 mL; (Q4/2002-Q1/2004) – 1.144 mL; and (Q1/2004 – present) – 1.111 mL.

123. Thus, when Aranesp was first introduced into the market, Epogen vials manufactured by Amgen contained 16.8% overfill, which was then reduced in 2002 to 14.4% overfill, then by 2004 to 11.1% overfill.

124. In 1999, Amgen set the initial overfill amount for Aranesp packaging at 16.8%, then soon increased the amount of Aranesp overfill to 17.7%.

125. The level of Aranesp overfill was a matter of concern to Amgen compliance and manufacturing employees. As Amgen's current Director of Regulatory Affairs, Cheryl Anderson, explained in an August 2000 e-mail to colleagues: "Considering that the EPO 1mL vial overfill = 0.168 +/- 0.04 and the USP recommendation is an overfill of 0.10 and the fact that one of our EPO distributors is being sued for double billing Medicare because of the ability to pool the EPO overfill and FDA required us to issue a Dear Doctor letter just 2/3 months ago warning users not to pool the EPO overfill, why are we proposing to increase the [ARA]NESP overfill even more than EPO?"

126. In fact, manufacturing and compliance personnel within Amgen recommended an almost immediate reduction of Aranesp overfill, shortly after Amgen began marketing Aranesp.

127. Similarly, in 2001, manufacturing personnel at Amgen recommended that the overfill in all products manufactured at Amgen Puerto Rico, including Epogen vials, be reduced from 16.8% to 10%.

128. Despite the concerns expressed about having too much overfill in Aranesp, for the launch of single use vials, the amount of overfill in Aranesp vials was *increased* above 16.8% and 17.7%.

129. According to an Amgen PowerPoint presentation, entitled "Update to Executive Committee," overfill in Aranesp vials was increased to 19% to assure success for launch of the Aranesp product in 2001. (The PowerPoint presentation also recommended decreasing the Aranesp overfill back to 16.8% in 2002, citing regulatory and manufacturing reasons, as well as a Department of Justice investigation into the overfilling of Epogen vials. The same document noted that reductions in overfill volume could have customer and reimbursement implications.).

130. As a result, at the launch of the Aranesp vial marketing campaign in 2001, Aranesp vials contained 90% more overfill than the 10% maximum overfill recommended by the USP.

131. Amgen did not advise the FDA of the increase in overfill in Aranesp vials to 19%, despite the fact that the increase was inconsistent with the Biologic License Application Amgen had obtained for Aranesp.

132. By comparison to the 19% overfill in Aranesp, PFS packaging of Aranesp contained considerably less overfill that was less than the USP 10% guideline.

133. By further comparison, although Amgen pegged the Aranesp overfill to Epogen overfill when it first manufactured Aranesp, by 2002, Amgen reduced Epogen overfill from 16.8% to 14.4%. By 2004, Amgen had reduced Epogen overfill to 11.1%.

134. Amgen made no corresponding reductions in Aranesp overfill despite the recommendation of the Amgen Global Operations Team that, as of April 11, 2002, fill volumes for Aranesp could "be reduced from 1.168 ml to the USP-recommended 1.10 ml" based on a three-year plan that would have ended with Aranesp overfill reduced to 10% in 2004.

135. Some time after the launch, Amgen resumed manufacturing Aranesp vials with 16.8% (or in some cases 17.7%) overfill, but Amgen never implemented the anticipated further reductions in Aranesp overfill, despite continuing concern within Amgen that Aranesp vials contained unnecessarily excessive overfill.

136. As of April 2005, the project to reduce Aranesp overfill was on hold pending an assessment to determine whether Aranesp overfill should be reduced "from a marketing standpoint."

137. Again, for example, in 2008, an internal company recommendation was made to decrease the overfill amounts contained in Aranesp vials. An Amgen PowerPoint presentation dated April 3, 2008, entitled "Overfill Reduction: Aranesp 1.0mL vials" recommends that the overfill amounts contained in Aranesp vials be decreased in two phases in order to reduce overfill amounts from 16.8% to 13%.

138. In the end the "marketing standpoint" won out over concerns of patient safety and compliance and manufacturing protocols. Amgen did not reduce the level of Aranesp overfill. Instead, Amgen maintained the level of Aranesp overfill so that Defendants could market the overfill, because the overfill was a necessary component of Aranesp's profitability versus the competing product Procrit (which Amgen also manufactured and for which Amgen held overfill to a lower amount).

C. The Economics of Overfill

139. Amgen's failure to reduce Aranesp overfill was part of Defendants' scheme to increase sales of Aranesp, Amgen's share of the EPO market, and INN's profits, by offering the Aranesp overfill as an economic incentive to medical providers, in violation of the law, including the Anti-Kickback Statute and the Federal FCA.

140. Aranesp overfill has value because Aranesp purchasers are charged for the drug based upon the *labeled* concentration and dosage. Overfill is not reflected on the label and purchasers are *not* charged for the overfill that they receive – *i.e.*, they do not pay for the extra micrograms of drug that are present in the overfill.

141. For example, if a physician buys a 1.0 ml single-dose vial containing a 60-mcg concentration of Aranesp, then the physician only pays Amgen (or ASD Healthcare or another drug provider) for 60 mcg worth of the drug. The physician does not pay for the additional 10.08

mcg of Aranesp present in the 0.168 ml of overfill for that particular 60-mcg vial. Likewise, a physician purchasing a 300-mcg vial of Aranesp would not pay for the extra 50.4 mcg of drug in the overfill for that vial.

142. Not charging for the overfill is consistent with the intended purpose of overfill, which is to ensure that the labeled dose of the medication can be administered. Overfill itself is not intended to be administered.

143. The amount of drug product in a vial of injectable drugs manufactured by Amgen (such as Aranesp) should include the labeled volume, plus the amount required because of drug product that may not be drawn out due to the functioning of the needle or the vial (which is sometimes referred to as "hold up volume" or "HUV").

144. When single use injectable drug vials are filled properly in such a manner, there typically should be little or no overfill that can be extracted from the vial, because the fill volume of the vial will consist of the labeled dosage and some additional liquid that is expected to stick (or be "held up") in the needle or the vial.

145. However, under Defendants' unlawful marketing scheme, Aranesp vials as manufactured by Amgen contained more overfill than was required to provide the labeled dose and HUV, so that Defendants were able to use the overfill to induce medical providers to submit claims to Government Health Care Programs for the free Aranesp overfill.

146. Defendants' efforts to induce the filing of claims relating to Aranesp overfill were successful. Medical providers submitted claims to Medicare and other Government Healthcare Programs to obtain money for the Aranesp overfill (despite the fact that the overfill had not cost the providers anything), often based on standing orders or protocols to submit overfill claims with respect to every patient, with no basis in medical necessity.

147. Amgen in fact knew that it was improper for medical providers to file such claims. Among other things, Amgen's own reimbursement consultant, a company called Covance, made clear to Amgen personnel in 2004 that medical providers could not bill for overfill:

> Fundamentally, overfill is not purchased product and should not be billed. If one argued that it was purchased, then the logic would be that payers' payment per unit would need to be readjusted to account for all the product in a vial, not what the vial's labeled amount is. . . . As for the purchaser's POV [point-of-view], I can see their wanting to bill for all product the[y] 'received,' but in fact they are only to bill for what they 'purchased.' Billing for non-purchased amount is the same as billing for samples. They did not incur the cost of these extra units, and therefore cannot bill for them. Your price is for the amount of the vial as labeled. According to Medicare regs, when they buy a 100 mcg vial of Aranesp, they purchased 100 mcgs, and they can only bill for the mcgs they purchased according to the package label, not what the vial might have contained beyond that.

148. Moreover, beginning in 2005, certain Government Health Care Programs including Medicare based the amount they would reimburse for drugs (such as Aranesp) on average sales price ("ASP") data to be reported by drug manufacturers (such as Amgen). Although Amgen knew that the Aranesp overfill materially affected medical providers' cost for Aranesp (such that the providers were, in essence paying less for Aranesp) Amgen did not include or account for the overfill in the Aranesp ASP pricing information it certified to Medicare.

149. In many cases, as well, Defendants' promotion of the filing of Medicare and other claims relating to Aranesp overfill involved efforts to induce medical providers to seek reimbursement for the maximum overfill expected to be in each Aranesp vial when, in fact, it would not have been possible for that much overfill to be withdrawn from every vial, based on

Amgen's own "tests" and other "justifications" for why an overfill level above the USP recommendation was appropriate for Aranesp single use vials.

150. Amgen knew, as well, from data received from customers and other sources that medical providers could not extract and administer all of the Aranesp overfill from each vial, yet Defendants encouraged medical providers to submit claims based on across-the-board billing for all (or virtually all) the Aranesp overfill, even though it was not possible that the medical providers actually administered those "doses" to patients, which would have been medically unnecessary in any event.

151. Thus, Defendants not only induced medical providers to submit claims for Aranesp overfill despite knowledge that Government Health Care Programs should not be charged as if the medical providers had paid for the overfill, they also induced and assisted medical providers in filing claims that were not based in medical necessity, as well as claims for Aranesp that was not actually administered.

152. Moreover, by failing to consider the Aranesp overfill that Defendants marketed to medical providers as part of its ASP computations, Amgen fraudulently certified to Medicare an ASP that was too high and by so doing, assured that the reimbursement amount paid by Government Health Care Programs such as Medicare would be fraudulently overstated for every submitted Aranesp claim.

153. A motive for Amgen to commit this misconduct was the "economics" of Aranesp versus Procrit, which demonstrate that Aranesp could be more costly to purchasers unless it was assumed that the purchasers would bill Medicare for all of the Aranesp overfill.

154. For example, the customer "economics" spreadsheet created by an Amgen employee attached as Exhibit H demonstrates that Procrit is more profitable for the medical

provider than Aranesp unless and until overfill is considered and it is assumed that Medicare claims will be submitted for all of the stated overfill.

155. The spreadsheet also demonstrates that Amgen's own projections indicated that Aranesp could be more expensive to Medicare than Procrit was unless reimbursements for overfill amounts were included.

D. Unlawful Promotion of and Billing for Aranesp "Overfill"

156. Medicare provides reimbursement for Aranesp based on the number of micrograms of Aranesp that were actually administered to the patient. The reimbursement amount was based on 5-microgram units when Aranesp single unit vials were first sold (from 2001 to the beginning of 2004) and based on 1-microgram units thereafter.

157. In unusual circumstances, such as when a dose consisting of part of an Aranesp vial might be delivered, Medicare regulations regarding unusable product that is considered necessary "waste" can permit a medical provider to submit a claim for reimbursement of up to the *labeled* amount on the vial, but that claim would not be allowed to include a request for reimbursement relating to the overfill.

158. Defendants have conspired with each other, and with providers and others to defraud both governmental (federal and state) and private health insurance programs by encouraging Aranesp purchasers to seek reimbursement for the additional micrograms of Aranesp contained in the overfill. This overbilling is improper for a number of reasons, including:

(a) the Aranesp purchasers did not actually pay for the overfill micrograms of drug;

(b) the Aranesp purchasers often do not administer the "overfill micrograms" of drug to their patients because to do so would be unreasonable and medically unnecessary, but they nevertheless bill for it;

(c) when the overfill has been administered, it is often unreasonable and medically unnecessary and posed a danger to patient health and safety, as is confirmed by the black box warnings and other studies referenced in this Complaint;

(d) the Aranesp purchasers have submitted claims for Aranesp overfill in excess of what they realistically could have drawn from the vials and administered; and

(e) some providers would pool the overfill from several vials of Aranesp until there was sufficient volume from the overfill to constitute a separate dose. The providers would then bill for the additional dose without disclosing that they had, in essence, obtained the dose for free.

159. Around the launch of Aranesp, in May 2001, Amgen commissioned an "Epogen Vial Study," that concluded that anemia managers and renal administrators at freestanding dialysis clinics were accustomed to recovering costs for some of the overfill from multi-use vials of Epogen (approximately 5% to 18%) in order to increase their centers' profits.

160. Consistent with the results of Amgen's study of what purchasers used to Epogen multiuse vials might want, Defendants sold Aranesp single use vials based on economic analyses for Aranesp purchases including "overfill discounts" or "overfill credits" that were used throughout the United States by the Amgen sales force to calculate potential profits for medical providers from putting their patients on Aranesp.

161. For example, an Amgen document entitled "WAP to AWP Pricing," which was authored by a sales representative based in Tennessee, contains an Aranesp and Procrit cost and revenue comparison and reflects a line item for "Overfill at 10%" credit for Aranesp purchases of 100 mcg vials. The analysis calculates a medical provider's potential profit in purchasing Aranesp based on Medicare reimbursement rates, and includes a dollar credit for "Overfill at 10%." This credit values 10% of overfill in a 100 mcg vial at $47.39. This economic worksheet was electronically mailed on September 16, 2003 to Amgen sales representatives located in Louisiana, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Tennessee, Vermont and the District of Columbia.

162. Amgen sales representatives, corporate account managers, district sales managers, and regional sales directors individualized these economic revenue models for specific physician practices or hospital accounts where that Amgen employee was marketing Aranesp. Further examples of economic analyses that included the overfill inducements that were distributed or used nationally include the following:

(a) An economic cost and revenue analysis completed for Balboa Nephrology Medical Group, a nephrology group with 13 clinical offices in San Diego, California, reflects a 16.8% overfill – all units credit versus a 11.1% overfill credit for Procrit;

(b) An e-mail dated February 7, 2005 to Amgen Northeast Regional Sales Director Mark Papineau from a New York City-based sales representative attaching a "clinic spreadsheet tool" comparing Aranesp to Procrit costs and reimbursements. The spreadsheet compares reimbursements for the Aranesp vials at 10% overfill and at 15% overfill against Procrit, as explained in Joe

Campagnuolo's cover e-mail. Within three days, Northeast Regional Sales Director Mark Papineau electronically forwarded this clinic reimbursement spreadsheet tool to the entire Northeast Management Team with the admonition: "This is truly an FYI. DO NOT SHARE WITH CUSTOMERS;"

(c) A "Neu Ara Plus" Aranesp contract analysis for St. Luke's Hospital in New York, New York, that reflects an overfill credit for Aranesp purchases; and

(d) An e-mail dated August 2, 2005 from an Oklahoma-based sales representative to a District Sales Manager referencing conversations – at a couple of hospitals – that there is more overfill with the Aranesp vial, while there is no overfill with the "Singleject [Aranesp PFS syringe]… 3 mcgs for free for Aranesp and they can bill for it."

164. During the time that Relator was employed by Amgen, she learned that Amgen PSRs would advocate to customers the increased profits that could be made if the customers were to seek reimbursement for the "overfill micrograms" of Aranesp in the single-dose vials that they had purchased.

165. The Relator has spreadsheets from her employment with Amgen that are examples of how the overfill was calculated and advocated by representatives and management. One example is attached as Exhibit E (showing, among other things, that Amgen encouraged medical providers to submit claims that would have resulted in billing Medicare for 99.2% of the overfill contained in 60mcg, 150mcg, and 300mcg vials of Aranesp). This spreadsheet includes computations of "Practice Cost Revenue Model," including assessment of revenues that medical providers could realize from Aranesp overfill. *See, e.g., id.* at 2 (displaying boxes for Procrit and

Aranesp units, AWP, and AWP + Overfill); *id.* at 3 (presenting tabular computations of "Aranesp Vs. Procrit and Overfill").

166. As another example, a spreadsheet called "2006 Comprehensive Reimbursement Worksheet" was sent from Amgen employee Tiffany Gaetano to Amgen District Manager Louis Deppe on January 21, 2006. In the cover e-mail, Ms. Gaetano explained that she had updated the spreadsheet so that one worksheet would "automatically include overfill in the calculations" as different vial sizes of Aranesp and Procrit were entered because many Aranesp sales representatives have customers who "utilize overfill." The concept behind the spreadsheet was that any Aranesp sales representative could compute the "Net Total Cost Recovery" in dollars of various dosings of Aranesp versus Procrit, simply by changing the "monthly dose" shown for each drug. Further, to compute the "Total Annual Impact" on the customer's office, the Amgen sales representative could also input a personalized number for the "total patients being treated."

167. The spreadsheet itself includes two worksheets labeled "ASP training" and "ASP training (with overfill)." Both worksheets include the reimbursement amount for Aranesp based on ASP+6% per mcg, with the key difference being that the first worksheet shows the amount $2.989 per mcg, while the second worksheet takes that amount and *multiplies* it by 1.168 to come up with a reimbursement amount of $3.491 per mcg. *See* Exhibits C ("ASP training") and D ("ASP training (with overfill)").

168. To further illustrate this concept, the spreadsheets have been printed to show the formulas underlying each cell. In the first worksheet, the cell for "ASP+6% per mcg/unit" (C13) contains the value "2.989." In the second worksheet, the same cell (C13) contains the value "1.168*2.989." Similar adjustments are made in the next cell (D13) to reflect Procrit overfill of

11.1%. *See* Exhibits F ("ASP training" – cell view) and G ("ASP training (with overfill)" – cell view).

169. As the worksheets indicate, Aranesp was less profitable for customers *unless* the Aranesp overfill was taken into account. *See* Exhibits C and D. If the customer stayed with Procrit (without overfill), based on the amounts Ms. Gaetano put in her spreadsheet, the "annual impact" – *i.e.*, profit – on dosing 50 patients with 40 units monthly would be about $15,000 (compared to about $7,300 for Aranesp). With overfill, the profits rise dramatically, to almost $39,000 per year using Procrit and *more than $43,000 per year* for Aranesp – with almost all of the difference coming from increased Medicare reimbursements based on the overfill.

170. Although the spreadsheet says "For internal Amgen Educational Purposes Only, Not for use with customers," such admonitions to keep projections relating to the "economics" of Aranesp versus Procrit, including overfill, internal were not followed by Defendants.

171. And, although Amgen's own position is that it would not be possible to withdraw all 16.8% of the overfill in any Aranesp vial (including that, according to Amgen, the reason so much overfill is required in Aranesp vials is because the overfill is not accessible), the economic projection information used with Aranesp customers modeled the profit that customers would achieve from submission of Medicare claims for all of the overfill, thereby encouraging and instructing customers to submit such fraudulent claims.

172. This spreadsheet also illustrates that Amgen did not consider overfill in providing certified ASP computations to The Centers for Medicare & Medicaid Services ("CMS") regarding Aranesp. It was created in January 2006. The "ASP training" worksheet reflects a Medicare reimbursement rate of ASP + 6% that is equal to $2.989 per Aranesp mcg (which is

increased by an additional 16.8% on the "ASP training (with overfill)" spreadsheet to reflect the value of the Aranesp overfill that Amgen gives to medical providers).

173. Spreadsheets such as the ones included as exhibits to this Complaint were created in order to sell Aranesp – and they were used by Amgen and INN representatives in selling Aranesp to customers in meetings set up to discuss "economics" or to "talk about the numbers," or to "convert" accounts.

174. Sometimes, an INN representative presented the "economics" of Aranesp (including overfill) to customers to make it appear as if Amgen was not participating in such discussions. Other times, Amgen representatives conducted or participated in the discussions. In either case, all Defendants knew what was occurring.

175. In addition, the presentation of the "economics" spreadsheets to customers was to take place using a laptop or was to be written on a napkin or paper that was not left behind, so that the customer could view the information, but the information would not remain in the customer's records. On occasion, however, customer requests for the model to be provided were honored by Defendants.

176. Relator also is aware of other PSRs and INN and IPN employees discussing with customers/providers how to fill out the Form CMS 1500 claim form (attached as Exhibit K) – they told the customer to simply write down for the dose they purportedly "administered" an amount that would include the overfill, on the Form CMS 1500 claim form, even if they did not actually administer the overfill amount. These instructions were intended so that the medical provider "could pass an audit" by Medicare.

177. Indeed, the standard materials available to Amgen sales representatives included "mock-ups" of Form 1500 Medicare claim forms so that they could assist with even the claims filing and "walk the claim through" the reimbursement process for the customer.

178. Although Relator never engaged in the practice of promoting "overfill" billing, she had numerous communications with other PSRs from around the country confirming that the practice existed and that other Amgen sales representatives engaged in the practice, and she personally observed it when she called on the multispecialty clinic, Bend Memorial Clinic, as well as major hospital systems in her territory with the oncology sales representatives.

179. For example, Chris Coates of Amgen reported to Relator that Balboa Nephrology of San Diego, California, had resolved to capture overfill. Between March and August 2004, Balboa Nephrology, 65% of whose patients used Medicare as their primary insurance, spent almost $700,000 on Aranesp.

180. Moreover, Relator is aware that other Aranesp customers did, in fact, engage in "overfill billing."

181. Furthermore, upper management of Amgen – including the National Sales Director ("NSD") and the Director of Marketing – were aware of the practice of advocating "overfill billing" to customers and did nothing to prevent it. Indeed, the Regional Sales Director (who reports to the NSD) authored spreadsheets that included overfill computations. Relator also witnessed conversations in meetings regarding overfill involving the NSD and Director of Marketing (among other management).

182. Amgen PSRs would often complain about overfill because they said J&J was actively marketing Procrit with promotional materials that advertised the use of overfill and the Amgen representatives wanted some similar materials to market Aranesp overfill.

183. The response of Amgen management was to say that Amgen could not come out with official company materials on overfill marketing but, instead, the PSRs could talk about how medical providers could bill for Aranesp overfill in private with customers and could let INN representatives discuss the "economics" of Aranesp, including billing for overfill, with customers.

184. Nevertheless, in order to have some materials to present to customers, some Aranesp sales representatives, district managers, and regional sales directors prepared detailed spreadsheets (ostensibly labeled "For Information Only") that expressly calculated the additional (and significant) revenue/profit that could be made by customers if they sought reimbursement for the "overfill micrograms" of Aranesp. They showed these spreadsheets to their customers during their office visits to market Aranesp – and, in particular, to market the greater profits that could be made on Aranesp as compared to the competing drug Procrit if reimbursement were sought for Aranesp "overfill."

185. Amgen's own *internal* spreadsheets also show that overfill had direct cash value in terms of the amount of reimbursement that a physician could receive. They compare "Aranesp" Medicare Allowable with a higher "Aranesp with Overfill" Medicare Allowable.

186. An INN nephrology "backgrounder" advises—under the heading "Over Flow Usage in Aranesp Vials"—that "You could also give the full 116 mcg (instead of 100mcg) bill and be reimbursed for the entire 116mcg."

187. One clinician who spoke with Amy Oliver, an Amgen Oncology Account Manager, asked if Aranesp contained Overfill "because 'that's how we make money.'"

188. Angela Miele, an INN account representative who used to work for Amgen wrote that a physician told her that the physician's rebate was higher for another drug because she was

"adding in the overfill," and then wrote "I take that out of my original analysis [when marketing Aranesp] to level the playing field [in comparison to other drugs]. Then you can speak to the fact that Ara has 16% overfill afterwards." Miele also wrote to a physician that "Providing Aranesp to your CKD patients could help pay for the private school."

189. To demonstrate the potential profitability of Aranesp "overfill" billing, the "overfill spreadsheets" typically would compare the reimbursement amounts and spreads for Aranesp + overfill to the reimbursement amounts and spreads for Procrit + overfill.

190. Amgen management not only saw but, in some cases, authored these spreadsheets, and did nothing to prevent the Amgen sales force from using them with their Aranesp accounts.

191. In fact, although the company's official "line" was that overfill – and comparative economics – were not to be discussed by Amgen personnel, Amgen sales representatives knew that they could ask to receive the "overfill spreadsheets" or similar information if they thought it could help sell Aranesp to an account. For example, on July 7, 2004, Amgen San Francisco District Sales Manager Jeremy Jaggi wrote an e-mail to Mark Bachleda (Amgen Senior Marketing Manager), copying Ray Chow, Claes Hornstrand, and Alex Lyons, entitled "Procrit Overfill Economics," which said:

> Numerous reports are coming in recently regarding the promotion of Procrit overfill and a 5% benefit over Aranesp. . . . Do you have a spreadsheet analyzing head to head dosing with the overfill for my background?

192. Amgen (and the other Defendants, as discussed below) knew they could influence the purchaser's choice of drug by using the "overfill" profit contained in each vial of Aranesp

compared to that for Procrit or Epogen. Amgen also knew it could manipulate the "overfill" economics because Amgen manufactured all three drugs.

193. This practice of advocating "overfill billing" to Amgen's customers constituted a form of free drug sample or "liquid kickback" in every vial. Yet, unlike traditional free drug samples which are heavily regulated – *i.e.*, they must be carefully accounted for by drug companies and cannot be the basis for governmental reimbursement – the free amounts of overfill found in every Aranesp vial were provided by Amgen without any such reporting requirements. When Amgen advocated, and conspired with other Defendants and their customers, to engage in "overfill billing," however, the unlawful effect was no different than it would have been had Amgen provided its customers with free Aranesp samples and then encouraged them to seek reimbursement for them from Government Health Care Programs.

194. Amgen's intention to exploit "overfill billing" as a means of gaining new customers and market share is further evidenced by the unusually large quantity of overfill found in the Aranesp vials, especially as compared to that in the multi-dose vials of Procrit and Epogen.

195. If anything, one would reasonably expect there to be more overfill in a multi-use vial than in a single use vial because with multiple injections there presumably is some risk of greater spillage, wastage, etc.

196. As is discussed in more detail below, Defendants INN and ASD Healthcare also improperly advocated and encouraged its/Amgen's customers to seek reimbursement for Aranesp overfill, in the course of seeking to achieve the goal described at a March 16, 2004 "Amgen-INN Strategy Meeting" as being to "Convert Procrit® users to Aranesp®."

197. Similarly, for example, on March 26 and 27, 2004, Relator attended a weekend seminar in Carmel, California, that was "sponsored" by INN, at which INN and IPN

representatives openly pushed physicians and office managers to bill for overfill when seeking reimbursement. The INN representatives advised the seminar attendees that as long as the overfill quantities were included on the patients' charts as having been administered – even though they were *not* administered – then the overfill reimbursement supposedly would pass an audit.

198. Defendant Amgen was aware that promoting billing of "overfill" in Aranesp vials was unlawful, but did it anyway. Numerous communications, meetings, e-mails and other documents reflect Amgen's overfill scheme and Amgen's knowledge of both the scheme and its fraudulent nature.

199. For example, Amgen's internal "compliance" mantra was that employees could not "proactively" discuss "overfill" with customers, but instead were to provide the customers with a "Business Reply Card" or "BRC" that would enable the customers to obtain a letter from Amgen's Medical Information department stating the amount of overfill in Aranesp vials.

200. Although Amgen's Medical Affairs or Information Department, and not the sales force, purportedly distributed these overfill letters to medical providers, the sales force had access to the overfill letters as one of their sales "tools." An Amgen document, entitled "Aranesp/Epogen/Sensipar Tools, Benefits and Strategies," lists the Aranesp overfill guidelines as among the *economic* tools that were accessible to the sales force in Microsoft Word format.

201. Moreover, the Amgen sales staff knew exactly why customers were requesting information about overfill. As New England Regional Sales Manager Mark Papineau testified:

> Q. Do you have any understanding as to why customers would be requesting the amount of overfill in Amgen's products?
> A. For certain customers, yes.
> Q. And what is that?

A. They would tell us that they were billing for it, they were using it, administering it and billing for it.

202. Nevertheless, despite the fact that overfill was, computed and discussed, Mr. Papineau explained that the official policy of Amgen remained that no one ever "proactively" discussed overfill:

Q. Why would a sales representative not be permitted to discuss overfill?
A. It's one of our policies.
Q. Is it written down somewhere?
A. Yes.
Q. Where would I find it?
A. Terri Zwicker.
Q. Is it a specific stand-alone policy or is it part of some larger policy?
A. I'm not sure of the details on that, but I know it has been reiterated many times that we are not to discuss overfill, proactively discuss overfill with customers.
Q. When you say proactively, are representatives permitted to discuss it reactively?
A. They're permitted to say, doctor, I'm not permitted to discuss overfill, that's a compliance violation, and I have to refer you to medical affairs if you want more information and I need for you to sign this card and they'll have it sent to you. So that's to the extent that they would be able to talk about it.

203. In response to further questioning, Mr. Papineau added, "It was clear to the [Amgen] representatives that they should not be selling or promoting on overfill and/or the profit of our medications. Whether those communications came out together or separate, I just don't know, but it was clearly put out there to the team." Mr. Papineau could not recall when the directives came out, but he asserted that every year he would give a presentation to his team and he would include a presentation about "making sure we're 100 percent compliant, and that includes no discussions on overfill, no discussions on profit." According to Mr. Papineau, it would be better to lose a customer than to discuss overfill.

204. Nevertheless, Mr. Papineau stated that Amgen sales representatives are permitted to talk to customers about overfill in the context of the BRC card, but only to say "that they can't talk about overfill." However, Amgen recently has changed its policies to permit more leeway on overfill. In the past, Amgen sales representatives purportedly were not even supposed to complete the BRC and were required to provide the BRC to the customer, so the customer could complete the request for overfill information. Amgen now permits its sales representatives to complete the BRC request for overfill.

205. Other evidence, in fact, supports that Amgen sales representatives had the "Medical Information Overfill Letter" at their disposal as a sales/economics tool, at the same time that Amgen sales representatives were discussing overfill and economics in detail with various customers.

E. Examples of Defendants' Misconduct in Relation to Particular Medical Providers

206. By way of example, Relator provides the following details regarding various nephrology groups throughout the United States that Defendants encouraged to submit false claims based on Aranesp dosing that was not medically necessary, that was not based on the doctors' legitimate medical judgment, or that was not actually provided to patients.

207. Defendants' conduct similarly affected other medical providers throughout the country. Claims data received to date support that providers throughout the country who were subject to Defendants' targeted sales efforts had a pattern of submitting claims to Government Healthcare Programs, including claims paid by Medicare or other federal funds, for close to 100% overfill from Aranesp vials.

1. Balboa Nephrology

208. Most of the patients of Balboa Nephrology Medical Group ("Balboa") in San Diego, California – 65% – use Medicare as their primary insurance. Amgen induced Balboa to bill Medicare for Aranesp overfill.

209. Amgen successfully converted Balboa from purchasing mostly Procrit to purchasing mostly Aranesp, between around 2002 and late 2004.

210. Following Balboa's conversion to Aranesp, and at the direction of Amgen representatives, Balboa submitted claims to Medicare relating to Aranesp overfill purportedly administered to some of its patients.

211. Amgen caused medical providers affiliated with Balboa to submit false certifications to Medicare that they were in compliance with state and federal laws, including the federal Anti-Kickback Statute. Defendants also provided particular incentives to Balboa physicians, including Steve Steinberg, who served on Amgen's Steering Committee and was a trained Amgen speaker. INN and Amgen jointly conducted a Practice Advisory Board at Balboa with Dr. Steinberg on October 30, 2003. INN offered Balboa physicians honoraria to participate in a meeting on November 6, 2004 at Huntington Beach.

212. Around late 2004 and early 2005, after aggressive marketing by Ortho Biotech, Balboa considered switching some of its patients from Aranesp back to Procrit. Amgen and INN employees actively discussed the economics of this decision and lobbied against it. For example, Claes Hornstrand created a model comparing the economics of using Procrit rather than Aranesp at Balboa, and he discussed the model by e-mail with his Amgen colleagues, Ray Chow and Daniel Brox. Mr. Hornstrand included overfill in the model's profitability calculations.

213. Amgen employees, including Julie Preston, Lisa Sherman, and Messrs. Hornstrand and Brox, also brainstormed openly with Gary Inglese of INN about the economics of Balboa's use of Aranesp.

214. During this time, Mr. Hornstrand also wrote to his fellow Amgen employees that the "critical question" with determining the economics for Balboa was "whether they do double-dipping or full pull." These are two methods by which overfill can be extracted from a vial and/or administered to patients. Double-dipping – also known as pooling – involves administering part of the contents of the vial to one patient, then re-entering the vial in order to extract and administer the rest of the vial to one or more other patients. Full pull involves withdrawing the entire amount of the vial, including as much of the overfill as can be withdrawn, and billing for the face-labeled amount plus overfill.

215. Ms. Preston, an Amgen sales representative who was involved in converting Balboa from Procrit to Aranesp, circulated a spreadsheet containing an economic analysis of Aranesp pricing under Balboa's Platinum Plus PACT Agreement for purchasing Aranesp.

216. The spreadsheet, attached hereto as Exhibit H, compares the pricing and reimbursement of Aranesp to the pricing and reimbursement of Procrit, including reimbursement for overfill for both drugs. The spreadsheet compares 16.8% overfill for Aranesp against 11.1% overfill for Procrit. The analysis also reflects a 20% off-invoice discount and an additional 4.5% discount from INN. Ms. Preston e-mailed the spreadsheet to Amgen employees, and also to Gary Inglese of INN, on February 11, 2005.

217. Amgen marketing and sales representatives advised the Clinics Manager and other Balboa staff that Aranesp was more profitable for Balboa than Procrit, by comparing the overfill amounts contained in Aranesp and Procrit vials. Amgen employees gave presentations to Balboa staff on a laptop about using Aranesp rather than Procrit, and in those presentations they compared Aranesp overfill to Procrit overfill, sometimes using spreadsheets. The Amgen sales representatives did not leave these overfill comparisons with the Balboa staff; they only permitted the Balboa staff to view the comparisons on the laptop computers.

218. Balboa employees were advised by Amgen representatives that billing for the overfill contained in Aranesp vials was not illegal.

219. Balboa communicated to Chris Coates of Amgen that it intended to capture Aranesp overfill, and Mr. Coates relayed that information to Relator.

220. Balboa issued a standing order for doctors to write patient orders for Aranesp in an amount that was 10% more than the standard dosage that would otherwise have been administered, after which the Medical Assistants were to try to draw up as much of the Aranesp vial as possible (which, according to the protocol, would usually increase the dosage by 5% or 10%), such that Medicare would be billed for the amount withdrawn, including the overfill. The order, in effect, mandated an across-the-board protocol at Balboa to increase dosages and to administer and bill for Aranesp overfill, for every patient that received Aranesp.

221. The Balboa standing order falsely stated that Medicare approved of this practice. The order also was in effect even after the FDA's black box warnings that warned of serious injury or death that could occur if patients received excess doses of Aranesp.

2. Bronx Westchester Medical Group

222. From 2004 through 2009, Amgen offered inducement, in the form of free Aranesp overfill, to Bronx Westchester Medical Group, located in Bronx, New York. Amgen representatives offered the overfill to Bronx Westchester Medical Group in order to prevent it from buying and administering Procrit.

223. Amgen sales representatives told a physician affiliated with the Bronx Westchester Medical Group about the overfill amounts contained in Aranesp vials. The Amgen sales representatives also told the physician that the practice could bill for the free overfill as a means to profit from administering Aranesp.

224. The Aranesp overfill was a "selling point" for Bronx Westchester Medical Group and dissuaded the practice from buying Procrit. The physician was shown economic analyses comparing Aranesp and Procrit and potential overfill profits by Amgen sales representatives. Amgen sales representatives never allowed the physician to keep those economic analyses but would only permit him to view them while an Amgen sales representative was present.

225. During the time that Bronx Westchester Medical Group was considering converting to Procrit, Amgen sales representatives also facilitated telephone calls or meetings between other medical providers, INN representatives, and Bronx Westchester Medical Group employees to pitch Aranesp as a lower-cost alternative to Procrit.

226. Amgen employees instructed the physician about how Bronx Westchester Medical Center should retrieve the overfill from the Aranesp vials and how the practice should bill the insurers, including Medicare and Medicaid, for the overfill.

227. Amgen also used the sham relationship between itself and INN to conspire with INN to offer overfill inducements to a nephrologist affiliated with Bronx Westchester, who met with an INN Strategic Account Manager ("SAM") who promoted Aranesp. The doctor stated that the INN SAM promoted the free overfill in Aranesp vials as a means for his practice to make profits.

228. The nephrologist further stated that he believed INN to be affiliated with Amgen and that INN SAMs were Amgen employees because of how heavily they pushed him to buy Aranesp. A July 19, 2004 INN PowerPoint, entitled "INN Update," confirms that an INN SAM and Amgen PSR jointly called on this Bronx Westchester nephrologist to pitch Aranesp.

229. At the direction of Amgen's sales representatives and INN representatives, physicians associated with the Bronx Westchester Medical Group billed third-party payors,

including Medicare and the New York Medicaid Program, for the free product it received from Amgen in the amount of 15% overfill in each Aranesp labeled dose. For example, for each 100 mcg vial of Aranesp that the practice purchased from Defendants, Bronx Westchester Medical Group's physicians billed 115 mcg, or 15% over the labeled dosage to the New York Medicaid program.

230. From August 10, 2004 to May 29, 2009, physicians affiliated with Bronx Westchester Medical Group submitted claims for reimbursement for the overfill contained in Aranesp vials to the New York Medicaid and Medicare programs. For the aforementioned time period, physicians affiliated with Bronx Westchester Medical Group submitted at least 139 separate claims for the overfill contained in Aranesp vials, amounting to at least $21,000 in Medicaid reimbursements paid by the New York Medicaid program for claims that were ineligible for payment. Some or all of these claims were "crossover" claims that were also reimbursed by federal Medicare funds.

231. These included, for example, six claims by one physician affiliated with Bronx Westchester in January and February of 2005 totaling $1299.18 in Medicaid payments and $4881.52 in federal Medicare payments, all of which included overfill. Another example are 45 claims by another Bronx Westchester-affiliated physician, each of which was submitted based on 115 mcg of Aranesp (thus, including a standard full dose of overfill), from 2007 to 2009, totaling $3,167.77 in Medicaid payments and $12,569.21 in federal Medicare payments

3. California Kidney Medical Group

232. For the relevant time period of this Complaint, California Kidney Medical Group ("California Kidney") billed Government Healthcare Programs for the free overfill it received from Amgen, at the rate of 15% more than each Aranesp vial's labeled dosage. For example,

with respect to each 100 mcg vial of Aranesp it purchased from Amgen, California Kidney billed 115 mcgs, or 15% over the labeled dosage, to the California MediCal program. These claims for 115% of a 1 mL vial are factually false, as it is not possible to withdraw 15% overfill from a single dose vial.

233. Moreover, just as California Kidney could not, in fact, retrieve 15% additional from every vial of Aranesp, it would also not be medically necessary to dose every patient who would otherwise have received 100 mcgs of Aranesp with 15% more Aranesp.

234. Such dosing was the practice at California Kidney, with assistance from Defendants. The files of INN sales representative Shelly Huttar contain an Inter Office Memorandum issued to California Kidney physicians and front office medical assistants on January 25, 2005, explaining that California Kidney had "received information from Amgen's medical information department about the overfill amount in an Aranesp vial. The amount of overfill is 16.8%. Please note that overfill is only VIALS only and that syringes do not have overfill."

235. The Memorandum thereafter included a table showing labeled Aranesp "DOSE" (based on standard Aranesp vial sizes) and "OVERFILL 16.8%" (based on multiplying the standard Aranesp vial size by 16.8%) and "Superbill/Progress Note" (which shows a rounded amount that could be billed in 5 mcg increments) as follows:

DOSE	OVERFILL 16.8%	Superbill/Progress Note
25 mcg	4.2	25 mcg
40 mcg	6.72	45 mcg
60 mcg	10.08	70 mcg
100 mcg	16.8	115 mcg
150 mcg	25.20	175 mcg
200 mcg	33.6	230 mcg
300 mcg	50.4	350 mcg

236. "Superbill" refers to a billing amount and "progress note" refers to notes. Accordingly, this Memorandum instructs California Kidney physicians and front office medical assistants to bill for and record amounts for Aranesp doses *including* overfill, when the intended dose was actually the labeled volume of Aranesp. For example, when a patient was to receive an Aranesp dose of 60 mcg, the billing and progress notes for that patient would indicate that 70 mcg had been administered and should be reimbursed.

237. Consistent with the Memorandum, California Kidney submitted claims to Government Healthcare Programs, including Medicare and Medicaid programs funded by the federal government, that were inflated by a standard amount of "overfill" that California Kidney did not pay for and did not administer. In other words, California Kidney's Medicare claims were false because the Aranesp dosage reported to Medicare was medically unnecessary and/or not actually administered.

238. As a result of Defendants' actions, California Kidney submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

4. Dallas Nephrology Associates

239. The account of Dallas Nephrology Associates ("DNA") was targeted by senior Amgen management in 2004 and 2006 through what were known as sales "blitzes," because it

was one of the largest and most influential nephrology practices in the United States. Such blitzes would provide a forum for important customers like DNA to discuss economic and reimbursement issues with senior Amgen management.

240. DNA received its own "special" contract from Defendants that provided an extra two or three percent discount just for DNA. Although there was internal discussion at Amgen that offering a better deal only to DNA through INN was not legal, Leslie Mirani approved the special pricing for DNA.

241. As a result of Defendants' actions, DNA submitted false and fraudulent claims for reimbursement to Medicare and Medicaid

5. Mid-Atlantic Nephrology Associates

242. Mid-Atlantic Nephrology Associates ("MANA") converted to 100% Aranesp use based on Defendants' aggressive sales tactics.

243. As MANA nurse Sheila Young explained on March 27. 2004, when she was recorded while speaking to other medical providers on "Infusion Management" at an INN "sponsored" seminar at the Wyndham Carmel Valley Ranch, in Carmel, California, her clinic had decided to go 100% with Aranesp in the future – on a monthly dosing plan marketed by Defendants:

> About two months ago we were 50/50 Procrit/Aranesp, since we've been with INN and we've got the Group Purchasing Organization [agreement], *Amgen's been very aggressive and right now the doctors made the financial decision that any new starts will be on Aranesp*. . . . Our protocol is pretty simple, we start everybody on 60 micrograms every other week, if they weigh over 180[4] lbs we put them on 100 micrograms every other week. What we do traditionally, what we've done is, using the 90 day rolling

[4] According to the National Center for Health Statistics, the average weight for an adult male in the United States is 189.8 pounds.

> average we never hold, we never hold drug through 90 day rolling [period] and extend the dosing, so if they are every two weeks what we will do is give them the dose and have them come back every three weeks. *Now what we are doing 'cause we've done it a couple of times and we've seen some data from Amgen, what we are going to do is, we're gonna try and get everybody to once a month. So essentially for every target what we are going to do is double their dose and have them come back once a month, so that was a real leap of faith on the doctors' part*, but I don't know about that, but there is some data and there have been some studies which show that that's a good way of doing it." (Emphases added).

244. MANA also received a "special" contract from Amgen and INN that offered larger discounts and rebates than were provided to any other account, and which was to remain a secret contract so that the same terms would not have to be offered to other INN members.

245. In 2004, MANA purchased approximately $1.8 million of Aranesp through INN.

246. These facts support that MANA's medical judgment was supplanted by Defendants' aggressive marketing tactics, which encouraged MANA to submit claims for off-label uses of Aranesp (e.g., dosing epo naïve patients every other week and monthly dosing) and pushed MANA to prescribe large amounts of Aranesp based on Defendants' presentations on the "economics" of Aranesp.

247. As a result of Defendants' actions, MANA submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

6. Nephrology Associates of Birmingham

248. In April 2004, an INN representative contacted ASD Healthcare to obtain the records relating to Aranesp purchases made by Nephrology Associates of Birmingham ("NA-Birmingham"). The INN representative explained that NA-Birmingham was "a big Procrit account" and that he wanted to see if they had started ordering Aranesp. ASD Healthcare

provided the information about NA-Birmingham's purchases, which the INN representative forwarded to the Amgen PSR, Kelly Carter.

249. Shortly thereafter, Mr. Carter sought INN's assistance in performing a "financial analysis" for NA-Birmingham to show discounts and rebates if their patients were switched over to Aranesp. Although NA-Birmingham had already increased Aranesp purchases by that time, Mr. Carter thought that "it would be timely to indicate the $$$ being left on the table."

250. Instead of expressing any concern that Amgen, INN and ASD Healthcare were exchanging information about a potential customer's orders and discussing "economics" of the customer's contracts, the Amgen District Manager thanked the INN representative and Amgen PSR for "all the teamwork around this account."

7. Nephrology Associates of Mobile

251. In February 2004, Nephrology Associates of Mobile ("NA-Mobile") was considering beginning an "anemia management program" and asked Amgen Aranesp PSR Kelly Carter to provide specific information on the economics of Aranesp versus Procrit, including a "spread sheet" of how Medicare reimbursement for the drugs would work, including the "overfill bonus." Mr. Carter discussed the request with an INN representative and Amgen District Manager, Louis Deppe.

252. Thereafter, "special" pricing provided to NA-Mobile by Defendants led Dr. Mazey from NA-Mobile to declare "why don't all Procrit users take advantage of this pricing?"

253. NA-Mobile's orders of Aranesp increased in April 2004, as a direct result of Defendants' marketing efforts, including overfill analysis and "special" concessions.

254. As a result of Defendants' actions, NA-Mobile submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

8. Portland Hypertension & Nephrology

255. Amgen sales representative Jarrett Gross demonstrated to the Portland Hypertension & Nephrology ("PH&N") staff how to extract Aranesp from dead space syringes and how to administer the medication, including overfill.

256. According to the PH&N Lead Medical Assistant, Amgen told them about the overfill contained in the Aranesp vials so that their staff would know that their patients would be administered the labeled dose plus overfill, rather than only the labeled dose amount.

257. PH&N submitted claims for reimbursement from Government Healthcare Programs that included Aranesp overfill.

258. Amgen's encouragement of PH&N to administer Aranesp overfill to patients who would otherwise have received the labeled dosage amount caused PH&N to submit claims for Aranesp dosing that was not medically necessary.

259. Moreover, Amgen's encouragement of PH&N to bill for all Aranesp overfill encouraged (and caused) the submission of false claims by PH&N that overstated the amount of Aranesp dosed.

260. As a result of Defendants' actions, PH&N submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

9. Renal Associates of Grand Rapids

261. The account of Renal Associates of Grand Rapids ("RAGR") received attention from high levels within Amgen, when the account went with Procrit for 2005 because of Procrit's overfill.

262. To convert the account, Syd Stevens (a friend of Amgen) encouraged RAGR's Renal Billing Specialist, Karie Hilley, to consider advantages of Aranesp monthly dosing, as well as that Aranesp had overfill if RAGR wanted to use it. This communication was shared with Ray Chow, Chris Coates, Terry Carney, and Lauren Hirsch.

263. In addition, an Amgen PSR, Ms. Bender, spoke with Ms. Hilley in October 2005 about a practice that billed for Aranesp overfill.

264. As a result of Defendants' actions, RAGR submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

10. Renal Associates of San Antonio

265. Senior Amgen executives, including Ray Chow, Lisa Sherman, and Claes Hornstrand, attended a "blitz" for employees of Renal Associates in San Antonio ("RASA") in 2004 at which Keith Woods and Mark Bachleda pitched the economics of how RASA could profit from Aranesp, including through monthly dosing, using a set of presentation slides. The presentation was made despite the fact that Amgen's internal policies purportedly prohibited discussing economics with medical providers.

266. At the end of the presentation, a woman in the audience asked for a copy of the slides and Bachleda told her that he would look into it, but later remarked to a colleague that "he could go to jail" if he had given her a copy of the slides.

267. As a result of Defendants' actions, RASA submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

11. Renal Physicians of Montgomery

268. Renal Physicians of Montgomery ("RPM"), in Conroe, Texas, had been purchasing equal amounts of Procrit and Aranesp until one of their representatives was flown out

to and paid to participate in an INN "Ad Board," that was part of the proceedings in March 2004 at the Wyndham Carmel Valley Ranch, Carmel. After the "Ad Board" junket, the RPM representative declared that her medical practice would purchase 100% Aranesp in the future because of the Ad Board.

269. Defendants' provision of the Ad Board to RPM caused RPM to purchase Aranesp.

270. As a result of Defendants' actions, RPM submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

12. San Antonio Kidney Disease Center

271. Dan Smitley, R.N., the one time director of clinical services at the San Antonio Kidney Disease Center, which was an account that was targeted by Amgen and INN.

272. The targeting worked: Mr. Smitley became an INN sales representative and the center made significant profits from Aranesp.

273. Mr. Smitley gave a presentation at an INN conference on anemia held at the St. Regis Hotel in Los Angeles, California, in December 2003. During the presentation he answered a question from the audience on how much money his practice made on Aranesp in the previous year. An audiotape of the meeting reveals the following exchange:

> [Q]: You're buying a million dollars of drug each year in your practice, is that right?
> [DS]: We bought, this year, it's about 1.3, 1.4 million.
> [Q]: What kind of profit are you making off that?
> [DS]: Not charging nurse visits 'cause that's a whole separate fee on top of that and everything, just based on the drug alone?
> [Q]: Right.
> [DS]: This year our numbers were about $350,000.

274. Mr. Smitley further explained that this profit margin of about 25% on Aranesp purchases was based on aggressive dosing of Aranesp, that Mr. Smitley referred to as "really industrial dosing":

> Most of our patients are anywhere from 120 to 200 mic[rogram]s . . . I mean we are starting *some really industrial dosing*, one of our physicians just had me last week a 300, sorry two weeks ago, the 300 mic[rogram]s he wants to get me further out, so we start with a much higher dose.

275. As a result of Defendants' actions, San Antonio Kidney Center submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

13. Southwest Kidney Institute

276. Amgen senior management was well aware that INN was presenting economic analyses that included overfill revenues to medical providers. By example, an overview and analysis of the Southwest Kidney Institute ("SKI"), with multiple locations in Phoenix, Arizona, maintained in the files of Vice President of Sales, Leslie Mirani, and prepared by a member of the Amgen sales force stated:

> INN has aggressively targeted this hospital. They have presented a contract to contract numbers comparison, *overfill analysis*, Aranesp in dialysis, and potential of ordering through different tax identification numbers to maximize both Ortho's and Amgen's contract. SKI is aware that top Amgen accounts get an additional 4% rebate in their P3 [purchase agreement] – and they do not. (Emphasis added.)

277. As a result of Defendants' actions, SKI submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

14. Terence Cardinal Cooke Health Care Center ("TCC"), New York, New York

278. In 2005, the Amgen sales representative advised the Administrator and the Quality Assurance Nurse for the TCC End Stage Renal Disease Clinic that Aranesp vials contained overfill

amounts above the labeled dosages. She further advised that TCC could capture an extra 15% of Aranesp and bill third-party payors for this free product.

279. In that year TCC employees administered Aranesp overfill amounts to TCC patients. At the direction of Amgen representatives, TCC billed third-party payors, including the New York State Medicaid Program and the Medicare program, for Aranesp overfill. TCC billed the Medicaid program for 15% more than each Aranesp vial's labeled dosage. Between June 15, 2005 and March 28, 2008, TCC made at least 3,445 separate and false reimbursement claims for overfill and received at least $1,290,000 from the New York Medicaid Program.

280. As a result of Defendants' actions, TCC submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

15. Nephrology Associates of Syracuse ("NAS"), Syracuse, New York

281. In 2004, NAS purchased Aranesp exclusive to any other ESA. It was one of Amgen's top twenty Aranesp accounts. In that year the Amgen sales representative informed the Chief Operating Officer that Amgen could no longer discount its Aranesp single dose syringes. However, the sales representative explained that instead NAS could receive "discounts" by purchasing Aranesp in single dose vials containing free product which NAS could bill to third-party payors.

282. NAS began purchasing Aranesp in vials, rather than in pre-filled syringes, and administered the overfill. NAS administered extra Aranesp to its patients in order to profit by billing for that extra product, not because patients required the additional medication. At Amgen's direction, NAS billed for the overfill at 10% above each labeled fill dose of Aranesp to Medicare and Medicaid. Between February 17, 2004 and January 9, 2008, NAS made at least 690 separate and false reimbursement claims for overfill and received at least $81,500 from the New York Medicaid Program.

283. As a result of Defendants' actions, NAS submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

16. Nephrology Associates of Western New York ("NAWNY"), Amherst, New York

284. During 2005 an Amgen sales representative advised the NAWNY billing clerk that Aranesp vials contained overfill amounts above the labeled dosages. He further advised them that NAWNY could capture the overfill and bill third-party payors for this free product, although he admitted he was not supposed to tell her this. The sales representative enlisted the help of a NAS nurse practitioner and made several presentations on this theme and how to bill for overfill

285. At the direction of Amgen's sales representative, NAWNY billed third-party payors, including Medicare and the New York State Medicaid Program, for 10% overfill over each Aranesp labeled dose. Between April 19, 2005 and August 21, 2006, NAWNY made at least 52 separate and false reimbursement claims for overfill and received at least $2,420 from the New York Medicaid Program.

286. As a result of Defendants' actions, NAWNY submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

17. Winthrop University Hospital ("Winthrop"), Mineola, New York

287. In 2006, Amgen employees, including District Manager Eric Hedge, offered free Aranesp product, in the form of overfill, to induce Winthrop to purchase and administer Aranesp. Winthrop switched from Epogen to Aranesp and began to administer and bill for Aranesp overfill.

288. The Clinic Administrator for Winthrop reported that 10% overfill was administered to the patients and billed to New York Medicaid and the Medicare programs. She also reported that Winthrop created a dosing protocol for Aranesp that included the overfill amounts in the physician's orders. Therefore, a physician would order that 110 micrograms be administered to a patient, so as to capture the 10% overfill. Between March 3, 2006 and December 28, 2008, Winthrop made at least

179 separate and false reimbursement claims for overfill and received at least $30,000 from the New York Medicaid Program.

289. As a result of Defendants' actions, Winthrop submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

18. North Shore University Hospital ("North Shore"), Manhasset, New York

290. Amgen employees, including District Manager Eric Hedge, offered free Aranesp, in the form of overfill, to induce North Shore to purchase and administer Aranesp. North Shore switched from Epogen to Aranesp and began to administer and bill for Aranesp overfill.

291. Subsequently North Shore billed third-party payors, including the New York State Medicaid Program, for the free product it received from Amgen, in the amount of 20% over each Aranesp labeled dose. Between September 5, 2005 and December 12, 2008, North Shore made at least 131 separate and false reimbursement claims for overfill and received at least $13,000 from the New York Medicaid Program.

292. As a result of Defendants' actions, North Shore submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

F. Defendants Knew Their Conduct Caused False Claims

293. Defendants were aware that their conduct caused Medical Providers to submit false claims.

294. Amgen's internal guidance on the Anti-Kickback Statute and FCA provides:

> For example, if a drug company or its representative helps or encourages a Healthcare Professional to submit a false claim to Medicare perhaps by suggesting that a physician bill for a free sample, the drug company and the representative can be held liable for the Healthcare Provider's false claim. Similarly, if a Healthcare Professional submits a claim that violates another federal law, such as the Anti-Kickback Law, then the

> whistleblower can file a False Claims Act claim based on the violation of the other law.

295. With respect to Aranesp overfill, Defendants did suggest that many physicians bill Medicare for false claims that were medically unnecessary, for services not actually rendered, and tainted by kickbacks.

296. Moreover, there is evidence that Defendants' encouragement of submission of false claims relating to overfill was directly contrary to what Defendants knew the law required. For example, in a May 2005 interview with reporter Chris Rowland of the *Boston Globe*, Amgen Vice President Helen Torley stated that her response to his question "did Amgen promote the use of overfill?" was, "I replied that we did not and explained [the] USP requirement that there be a small amount of overfill to assure [the] labeled amount can be withdrawn."

297. The transcript of Ms. Torley's interview supports her summary. In response to the question, "What is Amgen's position on the marketing of overfill?" Ms. Torley responded (falsely):

> Amgen does not discuss overfill in any way in any of our practices. As you're probably familiar, this is a United States Pharmaco[peia] requirement, that all pharmaceutical products are put in vials and specifically the Epogen vials need to have an excess volume so that it's sufficient to permit people to withdraw their full labeled volume. To me, this requirement in the Epogen 1 ml vial, for example is actually 1.11 mil, but Amgen does not discuss that or promote the use of overfill. It's simply a requirement to assure people can withdraw the right amount of labeled Epogen.

Ms. Torley added that Amgen did not comment on a Centers for Disease Controls' guideline on overfill, either, saying "We view that simply as a manufacturing requirement."

AMGEN'S CONSPIRACY WITH INN, AND ASD HEALTHCARE, TO OFFER KICKBACKS TO MEDICAL PROVIDERS

298. As part of her new position as Aranesp Product Manager in the marketing department in March 2004, Relator was assigned responsibility for Amgen's relationship with Defendant INN (a Group Purchasing Organization), which Relator had been led to believe was an independent entity that focused on nephrology practices and physicians.

299. The idea to create a purported GPO for nephrology came up in a discussion between George Esgro (Amgen's Anemia Sales, National Sales Director) and Scott Carmer (Amgen Aranesp Marketing Director) in early 2003. Both men had seen the success of IPN's International Oncology Network ("ION") in increasing Aranesp sales and resolved to create the International Nephrology Network ("INN").

300. By September 2003 INN was an operative new subsidiary of IPN, and Anthony Corrao left Amgen to become Vice President of the new company. As noted above, in 2002, Defendant ABC had acquired a 20% interest in IPN, INN's parent company and by 2004 wholly owned IPN.[5]

301. After Relator's promotion, she became privy to certain information and documentation that INN was not actually an independent GPO, but rather, was an entity that essentially functioned as a *de facto* marketing arm for Amgen, one that customers/members would see as neutral and objective as compared to Amgen (who was pushing Aranesp) or J&J/Ortho who was pushing Procrit.

[5] In 2002, Defendant ABC paid $5 million for a 20% interest, at that time giving IPN a nominal value of $25 million. In April of 2003 ABC purchased a further 40% for $24.7 million (valuing IPN at $61.75 million). ABC completed the acquisition of the remaining 40% of IPN in April 2004 for $30.9 million (valuing IPN at $77.25 million).

302. Meanwhile, Amgen funneled business to Defendants INN and ASD instead of other Aranesp distributors, INN targeted clinics to convert them to Aranesp, and INN and ASD used the administrative fee as a covert way to pass through additional discounts to customers (price concessions that should have been included in ASP calculations by Amgen).

303. In essence, INN's role was to do the things Amgen could not do and seemingly comply with the Anti-Kickback Statute because INN, as a GPO, purportedly enjoyed a "safe harbor" under the Anti-Kickback Statute, and to pass on price concessions under the guise of "bona fide" fees for purposes of Amgen's ASP calculations and submissions to CMS (*see* 42 C.F.R. § 414.802).

304. Specifically, Relator learned that INN shared highly confidential information with Amgen concerning INN's business operations, including detailed information regarding certain nephrologists and nephrology practices, their revenues, finances, prescribing patterns, and how many "untreated" chronic kidney disease patients an office had.

305. In turn, Amgen provided INN with "target lists" that included the names and addresses of its nephrology customers that both purchased Aranesp and/or purchased competing drugs.

306. Basically, Defendants Amgen and INN would trade any and all information back and forth that would help either or both of them get more business. For example, in an e-mail to Chris Coates of Amgen dated February 9, 2005, Gary Inglese, Director of INN, reported that the San Antonio Kidney Disease Center of San Antonio, Texas, was "finishing up a meeting with Ortho Biotech at this moment and sources tell me they are going to commit to 100% Procrit effect with Q2 due to promises of more favorable reimbursement. They did about 1.8M in

Aranesp in 2004. Looking to do extended dosing. Local Amgen rep has been notified. . . . My full report of endangered and lost accounts will be with you on Thursday."

307. At the same time, wholesaler Defendant ASD Healthcare was knowingly helping Amgen and INN get customers, and vice versa.

308. For example, an ASD representative on an account would "buddy up" with an Amgen PSR and tell him or her that ASD Healthcare would give an important customer a better price on Aranesp. The Amgen representative would then use various means and spreadsheets to let that important customer know that if they switched to ASD Healthcare, they would get a better price on Aranesp or some other medication (as a prelude to convincing the customer to switch to Aranesp).

309. The accounts targeted by Defendants included customers who were using Procrit (purchased from either ASD Healthcare or another supplier) whom the INN and Amgen representatives wanted to convert to using Aranesp or customers who were already using Aranesp but buying it from somewhere other than ASD Healthcare, as well as providers who could influence other providers to deal with Defendants. On occasion, ASD Healthcare would even offer a customer a slight discount on Procrit just to lure them to become a customer of ASD Healthcare, with the main objective being to then convert the account to purchasing Aranesp from ASD Healthcare.

310. Defendant ASD Healthcare also used Aranesp as a "loss leader" for getting the business it really wanted – oncology drugs. As one ASD Healthcare employee told Relator, the pricing he quoted to potential customers was based on how important the customer was to Amgen.

311. "Special" pricing, rebates, and discounts were also made available to certain customers by INN.

312. Basically, the Defendants were triangulating customers: ASD Healthcare, Amgen and INN were all targeting the customer from slightly different angles and the customer often had no idea that the different representatives were talking to each other and sharing information about the customer's business and product orders, or that each company was attempting to direct business to the other(s).

313. Relator also learned that Amgen was funneling large amounts of money to INN ostensibly identified as "administrative fees," when in fact the money was being used for purposes beyond INN's true operating costs as a GPO; rather, the fees were being used, e.g., to arrange and subsidize all expenses paid "retreats" or "educational seminars" for "targeted" physicians (the names of which Amgen provided to INN), to provide extra discounts to customers/target accounts; and to perform practice assessments of INN members and others. These target accounts were high dollar volume accounts and/or accounts that had important political ties to influential nephrology associations in the country that have ties to the government and setting the reimbursement rate for Amgen drugs.

314. INN marketed and led the programs like they were INN meetings, but in fact, all funding came from Amgen. At these "retreats" and "educational seminars," INN and Amgen representatives would lead "informational" sessions that placed heavy emphasis on Aranesp, to the exclusion of any competing drugs, and which placed heavy emphasis on the economic benefit that the physicians could realize if they purchased and administered Aranesp instead of competing drugs.

315. The original deal struck between Amgen and INN, which began on September 15, 2003, paid INN a fixed "administrative fee" of 3% of all sales made through INN to its members. INN used this income, at its discretion, to induce or reward purchasers depending on their size or importance to Amgen.

316. This "administrative fee" was restructured effective April 1, 2004, to include only a 1% fixed fee and the remaining 2% based on performance. The change in the administrative fee meant that INN would have to earn the 2% performance-related fee by demonstrable results.

317. The restructured administrative fee arrangement would prove untenable because a performance-related fee hampered INN's discretion to award kickbacks to customers, provided INN with an uncertain income stream, and jeopardized the 1% pass through from INN to ASD Healthcare, which affected the "bottom line."

318. Once the effect of the restructured administrative fee became evident, ASD Healthcare joined the debate in an attempt to revert the INN administrative fee structure back to the original 3% fixed fee under which INN was not accountable for its performance.

319. The proposal to revert back to the original administrative fee structure was to be put before the Amgen Pricing Committee in the form of a PowerPoint presentation, "The Admin Fee.ppt," prepared by Anthony Corrao and Gary Inglese of INN. This PowerPoint presentation was circulated by e-mail from Corrao to George Esgro, Relator, and Kevin Carlin (Amgen's Anemia Sales Ops/Plan, Senior Manager), on July 21, 2004, "to communicate the high sense of urgency regarding INN's request to reinstate our fixed admin fee back to 3%." According to the e-mail "[t]he executive team at ASD, has informed us, without the reinstatement, they will be raising their off invoice pricing for Aranesp to INN members and reducing the extended dating terms as well."

320. The PowerPoint presentation proclaimed that the administrative fee was set up to "provide for oversight and management of the INN GPO." Under "key points" the presentation acknowledged that "[i]nitially, 3% total of Aranesp sales go through the GPO paid to INN quarterly" and "INN passed through 1% of the sales to ASD the preferred vendor."

321. In case it was not absolutely clear why one third of INN's income as a GPO was being passed along to a for-profit entity such as ASD Healthcare, the PowerPoint presentation explained that "ASD will not be able to run their business at a 13 basis-point margin, which is essentially a break even proposition. No business can do this and thrive. Therefore, to make ASD a viable partner, INN passes through a percentage of its GPO admin fee to ASD." The remaining administrative fee (net of ASD's fee) "provides INN with 2% for operations, to deploy a sales and practice management team of 8, to target Procrit loyal customers."

322. This presentation made INN's status as a contract sales force for Amgen absolutely plain. The proposal even went so far as to suggest that "[i]f the Admin fee is increased beyond 3%, INN would pass through additional discount directly to its Aranesp GPO customers."

323. The slide deck also reported Defendant ASD Healthcare's position: "ASD maintains that failure to increase the admin fee will force them to raise their pricing, and that in turn will have devastating consequences to the INN/ASD competitive advantage for its customers." Thus, just a few months after ABC purchased outright ownership of INN, another of ABC's wholly-owned subsidiaries (ASD Healthcare) was negotiating INN's administrative fee: first through ASD Healthcare in the form of a 1% pass through; and second, in the form of a guaranteed income to INN.

324. By August 5, 2004, Hani Sefain, Amgen Associate Director of Contracting and Pricing, had become involved in the wrangling over the INN administrative fee. Mr. Sefain forwarded a revised draft contract regarding the fixed 3% administrative fee to Relator, Fred Manak, Amgen's Director of Corporate Pricing, and Ryan Bradley, Amgen's Contract Pricing and Marketing Manager. Mr. Sefain informed them that he was scheduled to discuss the administrative fee issue with Helen Torley, VP of the Amgen Anemia Business Unit.

325. Dave Auzat, Amgen Senior Operations Manager, Corporate Pricing Operations, and Fred Manak made the case for the administrative fee reversion to Amgen's Pricing and Contracting Committee and succeeded. By August 13, 2004, Mr. Sefain circulated an updated INN contract reverting back to the old fee structure, and the fixed fee was reinstated effective August 15, 2004.

326. By January 2005, Ryan Bradley of Amgen was turning his mind again to the INN administrative fee structure. In an e-mail of January 14, 2005, he raised the issue with Daniel Brox, Amgen Senior Manager of Aranesp Value Team, reminding Brox that "the intent was to initiate a performance-based admin fee." Brox countered with a proposal for the administrative fee that would "give them [INN] more upside opportunity while also putting some of their current fees at risk." Clearly the legality of the scheme was foremost in Brox's mind because he asked Ray Chow, Amgen Director of Aranesp Marketing: "If we put some fees at risk, do you think JW [a reference to in-house counsel] will go for it?"

327. According to an Amgen PowerPoint presentation, "INN admin fee", dated February 2, 2005, INN was worth every penny spent by Amgen. According to the Amgen analysis, increased sales directly attributable to INN's efforts between April and November 2004 equaled $980,000, and during that period Amgen paid INN $447,000 in "admin fees," giving

Amgen a 119% return on investment on fees paid to INN. INN started strongly in September 2003, and continued that way; it is now the country's largest GPO selling pharmaceuticals to medical providers and physicians specializing in nephrology.

328. Amgen's direction of the business of specific accounts to INN, and INN's targeting and conversion of those accounts to Aranesp, has cost the government millions of dollars in part because the majority of the relevant patients receive Medicare and/or Medicaid benefits and Aranesp had a higher reimbursement rate than Procrit (at times, Aranesp also had a higher reimbursement rate than Epogen).

329. At about the same time as the negotiation of the administrative fee took place, Relator also learned that INN representatives were not disclosing INN's direct relationship with Amgen to its customers, and instead were conveying the impression that INN was a wholly independent organization, with no affiliation with or ties to Amgen.

330. In fact, INN was not independent of Amgen, and functioned as a marketing arm of Amgen, engaging in practices on Amgen's behalf that Amgen fully supported and condoned, but could not legally do in its own name.

331. As part of these efforts, INN representatives would go into doctor's offices and meet with doctors, billing managers, office managers, etc., ostensibly to help them find billing errors or ways to increase reimbursement and revenue, or to offer or promote ancillary services that would improve office efficiency and economics.

332. As part of the conspiracy with Amgen, INN would audit target medical offices or clinics and, under the pretense of acting as an independent GPO, prepare "Practice Assessment" forms providing management advice. Unbeknownst to the target customer, INN would share the

results with Amgen and the Defendants would then formulate a plan about how to entice the clinic switch to Aranesp.

333. For example, two practice assessments done in late 2003, reveal the following information:

(a) On December 8, 2003, INN prepared a practice assessment ostensibly for the benefit of the Balboa Nephrology Medical Group of San Diego, California. According to the assessment which INN provided to Amgen, this 19 physician group served patients 65% of whose principal healthcare insurer was Medicare. A side report that INN prepared for Amgen noted that there was an "immediate opportunity" to "[e]xpand [the] CKD program and shift to Aranesp." Chris Coates, former Amgen District Manager and current Nephrology Business Unit Director of Corporate Accounts, reported to Relator that this practice had never before considered capturing the overfill but had resolved to do so after speaking with Defendants;

(b) On October 30, 2003, INN prepared a practice assessment ostensibly for the benefit of the Rockland Renal Associates of West Nyack. According to the assessment which was provided to Amgen, this five-physician practice served patients 65% of whose principal healthcare insurer was Medicare. However, of the 400 ESA prescriptions written per month at the time of the report, 100% were for Procrit. According to an internal Amgen document tracking INN's progress in converting target practices, twelve months later, Rockland Renal had been converted by Defendants and spent $231,240.00 on Aranesp in the month of October 2004;

(c) A physician affiliated with Rockland Renal Associates of Nyack, New York, confirmed that INN prepared a practice assessment for his nephrology practice. The

physician was surprised, however, that INN would have shared that practice assessment with Amgen. He stated that INN represented itself as a separate entity operating at arm's length from Amgen. Rockland Renal Associates was not a member of INN at the time the practice assessment was conducted; and

(d) A physician associated with Rockland Renal Associates also reported participating in a dinner meeting with an Amgen sales representative and INN sales representative before his practice converted from Procrit to Aranesp in 2004. He stated that at one point during the dinner, the Amgen sales representative left the table and the comment was made that the INN and Amgen sales representatives "can't talk in front of each other." INN and Amgen won the Rockland Renal Associates account, and Rockland Renal was a $1.2 million dollar account for Amgen.

334. INN shared its practice assessments with Amgen to give Amgen a competitive advantage in trying to undercut Procrit pricing and to provide the Amgen sales force with an understanding of the practice's financials and dynamics. This in turn increased INN's earnings under the administrative fee provision.

335. INN representatives were aggressive in other ways, as well. For example, INN representative Shelley Huttar wrote to a doctor that he should not miss the "revenue opportunity" of converting his patients to Aranesp "while it still lasts," and that it "could help pay for [his childrens'] private school [tuition]."

336. In an e-mail of November 4, 2004, Gary Inglese, director of INN, "pitched" "INN's capabilities" to Ray Chow of Amgen, explaining "we will build or design a program to look like what you want it to look like." Among other things, Inglese included a sample of a practice assessment adding "[t]hese require 2 days on site to gather data and interview. We can tailor to specific issues if you want to zero in on something specific. The price per assessment is

$30,000.00 each." In an e-mail of November 26, 2004, Gary Inglese sent Ray Chow a "Conversion Account Spreadsheet" showing three things purporting to justify INN's value for money to Amgen:

1. Conversion influence from Procrit® to Aranesp®

2. Growth influence of Aranesp® market share

3. Retention of the accounts from going over to Procrit®

337. A document entitled "INN Growth Report," also attached to the e-mail, showed that INN had added 1086 new doctors to its membership between January 2004 and October 15, 2004, and that sales of Aranesp to those new members grew from $901,684 in January 2004 to $4,343,055 in September 2004. Inglese was upbeat about INN's progress, "We continue to see positive, upward growth. The intangible items (the things one cannot quantify) remain the relationships we are building and have formed with over 348 practices. And we appreciate and value our relationship with each of you."

338. In a subsequent proposal that Inglese sent to Chow on February 10, 2005, Inglese expounded on the services INN could sell to Amgen:

(a) "Saturday Symposia" with Focus Groups for nephrologists and office managers. Inglese proposed that "Amgen may compile *a target list of nephrologists to be recruited by INN*." (emphasis added); and

(b) "Practice Assessments," Inglese explained, "This initiative will look at the top 20 Amgen accounts or targets and assemble the collected data into a unified and comprehensive database." This would allow INN "[t]o access a practice where 'pharma' cannot go" through an "intimate look inside a practice." This "intimate look" would reveal "Practice Financials; AR, aging reports, AP; Income sharing; Overhead allocation

method; Revenue sharing; Patient payment policy; Adjustments and write offs; Collections; Billing (in house or out sourced); Performance metrics; Bonus structure; and Revenue sharing models" all for $30,000 per practice.

339. A February 13, 2004 e-mail from Eric Price, Aranesp Team Product Manager before Relator took over the position, set out the cost of some of the services that INN performed for Amgen in 2003 and the proposed budget for 2004 (the reckoning did not include charges for practice assessments):

Summary of costs:

Total INN Costs

	2003	***2004***	***Program Total***
Regional Advisory Board Meetings	$948,000	$709,499	$1,657,499
Practice Level Advisory Board Meetings	$732,400	$720,016	$1,452,416
INN 2004 Standards Development Retreats		$56,250	$56,250
INN 2004 Nephrology Nurse Dinners		$148,800	$148,800
INN 2004 Communications Initiatives		$82,500	$82,500
INN 2004 Newsletters and Market Research Surveys		$17,500	$17,500
Total INN Costs	$1,680,400	$1,734,565	$3,414,965
Total estimated honoraria	$264,000	$178,000	$442,000
Total cost	$1,944,400	$1,912,565	$3,856,965
	budget	$1,800,000	
	current spend	$1,734,565	
	remainder	$65,435	

340. Amgen employees and INN representatives would also perform "chart audits" of patient records/charts in offices and clinics in an attempt to find additional patients who might be "candidates" for Aranesp.

341. In addition to the conduct alleged above which provided illegal inducements or kickbacks to promote the sale of Aranesp, during the time that Relator worked for Defendant Amgen, she was also exposed to, and/or required to participate in, various other types of kickback activity, including, without limitation, "seminars" and "retreats" for physicians (and/or their office staff) that were hosted or funded by Amgen and/or INN. These seminars and retreats ostensibly took place to provide neutral, educational information to the attendees – e.g., information concerning various competing drugs, and/or concerning billing practices. In fact, however, the seminars and retreats often were little more than thinly-disguised commercial presentations for Aranesp.

342. The Amgen/INN seminars and retreats typically were held at vacation locations such as Carmel, California (the location of one such event attended by Relator in March 26-27, 2004), with Amgen directly or indirectly paying all the travel, food, and accommodation expenses of the attendees. Furthermore, the physicians and their staff who attended the seminars and retreats typically were paid a so-called "honorarium" of anywhere from $500 to $3,000 – such amounts being paid even in cases where an attendee did not make a speech or otherwise make a presentation. Amgen footed the bill for these expensive seminars and retreats – and paid sizeable "honoraria" to the attendees – all with the express and knowing intention of inducing, and/or rewarding, the attendees for prescribing Aranesp.

343. Amgen also used the aforementioned seminars and retreats as a means of recruiting the office administrators/managers/billers of physicians or physician groups. In particular, Amgen encouraged office administrators/managers/billers who had attended an Amgen seminar/retreat, or who came from offices with a good track record of writing Aranesp prescriptions, to contact their counterparts at other physician offices in order to tout the financial

benefits of prescribing Aranesp. Such secondary contacts sometimes were referred to as "reimbursement roundtables," and the individuals who arranged and performed these contacts were paid an additional "honorarium" of $250 to $1,500 for doing so.

344. Amgen's internal documents show, and Relator knows from firsthand experience, that Amgen had several programs for so-called "medical education" including without limitation, speaker programs, educational grants/fellowships, advisory boards, focus groups, consulting services and preceptorships, all in conjunction with INN. Some nephrologists received substantial amounts of money from Amgen, with INN's knowledge, to be "consultants"; in fact, they did little if any consulting work, and the payments were in reality tied to their continued practice of writing substantial volumes of Aranesp prescriptions.

345. By way of further example, Relator offers the following information about Defendants' activities in promoting the sale of Aranesp:

(a) Relator has notes of several meetings or conversations where representatives of Amgen, INN, and/or ASD Healthcare discussed the overfill in Aranesp single use vials; how that overfill compared to the overfill in multi-dose Procrit vials and to the overfill in Aranesp PFS; marketing and billing of the Aranesp overfill; and customers' reactions to this marketing. Among her notes are records involving such communications on July 19, 2004 (attended by Gary Inglese, Helen Torley, George Esgro, Bob Azelby, Kevin Carlin and Relator); October 4 and 8, 2004; and November 12, 2004;

(b) Relator has notes of a conversation with INN (Inglese) on October 4, 2004, in which she noted "Amgen funds practice assessments to gain info on customers and get ASP message out . . . Gary is constantly hearing offices 'want an objective

opinion,' not 'Amgen or Ortho.'" For this same reason, Inglese by e-mail on June 28, 2004, told Relator he did not want her to accompany him on an upcoming practice assessment to a provider who was a "50/50 account and I think they would be hesitant to being open to me with anyone else there;"

(c) Relator has notes of numerous meetings in 2004-2005 which she attended or conversations she was part of where representatives of Amgen (e.g., Chow, Esgro, Azelby, Carlin, and Torley) and/or INN (Inglese and Corrao) discussed changing the INN administrative fee and the purpose or use to be made of the fee. From these meetings, as well as other evidence, it is apparent that Defendants were using the INN administrative fee to fund additional discounts of between at least 1-3% to be passed through to certain customers (through INN and/or ASD Healthcare) to obtain or retain the customers' business, as well as to enable INN to fund medical education programs and the other activities detailed herein. In Relator's notes of such conversations, there are also references to assertions that INN was in a "safe harbor" but Amgen was not. Among Relator's notes are notes of meetings on: June 21, 24, 25-28, and July 19 and 21, 2004; and

(d) An August 2004 PowerPoint presentation prepared by Joyce Tao at Amgen titled "Retrospective Analysis of Aranesp Contracts and Considerations for Future Contracting Decisions," contains a slide that reads: "Administration fees filtered through as discounts may not be included in ASP." Relator and numerous others (including Victoria Goldin, another Amgen marketing manager) received copies of this presentation. The presentation was made at an Amgen meeting.

346. In addition, an e-mail from Frank Messana of Amgen on November 3, 2004, to Chuck Halstenson, Executive Director of the National Renal Administrators Association, states: "Admin fees are used to pass back to customers, but they are all over the board, from 0 to over 3% depending on the customer size and importance, I guess."

347. On March 2, 2005, Relator attended a meeting with, among others, IPN/INN, Amgen and US Bioservices (another subsidiary of ABC). These corporations were represented by the following individuals: Barry Sandler, Anthony Corrao, David Gilardi, and Gary Inglese for IPN/INN; Peter Arkelian, Todd Goldberg, Matt Skelton, Bonnie Morgan, Sam McDade, and Bob Goria for Amgen; and Joe Paglisi, President of US Bioservices. At that meeting, US Bioservices made a presentation to Amgen of the services the Amerisource group as a whole could provide to Amgen and portrayed the Amerisource conglomerate as one coordinated, cohesive unit. The ostensible purpose of the meeting was to promote US Bioservices and Imedex to Amgen. (ABC had acquired US Bioservices in 2003 for $160 million and Imedex in May of 2004 for $17 million).

348. All parties were conscious that by January 1, 2005, Medicare Part B reimbursement for Aranesp in the physician clinic setting would be based on the new ASP ("average sales price") formula. US Bioservices was proposing that Amgen should contract with Imedex and US Bioservices to use the companies as channels through which to distribute discounts to customers without having to include those items in ASP data. US Bioservices was to be added as a specialty pharmacy provider for Aranesp and would handle 97% of all retail prescriptions for Aranesp. The proposal was to amend the INN contract to include US Bioservices. The advantage of using the existing INN shell as discussed at the March 2nd meeting was that the increased business would increase the absolute level of the administrative

fee and the increased administrative fee would enable INN to pass discounts to additional customers; whereas Imedex's role would be to take advantage of the imminent ASP change to go on an "educational" blitz and market the economics of Aranesp as well as administering "unrestricted educational grants" to favored clinics.

349. Just as INN was a means by which to funnel discounts to GPO members, so too it was proposed for Amgen to make further strategic alliances with ABC, with the plan that, by disguising these pass-throughs as administrative fees, Amgen need not include those fees in its subsequent ASP data. As noted above, Joyce Tao, a sometime employee of Amgen, had written in an August 2004 PowerPoint presentation, "Retrospective Analysis of Aranesp Contracts and Considerations for Future Contracting Decisions," that "Administration fees filtered through as discounts may not be included in ASP." Relator and others at Amgen received copies of this presentation.

350. Another example is an April 10, 2004 e-mail from Nicole Wilson to INN Director of Sales and Marketing, Gary Inglese. The e-mail concerns a joint meeting that Wilson held with an INN SAM and a physician in Sarasota, Florida. The e-mail states that the INN SAM, presented a financial analysis to the Sarasota physician comparing Procrit and Aranesp prices for vial sizes and Medicare reimbursement differences. The e-mail praises the INN SAM for convincing the physician to join INN on the spot, which required the physician to buy Aranesp through INN, and also states that the INN SAM successfully signed on three other Aranesp accounts totaling $530,000 in sales.

AMGEN MISTATED THE ARANESP ASP TO MEDICARE

351. Amgen's pass through payments to INN and ASD Healthcare, and ultimately ABC, should have been included in Amgen's Average Sales Price ("ASP") calculations for

Aranesp reported to CMS pursuant to 42 CFR § 414.804. Amgen's administrative fee pass through payments to Defendants were not "bona fide service fees," as defined by 42 C.F.R. § 414.802, and should have been included as a price concession, pursuant to 42 C.F.R. § 414.804(a)(2), in calculating the ASP for Aranesp. Amgen's failure to include these payments in its ASP calculations for Aranesp caused the quarterly ASP for Aranesp to be overstated as reported to CMS.

352. Amgen's failure to include these pass through payments in its ASP calculations resulted in its reported ASP for Aranesp being inflated. As a result of Amgen's failure to report these payments as price concessions in ASP calculations, the Government Health Care Programs were harmed as follows: (1) State Medicaid Programs that utilize the ASP reimbursement methodology, which is the mandated reimbursement methodology utilized by the Medicare program beginning in 2005, overpaid for Aranesp claims (including as to any federal funding for payment of those claims); (2) State Medicaid and Federal Medicare Programs overpaid for dually-eligible Medicare/Medicaid beneficiaries; and (3) other Government Health Care Programs, including Medicare, which used the ASP reimbursement methodology (the mandated reimbursement methodology utilized by the Medicare program beginning in 2005), overpaid for Aranesp claims.

353. Amgen also failed to include the value of overfill in the ASP information it reported to CMS, even though, as set forth in this Complaint, Amgen marketed and obtained sales of Aranesp based on the value of the Aranesp overfill and even though, under 42 U.S.C. § 1847A(c)(3), a drug manufacturer is required to take into account various things that reduce the cost of a drug for purposes of the ASP certification to Medicare, including discounts and "free goods that are contingent on any purchase requirement."

354. Defendants knew that the asserted value of the Aranesp overfill was material to the amount that medical providers paid for Aranesp and would affect the sales price data of Aranesp.

355. Among other things, Defendants knew that in the course of an analysis conducted by the HHS OIG to set the reimbursement rate for Epogen as of January 1, 1998, OIG noted that Amgen had provided 25% overfill in Epogen, allegedly so that medical providers could extract full doses of Epogen. (Amgen subsequently reduced the Epogen overfill to 16.8% by 1998).

356. For its analysis of the cost of Epogen, OIG obtained cost report information that included the cost per 1,000 units of Epogen administered, including overfill, from which OIG determined that "the average amount [free-standing dialysis facilities] were able to extract was approximately one half of the 25 percent overfill. *The use of this additional EPO would materially affect each provider's cost*." HHS OIG Office of Inspector General for Health Care Financing Audits, *Review of EPOGEN Reimbursement (A-01-97-000509)* ("1997 OIG Report") at 8 (Nov. 24, 1997) (emphasis added); *id.* at 5. As a result of its review, OIG recommended that the Medicare reimbursement rate for Epogen be lowered from $10.00 per 1,000 units to $9.00 per 1,000 units. *Id.* at 7.

357. Defendants also knew that their customers' receipt of Medicare reimbursements for Aranesp overfill would affect those customers' cost of Aranesp in a material way. Nevertheless, Defendants did not provide information about their promotion of the use and billing of Aranesp overfill to Medicare for purposes of setting the Aranesp ASP.

DEFENDANTS MISTATED THE AMOUNT OF OVERFILL "AVAILABLE" IN ARANESP

358. The analysis conducted by the 1997 OIG Report concluded that, on average, the free-standing dialysis facilities analyzed were able to extract about half of the 25% overfill from Epogen multi-use vials, or 12.5% overfill. *Id.* at 7-8.

359. Part of the OIG's review of Epogen included discussions with the Controller of Gambro (an operator of dialysis facilities) on May 28, 1997, in which he stated a belief that Gambro was able to use approximately 14% of total Epogen overfill of 25%. (Gambro's Controller also validated the OIG's cost analysis that included overfill units in the denominator).

360. With respect to Aranesp, Amgen has claimed that overfill that has varied between 16.8% and 19% is necessary because of manufacturing and other issues.

361. Amgen's justification for the amount of overfill in Aranesp is necessarily based on the premise that one could not, in fact, extract and administer all of the overfill in Aranesp vials.

362. Thus, Defendants understood that it was unlikely – if not physically impossible – for a medical provider consistently to withdraw and administer *all of the overfill* in Aranesp vials.

363. Nevertheless, Defendants marketed Aranesp to medical providers by encouraging them to seek and file Medicare claims for reimbursement for *all of the overfill* in Aranesp vials.

364. Defendants thus encouraged the submission of false and fraudulent claims to Medicare relating to Aranesp that was not paid for by a medical provider and that *was not actually administered to a patient.*

365. Defendants did, in fact, succeed in convincing medical providers to submit such false and fraudulent claims to Medicare, which were reimbursed by Medicare. Claims data

received to date indicates that medical providers throughout the United States who were contacted by Amgen did, in fact, increase their level of Aranesp purchases and submitted fraudulent claims to Medicare and other Government Healthcare Programs.

CLAIMS SUBMITTED AND DAMAGES CAUSED TO GOVERNMENT HEALTH CARE PROGRAMS

366. The Defendants' actions described above have caused the submission of false and fraudulent claims, and they have made and used, and/or caused to be made and used, false records and statements for the purpose of having false and fraudulent claims for Aranesp prescriptions submitted to, paid and/or approved by Government Health Care Programs including Medicare.

367. Among other things, claims filed with the Government Health Care Programs because of Defendants' actions have contained false and fraudulent statements and material omissions.

368. Defendants' actions have also caused medical providers who received Aranesp overfill and/or other benefits as a kickback to violate the conditions of their receipt of Medicare reimbursements, including the certification that they would comply with the Anti-Kickback Statute as a condition for the receipt of Medicare reimbursements.

369. Defendants' actions have also caused medical providers who received Aranesp overfill and/or other benefits as a kickback to file false certifications with Government Health Care Programs, including pursuant to Forms CMS-885, that they were in compliance and/or would comply with the Anti-Kickback Statute.

370. There is evidence that Defendants have caused the majority of medical providers purchasing Aranesp from Amgen to provide false certifications on Forms CMS-855A and CMS-

855I during the time that Defendants were providing Aranesp (with the related overfill kickback) to those medical providers.

371. The Provider Enrollment Chain and Ownership System ("PECOS") is a mandatory national enrollment system administered by CMS that was implemented after Amgen began to market Aranesp. It allows physicians and practice groups to enroll in Medicare or to make a change to their Medicare enrollment information online.

372. Enrollment in PECOS requires a medical provider to recertify compliance with the Anti-Kickback Statute at that time. Specifically, when enrolling in PECOS, a medical provider either must complete the paper Medicare enrollment application and certification by completing the appropriate Form CMS-855A or CMS-855I (including certification of compliance with federal law and the Anti-Kickback Statute), or must complete an online enrollment, followed by submission of a two-page hard copy certification statement that requires the same certification as Form CMS- 855A and CMS-855I.

373. CMS requires all medical providers that receive Medicare reimbursements, and who have not submitted a CMS-855 enrollment form since 2003, to enroll in PECOS through either of the processes described above, both of which require contemporaneous recertification by the medical provider of compliance with federal laws, including the Anti-Kickback Statute.

374. The PECOS registration requirement is mandatory and governing regulations provide that medical providers not enrolled in PECOS will not receive Medicare reimbursements. Although the deadline for the application of that sanction has been extended to January 3, 2011, by 2010, most medical providers had enrolled in PECOS (and, in so doing, had recertified their compliance with federal law, including the Anti-Kickback Statute, as a condition of receiving Medicare reimbursements).

375. Other common circumstances regularly require medical providers to submit Forms CMS-855A or CMS-855I, along with contemporaneous certification of compliance with federal law and the Anti-Kickback Statute. For example, CMS requires the submission of a new CMS-855A enrollment form in the event of an acquisition, merger, or consolidation of a medical practice enrolled in Medicare.

376. Further, in the event of a change of ownership of a practice enrolled in Medicare, the new owner can either submit a new enrollment form (with certification), or assume the obligations of the existing provider agreement through an assignment process. Where an agreement is assigned to the new owner, the new owner specifically assumes the agreement subject to "all applicable statutes and regulations and to the terms and conditions under which it was originally issued." 42 C.F.R. § 498.18.

377. Institutional medical providers must also complete the CMS-855A certification whenever they reactivate a Medicare enrollment, voluntarily terminate a Medicare enrollment, revalidate their Medicare enrollment, or change any of their Medicare information, including: identifying information, practice location information, payment address and medical record storage information, ownership interest and / or managing control information, chain home office information, billing agency information, special requirements for home health agencies, authorized officials, delegated officials, or information about adverse legal actions / convictions.

378. Similarly, physicians and other practitioners must complete a version of Form CMS-855I, including the certification of compliance with federal law including the Anti-Kickback Statute, whenever they do any of the following: change any of their Medicare information, including identifying information, practice location information, payment address and medical record storage information, information about individuals having managing control,

final adverse actions/convictions, and billing agency information. Recertification of compliance is also required when physicians and other practitioners enroll with another fee-for-service contractor, reactivate their Medicare enrollment, voluntarily terminate their Medicare enrollment, or revalidate their Medicare enrollment. Physicians are other practitioners are also required generally to notify the government if any of the certifications or statements on the Form change.

379. As of November 2009, the majority – *i.e.*, on the order of 70% — of all Medicare-eligible medical providers (including physicians and medical practices) had re-enrolled in Medicare since 2003, including for the above reasons.

380. These Medicare reenrollments took place after Amgen began to market Aranesp and to provide kickbacks, including in the form of Aranesp overfill, to medical providers. Any medical provider who received kickbacks from Defendants, including Aranesp overfill, prior to reenrollment in Medicare was caused by Defendants to submit (and did in fact submit) a false certification of compliance with federal law, including the Anti-Kickback Statute, upon reenrollment in Medicare. When the providers signed these reenrollment forms, they knew that they would be accepting kickbacks from the Defendants in violation of the anti-kickback statute. Also, as a result of Defendants' conduct, all Medicare claims, including claims for Aranesp, submitted by those medical providers after such false certification was executed, constituted false claims that Medicare should not and would not have paid.

381. Further, Defendants have marketed Aranesp in a way that has compromised physicians' independent medical judgment and threatened patient safety through the use of kickbacks, including the promotion of "overfill" billing, the passing through of INN administrative fees to customers, and the advisory boards and other inducements offered by Amgen, INN, and ASD Healthcare under the guise of operating as a legitimate GPO.

382. The impact of Defendants' misconduct is all the more profound on Government Health Care Programs, such as Medicare, given that Aranesp is more expensive than alternative therapies. According to an Amgen document dated August 10, 2004, Aranesp was 43% more expensive than Procrit.

383. By Defendant Amgen directing business to Defendants INN and ASD Healthcare, and INN and ASD Healthcare helping Amgen identify and convert target accounts, Government Health Care Programs have been damaged significantly because the majority of the patients who use Aranesp are Medicare or Medicaid beneficiaries.

384. As noted herein, Medicare spends substantial sums annually to reimburse providers for Aranesp, approximately $6 billion from 2003 into 2009 (*see* Table I, *infra*). Amgen recognizes the importance of, *e.g.*, Medicare reimbursement, to its business, and recognizes that it is subject to compliance with various federal and state laws such as the Anti-Kickback Statute. For example, in Amgen's 2008 Annual Report, under the section "Risk Factors" Amgen states: that pursuant to a Decision Memorandum of March 14, 2007,

> CMS issued changes to its Medicare National Coverage Determinations Manual that resulted in the reduced use of ESAs in clinical practice….We [Amgen] believe this restriction on reimbursement of ESAs in the Decision Memorandum has had a material adverse effect on the use, reimbursement and sales of Aranesp®, and our business and results of operations.

Under the section "Other," Amgen states:

> We are also subject to various federal and state laws, as well as foreign laws, pertaining to healthcare 'fraud and abuse,' including Anti-Kickback laws and false claims laws… Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs (including Medicare and

> Medicaid). If the government were to allege against or convict us of violating these laws, there could be a material adverse effect on our business, including our stock price.

385. Payment for Aranesp through Medicare is such an important component in Aranesp sales that Amgen gave the following warning in its 2004 annual report: "The Medicare Prescription Drug, Improvement and Modernization Act (or the 'Medicare Modernization Act' ('MMA')) was enacted into law in December 2003. We expect that, beginning in 2005, reimbursement changes resulting from the MMA are likely, to a degree, to negatively affect product sales of some of our marketed products."

386. Defendants' overfill and other inducements caused medical providers to submit false provider certifications that they were in compliance with the federal and state Anti-Kickback laws.

387. Compliance with the Anti-Kickback laws is a precondition to payment by the Medicare program, and by other Government Health Care Programs. By virtue of Defendants' overfill and other inducements to medical providers, the Medicare program and other Government Health Insurance Programs: (1) reasonably and foreseeably paid medical providers for overfill amounts; (2) reasonably and foreseeably paid medical providers for provider-administered and prescribed Aranesp that they would not have otherwise ordered or prescribed; (3) reasonably and foreseeably paid for renewed and continuing treatments of Aranesp for patients who might not have otherwise received that treatment; and (4) reasonably and foreseeably paid for the more expensive drug, Aranesp, rather than the less costly alternative, Procrit.

388. By way of example, Relator offers the following Tables I through V as evidence of claims submitted and damages caused to the Medicare Program.

(a) **Table I** contains totals of Aranesp claims submitted and paid by Medicare from 2003-part way through 2009;

(b) **Table II** has been compiled from practice assessments prepared by INN and shared with Amgen for strategic purposes, and from purchase data contained in INN tracking reports provided to Amgen. The assessments were done in two parts, a five or six page overview in which INN provided some advice to management and introducing themselves in anodyne terms:

> The International Nephrology Network (INN) is a newly constituted group purchasing, physician services organization specializing in programs, services and products for the nephrology network. INN's focus is in reducing pricing on office-administered pharmaceuticals and medical supplies, regulatory compliance, practice management support and clinical trials opportunities. INN is focusing predominately on large and premier accounts. Membership is free of cost and obligations.

The second two page report was an executive summary for Amgen's benefit including pithy statistics and advice such as "immediate opportunity….switch to Aranesp;"

(c) **Table III** contains purchase and other information gleaned from INN tracking reports provided to Amgen;

(d) **Table IV** shows Medicare Part A and Part B Aranesp claims submitted and reimbursement amounts for Rockland Renal Associates; and

(e) **Table V** shows the success that Defendants had in converting several clinics to using all Aranesp.

TABLE I

MEDICARE TOTALS FOR ARANESP CLAIMS AND DISBURSEMENTS FOR THE YEARS 2003-2009 (partial) (data for 2001 and 2002 not presently available).

	Claims	Disbursements
2003	$1,016,194,767.00	$419,989,693.00
2004	$1,987,718,083.00	$874,886,681.00
2005	$2,837,911,696.00	$1,107,282,522.00
2006	$3,295,890,250.00	$1,190,095,606.00
2007	$3,164,204,214.87	$1,157,163,947.00
2008	$1,974,024,674.91	$654,459,737.00
2009 partial	$413,708,136.54	$147,465,866.00
	$14,689,651,823.00	$5,551,344,052.00

TABLE II

COMPILED FROM PRACTICE ASSESSMENTS PREPARED BY INN AND SHARED WITH AMGEN FOR STRATEGIC PURPOSES, AND FROM PURCHASE DATA CONTAINED IN INN TRACKING REPORTS PROVIDED TO AMGEN.

Practice	**Details**	**Date of Assessment**	**Specialty**	**Medicare Population**	**Purchase**
Balboa Nephrology Medical Group 5353Mission Center Road, Suite 318 San Diego, CA 92108	19 physicians 10 nurses 8 offices	October 30, 2003	Nephrology	65% of the patients have Medicare as their primary insurance.	Spent $696,021.60 on Aranesp between March and August 2004.
Rockland Renal Associates Centerock East - 2 Crosfield Ave, Suite 312 West Nyack, NY 10994	5 physicians	December 8, 2003	Nephrology	65% of the patients have Medicare as their primary insurance.	In October 2004, the practice spent $231,240 on Aranesp.
Central Nephrology Group 5143 Office park	6 physicians, 1 assistant	December 16, 2003	Nephrology	65% of the patients Medicare as their	

Practice	Details	Date of Assessment	Specialty	Medicare Population	Purchase
Drive Bakersfield, CA 93309				primary insurance.	
Zak Maniya, MD Mercerville Professional Park 2333 White-Horse Rd, Suite 4 Hamilton, NJ	2 physicians	November 7, 2003	Primarily nephrology but has a significant portion of internal medicine patients.	50% of the patients have Medicare as their primary insurance.	In July 2004, the practice spent $6790.80 on Aranesp.
Houston Nephrology Group Memorial Professional Building 1 902 Frostwood Suite 166 Houston, Texas	5 physicians, 3 nurses	December 1, 2003	Nephrology	70% of the patients have Medicare as their primary insurance.	Spent $151,699.80 on Aranesp between August 31, 2003 and September 1, 2004.
Nephrology Associates 1584-02 Constitution Blvd Rock Hill, SC 29732	4 physicians, 1 nurse	October 21, 2003	Nephrology but it also has a significant focus on internal medicine patients	67% of the patients have Medicare as their primary insurance.	Spent $38,304.00 on Aranesp between March and August 2004.
Nephrology Hypertension Clinic, PC 1331 Monroe Dearborn, MI 48124	10 physicians with multiple offices	December 1, 2003	Nephrology but it also has a significant focus on internal medicine patients.	90% of the patients have Medicare as their primary insurance.	Spent $113.709.00 on Aranesp between March and August 2004.
Nephrology & Hypertension, PC G1071 N. Ballinger Hwy, Suite 310 Flint, MI 48504	7 physicians with 3 offices	December 1, 2003	Primarily nephrology but the clinic also has a significant portion of internal medicine patients.	90% of the patients have Medicare as their primary insurance.	Spent $57727.20 on Aranesp between March and August 2004.
Nephrology Associates of S. Miami 9193 SW 72nd Street Suite 200	6 physicians	December 23, 2003	Primarily nephrology but it also has a significant portion of	40% of the patients have Medicare as their primary insurance.	Spent $52,192.00 on Aranesp between March and August 2004.

Practice	Details	Date of Assessment	Specialty	Medicare Population	Purchase
Miami, FL 33173			internal medicine patients.		
Nephrology Medical Associates 5525 Etiwanda Ave Suite 305 Tarzana, CA. 91356	5 physicians, one nurse practitioner and 24 staff	October 21, 2003	Primarily nephrology but also a number of internal medicine patients.	60% of the patients have Medicare as their primary insurance.	Spent $168,101.00 on Aranesp between March and August 2004.
Queens Nassau Nephrology Services 877 Stewart Ave, Suite 1 Garden City, NY	6 physicians, 10 ancillary staff	October 28, 2003	Primarily nephrology and significant portion of internal medicine patients.	40% of the patients have Medicare as their primary insurance.	In September 2003, the practice spent $5,107.20 on Aranesp.
South Texas Kidney Specialist 910 S. Bryan Road Suite 204 McAllen, Texas	4 physicians 1 Physician Assistant	November 18, 2003	Nephrology	80% of the patients have Medicare as their primary insurance.	Spent $222,289.00 on Aranesp between March and August 2004.
South Carolina Nephrology and Hypertension 1184 Orangeburg Mall Road Orangeburg, SC 29115	3 physicians	November 19, 2003	Nephrology	70% of the patients have Medicare as their primary insurance.	
Carabello Nephrology 201 S. Alvarado Street Ste. 410 Los Angeles, CA	3 physicians, 1 nurse	November 20, 2003	Nephrology	95% of the patients have Medicare as their primary insurance.	Spent $27,573.00 on Aranesp as at July 2004.
Clinical Nephrology Associates 205 North Broad Street Ste. 600 Philadelphia, PA	7 doctors, 2 nurses, 2 physician's assistant/nurse practitioners	November 7, 2003	Nephrology	60% of the patients have Medicare as their primary insurance.	In April 2004, this practice spent $19,843.60 on Aranesp.
Sakhrani and Minasian Nephrology Group 1427 S. Glendale Avenue Glendale, CA	5 physicians, 2.5 physician's assistants	December 15, 2003	Nephrology	40-60% of the patients have Medicare as their primary insurance.	Spent $61,709.40 on Aranesp between March and August 2004.

Practice	Details	Date of Assessment	Specialty	Medicare Population	Purchase
91205					
Milwaukee Nephrologists, SC St. Luke's Health Science Building 2901 W. Kinnickinnic River Prkwy Ste. 405 Milwaukee, WI 53215	11 physicians, 2 nurse practitioners (hospital based), 4 nurses (dialysis center based), 1.5 billing staff, 5.5 receptionist/sec, 1.0 Other Office Staff	December 11, 2003	Nephrology	80% of the patients have Medicare as their primary insurance.	Spent $11,060.28 on Aranesp in June 2004.
Nephrology, Hypertension and Transplant Nephrology 230 West Dares Beach Road, Ste. 106 Prince Fredrick, MD 20678	3 physicians	November 10, 2003	Nephrology	65% of the patients have Medicare as their primary insurance.	In July 2004, this practice spent $30,484.80 on Aranesp.
Renal Hypertension Physicians 1025 Briggs Road Ste 148 Mount Laurel. NJ 08054	7 physicians 1 nurse practitioner, 1 medical assistant	November 10, 2003	Nephrology	50% of the patients have Medicare as their primary insurance.	In October 2004, this practice spent $16,807.20 on Aranesp.
Vita Medical Center 6333 Wilshire Blvd Ste 200 Los Angeles, CA 90048	1 physician	November 20, 2003	Nephrology	95% of the patients have Medicare as their primary insurance.	

TABLE III
SAMPLE PURCHASES BY INN MEMBERS, COMPILED FROM INN TRACKING REPORTS

Providers in States that Were Plaintiffs:

Practice	Sample Purchase
CALIFORNIA	
California Kidney Medical Group, Simi Valley, CA	Spent $759,840.00 on Aranesp between March and August 2004.
Tower Nephrology, Los Angeles, CA	Spent $ 327,661.20 on Aranesp between March and August 2004.
Napa Valley Nephrology, Napa Valley, CA	Spent $ 118,316.40 on Aranesp between March and August 2004.
DELAWARE	
Nephrology Associates, Wilmington, DE	Spent $25,376.40 on Aranesp between September 1, 2003 and August 31, 2004
Nephrology Associates, Newark, DE	Spent $33,755.40 on Aranesp between September 1, 2003 and August 31, 2004
FLORIDA	
Boca Nephrology, Boca Raton, FL	Spent $1,327,596.00 on Aranesp between March and August 2004.
Main Street Medical, Dunedin, FL	Spent $428,128.80 on Aranesp between March and August 2004.
Gulf Coast Kidney Associates, Sarasota, FL	Spent $ 340,776.00 on Aranesp between March and August 2004.
GEORGIA	
Metro Atlanta Kidney Specialists, P.C., Atlanta, GA	Spent $214,560.60 on Aranesp between March and August 2004.
Renal Physicians of Georgia, P.C., Macon, GA	Spent $144,517.80 on Aranesp between March and August 2004.
North Georgia Nephrology Consultants, Athens, GA	Spent $41,256.00 on Aranesp between March and August 2004.
HAWAII	
Waimea Medical Associates, Kamuela, HI	Spent $18,753.00 on Aranesp between September 1, 2003 and August 31, 2004
ILLINOIS	
J.R. Nephrology, Oaklawn, IL	Spent $10,342.08 on Aranesp in May 2004.
Kidney Specialists of Central Illinois, Decatur, IL	Spent $419,316.00 on Aranesp between March and August 2004.
Central Illinois Kidney and Dialysis Associates, Springfield, IL	Spent $184,423.20 on Aranesp between March and August 2004.
INDIANA	
Southern Indiana Nephrology and Hypertension Center, Columbus, IN	Spent $27,291.60 on Aranesp in May 2004.

LOUISIANA	
Northwest Louisiana Nephrology, Shreveport, LA	Spent $10,198.44 on Aranesp in May 2004.
MASSACHUSETTS	
Jeffrey D. Horowitz and Thomas A. Krahn, Fall River, MA	Spent $ 32,462.64 on Aranesp in May 2004.
MICHIGAN	
Nephrology Associates of Michigan Ypsilanti, MI	Spent $28,009.80 on Aranesp in April 2004.
NEVADA	
Nephrology and Endocrine Associates, Las Vegas, NV	Spent $50,194.20 on Aranesp between September 1, 2003 and August 31, 2004.
NEW MEXICO	
University of New Mexico Sciences Center	Spent $142,880.00 on Aranesp in 2005.
CKD Services, Santa Fe, NM	Spent $998.00 on Aranesp.
Lovelace Clinic, Albuquerque, NM	Spent $36.00 on Aranesp.
NEW YORK	
Albert M. Defabritus M.D., New York, NY	Spent $2,585.52 on Aranesp in May 2004.
TENNESSEE	
Cumberland Kidney Center, Crossville, TN	Spent $861.84 on Aranesp in May 2004.
TEXAS	
Milton A. Giron, M.D. of Amarillo, TX	Spent $3,591.00 on Aranesp in April 2004.
San Antonio Nephrology Associates, San Antonio, TX	Spent $4,309.20 on Aranesp in May 2004.
Permian Nephrology Associates, Midland, TX	Spent $7,182.00 on Aranesp in May 2004.
San Antonio Kidney Disease Center Physicians Group, San Antonio, TX	Spent $1,014,376.80 on Aranesp between March and August 2004.
Kidney and Blood Pressure Center, San Antonio, TX	Spent $849,903.00 on Aranesp between March and August 2004.
West Texas Nephrology Associates, San Angelo, TX	Spent $567,504.00 on Aranesp between March and August 2004.
VIRGINIA	
New River Nephrology, Christiansburg, VA	Spent $4,596.48 on Aranesp in May 2004.

Providers in non-Plaintiff States:

ALABAMA	
Athens Internal Medicine and Nephrology Associates, Athens, AL	Spent $14,794.92 on Aranesp in May 2004.
ARKANSAS	
South Nephrology and Hypertension Clinic, Pine Bluff, AR	Spent $9,192.96 on Aranesp in May 2004.
COLORADO	
Summit Medical Clinic, Colorado Springs, CO	Spent $2,298.24 on Aranesp in May 2004.
CONNECTICUT	
Metabolism Associates, New Haven, CT	Spent $21,147 on Aranesp between September 1, 2003 and August 31, 2004.
IDAHO	
Idaho Nephrology Associates, Boise, ID	Spent $17,875.20 on Aranesp between September 1, 2003 and August 31, 2004.
IOWA	
Renal Associates, Sioux City, IA	Spent $31,743.60 on Aranesp between March and August 2004.
KANSAS	
Kansas Medical Clinic, P.A., Topeka, KS	Spent $33,330.60 on Aranesp between March and August 2004.
KENTUCKY	
Tri State Nephrology Associates, Ashland, KY	Spent $4,309.20 on Aranesp in May 2004.
MARYLAND	
Metropolitan Nephrology Associates, Clinton, MD	Spent $4,883.76 on Aranesp in May 2004.
MINNESOTA	
Dakota Clinic, Thief River Falls, MN	Spent $104,139 on Aranesp between September 1, 2003 and August 31, 2004.
MISSISSIPPI	
Nephrology and Hypertension Ltd., Tupelo, MS	Spent $23,987.88 on Aranesp in May 2004.
MISSOURI	
Branson Nephrology, Branson, MO	Spent $6,032.88 on Aranesp in May 2004.
NEBRASKA	
Wagoner Medical Group, Grand Island, NE	Spent $6,543.60 on Aranesp between September 1, 2003 and August 31, 2004.
NEW JERSEY	
Renal Hypertension Physicians, P.A., Mount Laurel, NJ	Spent $9,480.24 on Aranesp in May 2004.
NORTH CAROLINA	

Carolina Kidney Associates P.A., Greensboro, NC	Spent $2,298.24 on Aranesp in May 2004.
NORTH DAKOTA	
Great Plains Clinic, Dickinson, ND	Spent $11,491.20 on Aranesp between September 1, 2003 and August 31, 2004.
OHIO	
George Varghese, M.D. and Associates Inc., Springfield, OH	Spent $21,911.40 on Aranesp between March and August 2004.
OKLAHOMA	
Anupa Khastigir, M.D., Oklahoma City, OK	Spent $20,289.60 on Aranesp between March and August 2004.
OREGON	
Kidney and Hypertension Center P.C., Roseberg, OR	Spent $15,513.12 on Aranesp in May 2004.
PENNSYLVANIA	
Nephrology Hypertension Associates of Lehigh Valley, Easton, PA	Spent $8,618.40 on Aranesp in May 2004.
RHODE ISLAND	
Nephrology Associates, East Providence, RI	Spent $ 7,341.60 on Aranesp between September 1, 2003 and August 31, 2004
UTAH	
Southern Utah Neurology Center, Ivins, UT	Spent $30,324 on Aranesp between September 1, 2003 and August 31, 2004.
WASHINGTON	
East Side Nephrology and Hypertension, Bellevue, WA	Spent $38, 880 on Aranesp between March and August 2004.
WEST VIRGINIA	
Westvaco Family Medical Center, Piedmont, WV	Spent $2,872.80 on Aranesp between September 1, 2003 and August 31, 2004.
Hospital Plaza, Clarksburg, WV	Spent $159,679.80 on Aranesp between September 1, 2003 and August 31, 2004
WISCONSIN	
Milwaukee Nephrology CKD Clinic, Milwaukee, WI	Spent $16,662.24 on Aranesp in May 2004.
WYOMING	
Associates in Internal Medicine, Cheyenne, WY	Spent $23,616.00 on Aranesp between March and August 2004.

TABLE IV
EXAMPLES OF MEDICARE CLAIMS BILLED TO AND PAID BY MEDICARE

Rockland Renal Associates
Centerock East - 2 Crosfield Ave, Suite 312
West Nyack, NY 10994

Medicare Part B Billing (count=number of claims)

	year of service Data													
	2001		2003		2004		2005		2006		2007		2008	
ProvUPIN	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt
[redacted]					218	$208,636	264	$260,740	171	$105,179	228	$186,817	60	$42,293
	1	$0			539	$528,370	751	$807,284	565	$330,076	679	$532,588	157	$110,325
	1	$0	4	$3,034	410	$342,578	568	$495,225	482	$254,553	693	$447,088	170	$97,320

Part A Billing

	year of Data					
	2006		2007		2008	
UPIN	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt
JONATHAN S WOLF [redacted]	177	$471,583	231	$699,640	93	$234,847
STEVEN B YABLON	95	$225,889	124	$293,315	51	$107,631
KENNETH S SHAPIRO	992	$2,355,107	1,452	$3,576,475	484	$1,177,431

TABLE V

The following clinics were purchasing another ESA rather than Aranesp at the time they enrolled with INN. However, after their enrollment, they stopped purchasing any other ESA and instead bought Aranesp to the exclusion of any other ESA:

NAME	LOCATION	ENROLLED
Northwest Louisana Nephrology	Shreveport, LA	March 04
Mid-Atlantic Nephrology Associates		Jan 04
Renal Specialists of Naples	Naples, FL	Feb 04
Milwaukee Nephrology Ckd	Glendale, WI	Oct 03
Naushad Zafar, M.D.	San Antonio, TX	March 04
Bashar Alzahabi, M.D.	Effingham, IL	Feb 04
Associates in Internal Medicine and Nephrology	Norfolk, VA	Jan 04
Coastal Nephrology Associates	Punta Gorda, FL	May 04
Renal Associates	Sioux City, IA	April 04

DEFENDANT AMGEN'S UNLAWFUL RETALIATION AGAINST RELATOR

389. In or about March 2004, Relator left the Aranesp sales force and accepted a promotion to become an Aranesp Product Manager, which required Relator to relocate from Portland, Oregon to Amgen's home office in Thousand Oaks, California. As part of Relator's new position in Amgen's marketing department, Relator was assigned responsibility for Amgen's relationship with Defendant INN (a Group Purchasing Organization), which Relator had been told was an independent entity that focused on nephrology practices and physicians.

390. After Relator relocated to California and began working in Amgen's marketing department, Relator became privy to certain information and documentation that caused Relator to begin to question various aspects of the Amgen and INN relationship, and whether INN was, in fact, an independent GPO, or rather, an entity that essentially functioned as a *de facto* marketing arm for Amgen and for Aranesp. Relator learned, for example, that INN routinely

shared highly confidential information with Amgen concerning INN's business operations, including detailed information regarding certain nephrologists and nephrology practices that INN did business with, the revenues and finances of INN customers, and how many "untreated" chronic kidney disease patients any particular nephrology office had. In turn, Amgen provided INN with "target lists" that included the names and addresses of its nephrology customers that purchased Aranesp and/or purchased competing drugs. Defendants Amgen and INN traded this information back and forth for the purpose of helping either or both generate more business, reap higher profits, and/or convert non-Aranesp doctors and nephrology practices to Aranesp.

391. At or about the same time, Relator learned that wholesaler Defendant ASD Healthcare (which is owned by ABC and ABSG) was knowingly working with Amgen sales representatives and INN to obtain customers, and vice versa. For example, ASD representatives would "buddy up" with Amgen sales representatives and tell the Amgen representatives that they would give a big customer a better price on Aranesp. The Amgen representatives would create an economic spreadsheet concerning the proposed transaction to demonstrate to the customer the higher profit it would realize if it purchased its Aranesp through ASD Healthcare.

392. This "marketing" technique was employed both with respect to purchasers who already were using Aranesp but buying it from another wholesaler (not ASD Healthcare), and with respect to prospective customers who were using Procrit, which the Amgen sales representative (and INN) were trying convert to Aranesp.

393. Relator learned that ASD Healthcare would even offer prospective customers discounts on Procrit to lure that customer to become affiliated with ASD Healthcare, with the main objective being to convert the account to Aranesp once the customer had switched to ASD Healthcare.

394. ASD Healthcare, Amgen and INN were working together to target customers from different sales perspectives, while the prospective customer had no idea that the different representatives were talking to each other and sharing information, and that each company was attempting to direct the other's business.

395. Relator learned that Amgen was funneling large amounts of money to INN ostensibly identified as "administrative fees," when in fact the money was being used to arrange and subsidize all expenses paid "retreats" or "educational seminars" for targeted physicians and/or large nephrological practice groups (the names of which Amgen provided to INN), and/or to provide extra discounts to customers and/or high dollar volume "target accounts." In addition to high dollar accounts, certain of these "target accounts" had important political ties to influential nephrology associations throughout the country and had the ability to influence governmental reimbursement rates for Amgen drugs.

396. INN promoted and marketed these retreats/seminars and conducted the programs as if they were INN sponsored events, when in fact, all of the funding came from Amgen.

397. Moreover, INN and Amgen representatives would lead "informational" sessions at the retreats that placed heavy emphasis on Aranesp, to the exclusion of any competing drugs, and which placed heavy emphasis on the economic benefit that the physicians would realize if they purchased and administered Aranesp instead of competing drugs.

398. By Amgen directing business to INN, and INN targeting and converting these accounts, it potentially cost the government millions of dollars because the majority of these patients are Medicare/Medicaid patients, and because Aranesp had a higher reimbursement rate than competing drugs.

399. In conjunction with Amgen, INN sold this price "spread' to physicians, along with help from Amgen sales representatives. INN and Amgen representatives also encouraged the billing for overfill, as well as the conversion of Epogen dialysis business to Aranesp, which also made the physicians significantly larger profits since an Aranesp dialysis reimbursement rate had not yet been established.

400. Relator learned that INN representatives intentionally concealed INN's direct relationship with Amgen from its customers, and conveyed the impression that INN was an independent organization with no affiliation or ties to Amgen. In fact, INN was not independent of Amgen, as it essentially functioned as a marketing arm of Amgen, engaging in marketing practices on Amgen's behalf that Amgen fully supported and condoned.

401. For example, INN representatives would go into doctors' offices and meet with doctors, billing managers, office managers, etc., ostensibly to help them find billing errors or ways to increase reimbursement and revenue, or to offer or promote ancillary services that would improve office efficiency and economics.

402. INN also prepared Physician Assessment Forms and then, unbeknownst to the physician, shared the results with Amgen, and Defendants would formulate a plan to get the doctor to switch to Aranesp.

403. In addition, Amgen employees and INN representatives together would conduct "chart audits" of patient records/charts in doctor's offices and clinics.

404. As Relator became aware of the above information, Relator became more and more concerned about the relationship between INN and Amgen, and about the specific activities that she had become aware of.

405. In Fall 2004, Relator approached her immediate supervisor, Laurence "Matt" Skelton, and told Mr. Skelton that she was concerned about the propriety and legality of the INN/Amgen relationship, was concerned about the way INN was being used by Amgen to market Aranesp, and was concerned that she was unclear and uncertain as to what activities were authorized and legal and what activities were unauthorized and illegal.

406. At about the same time, Relator communicated these same concerns to another of her supervisors, Ray Chow.

407. Relator had multiple discussions with both Mr. Skelton and Mr. Chow in the second half of 2004 and early 2005 about her concerns regarding the propriety and/or legality of the relationship between INN and Amgen generally, and the above-described sales and marketing activities specifically.

408. In early 2005, after Relator had become more vocal about her concerns regarding the INN/Amgen relationship – specifically stating that she believed the INN/Amgen relationship to be improper and/or illegal in many respects – Relator was relieved of her INN responsibilities and was told that she no longer would be involved in, or have any responsibility for, the INN/Amgen relationship.

409. When Relator thereafter continued to express concerns about aspects of the INN/Amgen relationship – such as the lavish all-expenses-paid weekend retreats that were being contemplated and/or scheduled – Relator was told by Mr. Skelton and/or Mr. Chow to "stay out of it," that it "wasn't Relator's problem anymore because INN was now being handled by someone else."

410. The more Relator continued to express her concerns regarding INN, the more Messrs. Skelton and Chow became nervous and uncomfortable being around Relator. Indeed,

Mr. Skelton told Relator that he was relieved when Relator's INN responsibilities had been taken away because Relator now "could not complain to him anymore about it being wrong."

411. In early 2005, at approximately the same time that Relator's INN responsibilities were taken away, and about the same time that Relator was told by Messrs. Skelton and Chow to "stay out of [INN]," Amgen questioned certain of Relator's previously submitted and approved expense reports, and falsely accused Relator of having misused her expense account and of submitting false expense reports.

412. Messrs. Skelton and Chow made these accusations despite the fact that Relator had prepared and electronically submitted monthly expense reports pursuant to Amgen's policies and procedures, which had been subject to prior contemporaneous audit by Amgen representatives.

413. Nevertheless, Messrs. Skelton and Chow advised Relator that she would be required to undergo an audit of past expense items that previously had been submitted and approved, to be conducted outside the ordinary procedures by Messrs. Skelton and Chow.

414. Despite the fact that Relator had followed company policy and directives regarding her expense account, Messrs. Skelton and Chow advised Relator that she would be expected to reimburse Amgen for certain items that were deemed inappropriate business expenses.

415. Relator complained to Messrs. Skelton and Chow that she was being singled out in that fashion, and that Relator's expense accounting procedures were no different from any of the other Sales and Marketing team.

416. Relator was particularly concerned about her expense audit, because Mr. Skelton previously had told Relator that a "favorite method" of retaliating against employees or forcing

employees to quit was to commence aggressive audits relating to that employee's expense reports.

417. When Relator told Messrs. Skelton and Chow that she expected any expense audit to be conducted by the appropriate finance department supervisors, she was subjected to verbal threats and abuse by Messrs. Skelton and Chow.

418. Relator thereafter was told by Mr. Skelton that she would be required to reimburse Amgen for many thousands of dollars of expenses that previously had been approved, and that if Relator did not immediately write a check to Amgen in the requested amount, that Relator's employment with Amgen would be terminated.

419. Messrs. Skelton and Chow also told Relator that, in order to continue her employment with Amgen, she also would be required to sign a document "acknowledging" the issues with her expense reports, although they purported to promise to Relator that they would not show the document to anyone else (not even Amgen's Human Resources department) or use it in any manner. Messrs. Skelton and Chow told Relator that the document was "just for their files."

420. The stress and anxiety resulting from the series of confrontations with her superiors as set forth above caused Relator to go on temporary disability leave from Amgen in March 2005. Relator remained on disability for an extended period of time until she eventually was terminated.

421. Amgen was aware that Relator's expense reports were consistent with company practices, yet nonetheless her supervisors harassed her about them, in an attempt to retaliate against her for raising issues regarding Defendants' relationships and misconduct.

422. In fact, regardless what Amgen's corporate compliance manuals stated for public consumption, Amgen encouraged its sales representatives to incur lavish expenses to entertain medical professionals and to minimize the documentation provided about such expenses.

423. That issue was so prevalent and obvious at Amgen during the time of Relator's employment and thereafter, that the script for the July 2007 meeting of Amgen's Nephrology Business Unit from the files of Amgen Vice President of Sales Leslie Mirani included not only a joke about black box warnings, but also a joke about the fact that "expense reports without receipts" and "taking a wine-loving doc[tor] to dinner" were under "reimbursement pressure" along with reimbursement for ESAs, such as Aranesp.

424. As set forth in detail above, Amgen threatened, harassed, intimidated and otherwise discriminated against Relator directly because of her lawful acts involving a potential violation(s) of the False Claims Act by Amgen regarding its unlawful relationship and activities with Defendant INN. By these actions, Amgen violated the False Claims Act, 31 U.S.C., § 3730(h), as set forth below.

425. Relator has been damaged as a direct result of these illegal actions, and has suffered great economic harm, loss of income, and emotional injury.

CLAIMS ON BEHALF OF THE UNITED STATES OF AMERICA

COUNT ONE
FALSE CLAIMS ACT

ALL DEFENDANTS

Defendants Knowingly Caused the Submission of False and/or Fraudulent Claims by Providers in Violation of 31 U.S.C. § 3729 (a)(1)(A) Because Such Claims were not for Aranesp that was Medically Indicated for the Health of the Patient and/or was not Administered in the Number of Units Claimed

426. The named Plaintiff the United States of America has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the allegations in paragraphs 1 through 425 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

427. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

428. Through the acts and omissions described herein, and from at least on or before September 2001 to the present, Defendants knowingly caused medical providers throughout the United States to present for payment and approval false and/or fraudulent claims to officers of the United States Government, including without limitation, claims submitted to Medicare on CMS Form 1500 claims forms and other claims submitted for payment from federal funds.

429. Defendants induced providers through kickbacks described in this Complaint and other statements and representations to present claims to Medicare for reimbursement based on alleged provision of medical services that were unnecessary and/or not actually rendered. Defendants' kickbacks and other misconduct tainted the medical providers' services and the resulting claims are materially false and/or fraudulent. *See United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 2010 WL 938361, at *16 (D. Mass March 12, 2010).

430. As described herein, such claims were false and/or fraudulent because:

(a) by signing the form (see, e.g., Box 31), the provider certified that the Aranesp units administered were "medically indicated and necessary for the health of the patient" (see reverse side of claim form), when in fact, they were not; and

(b) by signing the form (*see, e.g.*, Box 31), the provider certified that the number of units shown on the form as being administered (see, e.g., Box 24G) were actually administered or furnished (see also reverse side of claim form) when, in fact, they were not.

431. Moreover, such claims were submitted for payment in violation of provisions of the Medicare statute and regulations, which specify that services are only covered or reimbursable when "medically indicated and necessary." *See, e.g.*, 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"). It is axiomatic that claims submitted for goods or services that were not actually provided to patients are factually false claims and are not reimbursable by Medicare.

432. In addition to the other specific certifications and statements cited in this Complaint, the reverse side of the claim form, which is expressly incorporated into the provider's signature in Box 31, contains three explicit notices to the provider:

> NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.
>
> NOTICE: Anyone who misrepresents or falsifies essential information to receive payment from Federal funds requested by

> this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.
>
> NOTICE: this is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws

Exhibit K.

433. The Medicare Provider Enrollment Application contains similar representations and certifications and warnings, as does the two-page PECOS certification form.

434. The claim forms were false and/or fraudulent because the claims falsely represented on their face that the provider had administered Aranesp in a dose that was "medically indicated and necessary and indicated for the health of the patient" when, in fact, the patient had been administered more than the labeled fill volume on the Aranesp vial, *i.e.*, had been administered units of Aranesp that were not intended to be administered to patients.

435. Moreover, in many instances, providers administered Aranesp overfill units across the board, to every patient in the practice or a group of patients, because of standing orders or other protocols that were not based on assessment of what was "medically indicated and necessary" for each patient's health.

436. Such overdosing of patients was not medically indicated and necessary; indeed, it was contraindicated particularly in light of the serious adverse safety risks to patients from overdosing of Aranesp (and other ESAs).

437. The related claims were submitted for payment in violation of the Medicare statute and regulations which specify that services are only covered or reimbursable when "medically indicated and necessary." "Since § 1395y(a)(1)(A) expressly prohibits payment if a

provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision." *Mikes*, 274 F.3d at 701. Moreover, the Provider Enrollment Application makes clear that continued compliance with the Anti-Kickback Statute is a condition of payment for any claim.

438. The claim forms were also false and/or fraudulent because, as Amgen's own analyses and other evidence demonstrates, it was not feasible for providers to be able to withdraw or capture and administer anywhere near the full amount of overfill from every Aranesp vial.

439. Nevertheless, based on Defendants' presentations and instructions on Medicare claims submission, providers would seek reimbursement from Medicare on CMS 1500 claim forms for all or a very large portion of the Aranesp overfill in every vial. As Defendants were aware, the providers, however could not (and did not) administer the Aranesp overfill as stated on the claims forms to any patient.

440. Defendants caused the claims for Aranesp described in this Count to be submitted for Medicare reimbursement when Defendants knew (within the meaning of the FCA) that such claims were not eligible for reimbursement in whole or in part, and it was a natural and foreseeable consequence of Defendants' misconduct that providers would submit such claims.

441. Providers submitted such claims as a natural and foreseeable result of the illegal marketing and promotional activity of Defendants described in this Complaint including without limitation, Defendants' making of oral and written statements to providers that showed or illustrated to them the amount of overfill contained in the Aranesp vial, compared the same to the overfill contained in Procrit vials, showed extra reimbursement and profit that could be made from billing the Aranesp single dose vial overfill (versus, e.g., the Procrit multi-dose vial

overfill) to Medicare, encouraged the use of standing orders or protocols despite the fact that Aranesp should be dosed according to each particular patient's medical condition, and advised providers how they could "pass an audit" by the Government.

442. Government Health Care Program officials, their contractors, carriers, intermediaries and agents, paid and approved claims for payment for Aranesp that should not have been paid or approved.

443. Defendants, through the means described above, deliberately and intentionally concealed material information, including the false or fraudulent nature of the claims, from officials with Government Health Care Programs, and other Government officials, their contractors, carriers, intermediaries and agents, in order to induce payment of the false or fraudulent claims.

444. Government Health Care Program officials and their contractors, carriers, intermediaries and agents, would not have paid the claims for Aranesp had they known the truth.

445. By reason of the above-described actions and the submission of claims that were false and/or fraudulent, the United States has suffered significant losses in an amount to be determined.

COUNT TWO
FALSE CLAIMS ACT

ALL DEFENDANTS

Defendants Knowingly Caused the Submission of False and/or Fraudulent Claims in Violation of 31 U.S.C. § 3729 (a)(1)(A) by Offering Overfill as Illegal Remuneration to Induce Providers to Purchase Aranesp in Violation of the Anti-Kickback Statute

446. The named Plaintiff the United States of America has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the

allegations in paragraphs 1 through 445 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

447. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

448. From at least 2001 to present, Amgen and INN knowingly offered kickbacks to medical providers in the form of overfill contained in vials of Aranesp and encouraged medical providers to submit claims for payment for the free product.

449. Through the acts and omissions described herein, and from at least on or before September 2001 to the present, Defendants knowingly caused medical providers to present for payment and approval false and/or fraudulent claims to officers of the United States Government, including without limitation, claims submitted to Medicare on CMS Form 1500 claims forms and other claims submitted for payment from federal funds.

450. As described herein, such claims were false and/or fraudulent because:

(a) by signing the form (*see, e.g.*, Box 31), the provider certified that the Aranesp units administered were "medically indicated and necessary for the health of the patient" (see reverse side of claim form), when in fact, they were not and were therefore not reimbursable by Medicare. *See, e.g.*, 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"). "Since § 1395y(a)(1)(A) expressly prohibits payment if a provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision." *Mikes*, 274 F.3d at 701; and

(b) The kickbacks by Defendants tainted the services and the resulting claims are false, and materially false, including that medical services provided based on, because of, or by reason of a kickback are *per se* not "reasonable and necessary for the diagnosis or treatment of illness or injury."

451. The submitted CMS 1500 claim forms also contain "misrepresentations" and "false, incomplete or misleading information," or "misrepresent essential information to receive payment," are not "true, accurate and complete," and are based upon "concealment of a material fact," including that the provider was offered and accepted a kickback which tainted the claim and rendered it ineligible for payment. Providers on are notice from Form 855 that each claim was "conditioned upon the claim and the underlying transaction complying with . . . the Federal anti-kickback statute." CMS 855. The claim forms are thereby rendered "false" and "fraudulent" within the meaning of the FCA.

452. The submitted CMS 1500 claims forms seek (and have resulted in) payment of government money to which the provider is not entitled and that the Government paid by mistake, which constitutes a violation of the FCA.

453. Violation of the Anti-Kickback Statute renders related claims, such as the submitted CMS 1500 claims forms *per se* false or fraudulent, including because:

(a) Compliance with the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, is a condition of payment under the Medicare program. *United States ex rel. Westmoreland v. Amgen Inc.*, No. 06-10972-WGY, 2010 WL 1634315, at *8 (D. Mass. Apr. 23, 2010);

(b) The legislative history of the 1986 amendments to the FCA also make clear that violation of the Anti-Kickback Statute renders claims false ("[A]

false claim may take many forms, the most common being a claim for goods or services not provided, *or provided in violation of contract terms, specification, statute or regulation* …" S. Rep. No. 345, 99th Cong., 2d Sess. 9 (1986), U.S.C.C.A.N. 5266, 5274 (emphasis added));

(c) The legislative history of the 2009 amendments to the FCA[6] make clear that violation of the Anti-Kickback Statute renders a claim false (*e.g.*, Cong. Rec. E1296-97 (Rep. Berman stating that among the various types of conduct that, when done knowingly, violate the Act, are "submitting a claim for payment even though the defendant was violating the Government-funded program's conditions of participation of payment; fraudulently cashing a Government check or knowingly keeping Government funds that were initially wrongfully or mistakenly obtained.")); and

(d) Congress has since eliminated any conceivable argument that the False Claims Act does not reach claims tainted by a violation of the Anti-Kickback Statute. On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119. In that Act (at p. 1703 of the Act, Section 10104(f)), Congress included an amendment to the Anti-Kickback Statute, stating that "a claim that includes items or services

6 Because Relator's case was pending as of June 7, 2008, "the potentially applicable provisions in this case are former § 3729(a)(1), establishing liability for 'knowingly present[ing], or cause[ing] to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval," and current § 3729(a)(1)(B), establishing liability for 'knowingly mak[ing], us[ing], or caus[ing[to be made or used, a false record or statement material to a false or fraudulent claim." *United States ex rel. Kirk v. Schindler Elevator Corp.*, --- F.3d ---, Docket No. 09-1678-cv, 2010 WL 1292143, at *14 (2d Cir. Apr. 6, 2010) (quoting FERA §4(a), 123 Stat. at 1621).

resulting from a violation of this section constitutes a false or fraudulent claims for purposes of [the False Claims Act]."

454. Violation of the Anti-Kickback Statute rendered the providers ineligible to receive Medicare reimbursement for the submitted claims, particularly where a provider had recertified compliance with the Anti-Kickback Statute after having received any kickback from Defendants or otherwise.

455. Defendants caused such claims to be submitted for reimbursement for Aranesp when the Defendant knew (within the meaning of the FCA) that because of their offering overfill as a kickback such items or units of Aranesp were not eligible for reimbursement in whole or in part, and it was a natural and foreseeable consequence of Defendants' misconduct that providers would submit such claims.

456. Providers submitted such claims as a natural and foreseeable result of the illegal marketing and promotional activity of Defendants described in this Complaint including without limitation, Defendants' making of oral and written statements to providers that showed or illustrated to them the amount of overfill contained in the Aranesp vial, compared the same to the overfill contained in Procrit vials, showed extra reimbursement and profit that could be made from billing the Aranesp single dose vial overfill (versus, *e.g.*, the Procrit multi-dose vial overfill) to Medicare, encouraged the use of standing orders or protocols despite the fact that Aranesp should be dosed according to each particular patient's medical condition, and advised providers how they could "pass an audit" by the Government.

457. The unlawful overfill marketing and promotional activities made by Defendants resulted in claims which failed to disclose the material violations of the Anti-Kickback Statute

and other laws. As a result of this illegal activity, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1)(A).

458. Defendants knowingly caused to be presented false or fraudulent claims for Aranesp resulting from the kickbacks and thereby causing Government Health Care Programs, including the Medicare and Medicaid Programs, to reimburse ineligible claims.

459. Government Health Care Program officials, their contractors, carriers, intermediaries and agents, paid and approved claims for payment for Aranesp that should not have been paid or approved.

460. Defendants, through the means described above, deliberately and intentionally concealed material information, including the false and fraudulent nature of the claims, from officials with Government Health Care Programs, and other Government officials, their contractors, carriers, intermediaries and agents, in order to induce payment of the false and fraudulent claims.

461. Government Health Care Program officials and their contractors, carriers, intermediaries and agents, would not have paid the claims for Aranesp had they known the truth.

462. By reason of the above-described actions and the presentment of false or fraudulent claims, the United States has suffered significant losses in an amount to be determined.

COUNT THREE
FALSE CLAIMS ACT

DEFENDANTS INN AND ASD HEALTHCARE

Defendants Knowingly Caused the Submission of False and/or Fraudulent Claims in Violation of 31 U.S.C. § 3729 (a)(1)(A) by Offering Other Kickbacks as Illegal Remuneration to Induce Providers to Purchase Aranesp in Violation of the Anti-Kickback Statute

463. The named Plaintiff, the United States of America, has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the allegations in paragraphs 1 through 462 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

464. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

465. Through the acts and omissions described herein, and from at least on or before September 2003 to the present, Defendants knowingly caused medical providers to present for payment and approval false and/or fraudulent claims to officers of the United States Government, including without limitation, claims submitted to Medicare on CMS Form 1500 claims forms.

466. As described herein, such claims were false and/or fraudulent because:

(a) by signing the form (see, e.g., Box 31), the provider certified that the Aranesp units administered were "medically indicated and necessary for the health of the patient" (see reverse side of claim form), when in fact, they were not and were therefore not reimbursable by Medicare. *See*, *e.g.*, 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"). "Since § 1395y(a)(1)(A) expressly prohibits payment if a provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision." *Mikes*, 274 F.3d at 701; and

(b) The kickbacks by Defendants tainted the services and the resulting claims are false, and materially false, including that medical services provided based on, because of, or by reason of a kickback are *per se* not "reasonable and necessary for the diagnosis or treatment of illness or injury."

467. The submitted CMS 1500 claim forms also contain "misrepresentations" and "false, incomplete or misleading information," or "misrepresent essential information to receive payment," are not "true, accurate and complete," and are based upon "concealment of a material fact," including that the provider was offered and accepted a kickback which tainted the claim and rendered it ineligible for payment. The claim forms are thereby rendered "false" and "fraudulent" within the meaning of the FCA.

468. The submitted CMS 1500 claims forms seek (and have resulted in) payment of government money to which the provider is not entitled and that the Government paid by mistake, which constitutes a violation of the FCA.

469. Violation of the Anti-Kickback Statute renders related claims, such as the submitted CMS 1500 claims forms *per se* false or fraudulent.

470. Violation of the Anti-Kickback Statute rendered the providers ineligible to receive Medicare reimbursement for the submitted claims, particularly where a provider had recertified

compliance with the Anti-Kickback Statute after having received any kickback from Defendants or otherwise.

471. Defendants caused such claims to be submitted for reimbursement for Aranesp when the Defendant knew (within the meaning of the FCA) that because of their offering kickbacks, including compensation, travel, and other valuable benefits, the Aranesp claims were not eligible for reimbursement in whole or in part, and it was a natural and foreseeable consequence of Defendants' misconduct that providers would submit such claims.

472. Providers submitted such claims as a natural and foreseeable result of the illegal marketing and promotional activity of Defendants described in this Complaint including without limitation, Defendants' provision of compensation, travel, and other benefits to providers.

473. The unlawful marketing and promotional activities made by Defendants resulted in claims which failed to disclose the material violations of the Anti-Kickback Statute and other laws. As a result of this illegal activity, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1)(A).

474. Defendants knowingly caused to be presented false or fraudulent claims for Aranesp resulting from the kickbacks and thereby causing Government Health Care Programs, including the Medicare and Medicaid Programs, to reimburse ineligible claims.

475. Government Health Care Program officials, their contractors, carriers, intermediaries and agents, paid and approved claims for payment for Aranesp that should not have been paid or approved.

476. Defendants, through the means described in this Complaint, deliberately and intentionally concealed material information, including the false and fraudulent nature of the claims, from officials with Government Health Care Programs, and other Government officials,

their contractors, carriers, intermediaries and agents, in order to induce payment of the false and fraudulent claims.

477. Government Health Care Program officials and their contractors, carriers, intermediaries and agents, would not have paid the claims for Aranesp had they known the truth.

478. By reason of the above-described actions and the presentment of false or fraudulent claims, the United States has suffered significant losses in an amount to be determined.

COUNT FOUR
FALSE CLAIMS ACT

DEFENDANT AMGEN

Defendant Amgen Knowingly Caused the Submission of False and/or Fraudulent Claims by Providers in Violation of 31 U.S.C. § 3729 (a)(1)(A) Because Such Claims Were Tainted by a False or Fraudulent ASP for Aranesp

479. The named Plaintiff, the United States of America, has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the allegations in paragraphs 1 through 478 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

480. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

481. From at least 2001 to present, Amgen and INN knowingly offered kickbacks to medical providers in the form of overfill contained in vials of Aranesp, and encouraged medical providers to submit claims for payment for the free product.

482. Through the acts and omissions described herein, and from at least on or before January 1, 2005 to the present, the Defendants knowingly caused medical providers to present

for payment and approval false and/or fraudulent claims to officers of the United States Government including without limitation, claims submitted to Medicare on CMS Form 1500 claims forms and other claims submitted for payment from federal funds.

483. As described herein, such claims were false and/or fraudulent because the reimbursement rate at which CMS paid such claims, *i.e.*, the Average Sales Price for the drug, was misrepresented to CMS by Amgen. Defendant Amgen failed to include in its ASP calculation reported to CMS the overfill units of Aranesp provided to and accessible by every customer.

484. Defendant Amgen caused such claims to be submitted for reimbursement for Aranesp when Defendant knew (within the meaning of the FCA) that it had falsely and fraudulently caused the ASP to be higher than it truly was, which made prescribing Aranesp more lucrative for the provider. It was a natural and foreseeable consequence of Defendant's misconduct that providers would submit such claims.

485. Government Health Care Program officials, their contractors, carriers, intermediaries and agents, paid and approved claims for payment for Aranesp that should not have been paid or approved.

486. Defendant Amgen, through the means described above, deliberately and intentionally concealed material information, including the false or fraudulent nature of the claims resulting from the false ASP, from officials with Government Health Care Programs, and other Government officials, their contractors, carriers, intermediaries and agents, in order to induce payment of the false or fraudulent claims.

487. Government Health Care Program officials and their contractors, carriers, intermediaries and agents, would not have paid the claims for Aranesp had they known the truth.

488. By reason of the above-described actions and the submission of claims that were false and/or fraudulent, the United States has suffered significant losses in an amount to be determined.

COUNT FIVE
FALSE CLAIMS ACT

ALL DEFENDANTS

Defendants Knowingly Caused Providers to Make or Use False Records or Statements Material to Payment or Approval of a Claim in Violation of 31 U.S.C. § 3729 (a)(1)(B)

489. The named Plaintiff, the United States of America, has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the allegations in paragraphs 1 through 488 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

490. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

491. Through the acts and omissions described herein, and from at least on or before September 2001 to the present, Defendants knowingly caused medical providers to make or use false records or statements material to payment or approval of a claim, including without limitation, claims submitted to Medicare on CMS Form 1500 claims forms.

492. As described herein, such false records or statements include without limitation, the statements and records alleged above (including in Counts One-Three):

(a) False statements on the CMS 1500 form as to medical necessity;

(b) False statements on the CMS 1500 form as to units administered/services furnished;

(c) False statements on the CMS 1500 form as to the truthfulness, accuracy and completeness of the form, the absence of any material omission or

the concealment of a material fact (including concealment of kickbacks which render the claim ineligible for payment); and

(d) False statements on the Provider Enrollment Agreements as to compliance and continuing compliance with the terms of that agreement. Such false statements include both certifications of compliance with the Anti-Kickback Act at a time when those providers were receiving kickbacks from Aranesp in the form of overfill, as well as providers' failure to notify the government upon accepting overfill from Aranesp subsequent to signing the Provider Enrollment Agreement.

493. Defendants knowingly caused such false records or statements to be made, and knew that such records or statements were material to getting claims for Aranesp paid or approved. Defendants knew (within the meaning of the FCA) that because of their conduct, such claims for Aranesp were not eligible for reimbursement in whole or in part. It was a natural and foreseeable consequence of Defendants' misconduct that providers would submit make or use such records or statements.

494. Providers made or used such records or statements as a natural and foreseeable result of the illegal marketing and promotional activity of Defendants described in this Complaint including without limitation, the manner in which Defendants marketed Aranesp based on overfill and the provision of other kickbacks.

495. Government Health Care Program officials, their contractors, carriers, intermediaries and agents, paid and approved claims for payment for Aranesp that should not have been paid or approved.

496. Defendants deliberately and intentionally concealed the false and fraudulent nature of the claims from officials with Government Health Care Programs, and other Government officials, their contractors, carriers, intermediaries and agents, in order to induce payment of the false and fraudulent claims.

497. Government Health Care Program officials and their contractors, carriers, intermediaries and agents, would not have paid the claims for Aranesp had they known the truth.

498. By reason of the above-described actions and the presentment of false or fraudulent claims, the United States has suffered significant losses in an amount to be determined.

COUNT SIX
FALSE CLAIMS ACT

ALL DEFENDANTS

Defendants Conspired to Violate the False Claims Act by Getting False or Fraudulent Claims Allowed or Paid by the United States in Violation of 31 U.S.C. § 3729 (a)(1)(C)

499. The named Plaintiff, the United States of America, has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the allegations in paragraphs 1 through 498 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

500. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

501. Through the acts and omissions described in this Complaint, and from on or before at least 2003 to the present, Defendants, with each other and with persons known and unknown, knowingly agreed and conspired to defraud the federal and state governments by having false or fraudulent statements, records, certifications, and claims for Aranesp submitted to, paid and approved by Government Health Care Program officials, their contractors, carriers, intermediaries and agents.

502. From on or before 2003 to present, Defendants Amgen, INN, ASD Healthcare (and others) conspired to defraud the United States by knowingly offering kickbacks to medical

providers including in the form of overfill contained in vials of Aranesp and by understating the true ASP of Aranesp. In addition, INN and ASD Healthcare offered sham consultancy agreements, weekend retreats, price concessions/discounts, and/or other services, encouraging medical providers to present, make and/or use claims for payment that were ineligible for reimbursement, and understating the true ASP of Aranesp.

503. From at least 2003 to present, Defendants conspired to defraud the United States by knowingly causing medical providers to submit false certifications to Government Health Care Programs, including the Medicare and Medicaid Programs, that the provider was in compliance with state and federal laws, including the Anti-Kickback Statute.

504. From at least 2003 to present, Defendants conspired to defraud the United States by knowingly causing medical providers to present, make and/or use claims for Aranesp, thereby causing Government Health Care Programs, including the Medicare and Medicaid Programs, to reimburse ineligible claims.

505. By virtue of their conspiratorial agreement, Defendants caused to be presented, made and/or used false or fraudulent claims, and/or false records or statements, including provider certifications, to Government Health Care Programs, including the Medicare and Medicaid Programs, causing the United States to suffer significant damages.

506. The United States is therefore entitled to recover from Defendants treble damages under the federal FCA, in an amount to be proved at trial, plus a civil penalty of at least $5,500 for each violation.

COUNT SEVEN
FALSE CLAIMS ACT

ALL DEFENDANTS

Defendants Made and Caused to be Made Statements Material to a False or Fraudulent Record as Part of a Fraudulent Scheme

507. The named Plaintiff, the United States of America, has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the allegations in paragraphs 1 through 506 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

508. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

509. Through the acts and omissions described in this Complaint, and from on or before at least 2003 to the present, Defendants, with each other and with persons known and unknown, engaged in a overarching fraudulent scheme to systematically reap greater profits by boosting Aranesp sales using manufacturing and sales techniques that were fraudulent. Defendants, as part of this fraudulent scheme, knew that every claim submitted to a Government Health Care Program, would be tainted by Defendants' fraud, and would hence constitute a fraudulent claim under the FCA, thereby causing damages to Government Health Care Programs.

510. Defendants also knew that their statements and records made to medical providers would made and used in connection with a false or fraudulent claim by a medical provider.

CLAIMS ON BEHALF OF THE RELATOR PERSONALLY

COUNT EIGHT
FALSE CLAIMS ACT

AGAINST DEFENDANT AMGEN
Defendant Amgen's Unlawful Retaliation Against Relator Under 31 U.S.C. § 3730(h)

511. Relator restates and realleges the allegations in paragraphs 1 through 510 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

512. As set forth in detail above, Amgen threatened, harassed and otherwise discriminated against Plaintiff/Relator Westmoreland because of her lawful acts involving a potential violation(s) of the False Claims Act by her employer, Amgen. By these actions, Amgen violated the False Claims Act, 31 U.S.C. § 3730(h).

513. Plaintiff/Relator has been damaged as a direct result of these illegal actions. She has suffered great economic harm, loss of income and future earnings, and emotional injury.

514. Amgen's conduct as alleged herein was done knowingly, maliciously, oppressively, and with conscious disregard for the rights of Relator. Therefore, Relator is entitled to recover exemplary and punitive damages against Amgen in an amount to be determined at trial.

COUNT NINE
CALIFORNIA LAW

AGAINST DEFENDANT AMGEN
Defendant Amgen's Wrongful Termination of Relator and Violation of Public Policy Under California Law

515. By this reference, Relator hereby incorporates paragraphs 1 through 514 above, inclusive, as though set forth fully herein.

516. Amgen constructively terminated Relator's employment in March 2005, when Relator was forced to go on disability leave because of the harassment and retaliation that she suffered, as alleged above.

517. Amgen's termination of Relator was wrongful and in violation of public policy under California law because Relator was terminated based on her having voiced her legitimate and serious concerns to Amgen management about various unlawful practices of Amgen as concerned Amgen's relationship and activities with INN, and Amgen's illegal kickbacks, as alleged above.

518. Amgen's wrongful termination of Relator was done in violation of numerous laws and public policies, including (1) those that prohibit employer retaliation against employees who refuse to participate in unlawful activities (*e.g.*, Cal. Labor Code § 1102.5(c)); (2) those that protect an employee from retaliation by an employer based on the employee's having complained to management about unlawful activities (*see, e.g.*, *Green v. Ralee Eng. Co.*, 19 Cal. 4th 66, 85, 78 Cal. Rptr. 2d 16, 27 (1998); *Collier v. Superior Court*, 228 Cal. App. 3d 1117, 1123, 279 Cal. Rptr. 453, 455 (1991)); and (3) those that require a licensed pharmacist (like Relator) to adhere to various professional and ethical standards and precepts.

519. As a direct and proximate result of Amgen's wrongful conduct as alleged herein, Relator has suffered harm, including, but not limited to, lost past and future earnings, lost employment benefits (*e.g.*, health insurance benefits, and retirement contributions, job-search expenses, humiliation, embarrassment, mental anguish, and severe emotional distress – all to her damage in an amount to be determined at trial.

520. Amgen's conduct as alleged herein was done knowingly, maliciously, oppressively, and with conscious disregard for the rights of Relator. Therefore, Relator is

entitled pursuant to § 3294 of the California Civil Code to recover exemplary and punitive damages against Amgen in an amount to be determined at trial.

PRAYERS FOR RELIEF

WHEREFORE, Relator, acting on behalf of and in the name of the United States of America, and on her own behalf, demands and prays that judgment be entered as follows:

(a) In favor of the United States against the Defendants jointly and severally for treble the amount of damages to Government Health Care Programs from the illegal marketing, selling, prescribing, pricing and billing alleged herein, plus maximum civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

(b) In favor of the United States against the Defendants for disgorgement of the profits earned by Defendants as a result of their illegal schemes;

(c) In favor of the Relator for the maximum amount allowed as a Relator's share pursuant to 31 U.S.C. § 3730(d) and in favor of Relator against Defendants for reasonable expenses, attorneys' fees and costs incurred by Relator;

(d) In favor of the Relator and the United States and against the Defendants for all costs of this action;

(e) In favor of the Relator and the United States and against the Defendants for such other and further relief as this Court deems to be just and equitable;

(f) In favor of the Relator for the maximum amount allowed as a Relator's share pursuant to the State FCAs as follows: Cal. Gov't Code 12652(g); Del. Code Ann. Tit. 6, § 1205; D.C. Code § 2-308.14(f); Fla. Stat. § 68.085; Official Code of Georgia Annotated, 49-4-168; Haw. Rev. Stat. § 661-27; 740 Ill. Comp. Stat.

§ 175/4(d); IC 5-11-5.5; 46 La. Rev. Stat. c. 3, § 437.1 et seq.; Mass. Gen. Laws Ch. 12, § 5F; Nev. Rev. Stat. §§ 357.210, 357.220, MI ST Ch. 400; N.H. RSA §§ 167:61-b; N.M. Legis 49 (2004); Chapter 4, NY laws 58, s. 39, Art. XIII, §189; Tenn. Code Ann. § 71-5-183(c); Tex. Hum. Res. Code § 36.110, and Va. Code Ann. § 8.01-216.7;

(g) In favor of the Relator and against the Defendants for all costs and expenses associated with the supplemental State claims, including attorneys' fees and costs;

(h) In favor of the State Plaintiffs and the Relator and against the Defendants for all such other relief as the Court deems just and proper; and

(i) In favor of Relator Westmoreland against Defendant Amgen for all available damages and relief under 31 U.S.C. § 3730(h), and California law, including, without limitation, two times back pay plus interest (and prejudgment interest), reinstatement or in lieu thereof front pay, and compensation for any special damages and/or exemplary or punitive damages, and litigation costs, and attorneys' fees.

PLAINTIFF/RELATOR DEMANDS A TRIAL BY JURY ON ALL COUNTS

May 27, 2010

Respectfully submitted,

RELATOR KASSIE WESTMORELAND

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on May 28, 2010.

/s/ Silvija A. Strikis