

**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;
AMERISOURCEBERGEN SPECIALTY GROUP;
ASD HEALTHCARE; and
AMERISOURCEBERGEN CORPORATION,

Defendants.

CIVIL ACTION NO.

06-10972-WGY

JURY TRIAL DEMANDED

RELATOR'S SECOND AMENDED FALSE CLAIMS ACT 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 Federal Civil False Claims Act, 31 U.S.C. §§ 3729-33 ("Federal FCA" or "FCA"), and on behalf of the States of Georgia, New Mexico, and Texas, under their respective State False Claims Acts ("State FCAs") (together referred to herein as "*Qui Tam* Action").

Pursuant to 31 U.S.C. § 3730(b)(2), and comparable provisions in the State FCAs, this action was brought *in camera* and under seal. Relator also alleges on her own behalf that Defendant Amgen retaliated against her in violation of the anti-retaliation provisions of the federal False Claims Act, 31 U.S.C. § 3730(h) and California law.

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").

3. As more fully described below, Aranesp is an injectable prescription drug developed and manufactured by Defendant Amgen. 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.

5. At all times relevant to this Complaint, Aranesp was marketed to medical providers by Defendant Amgen with assistance from Defendants International Nephrology Network ("INN"), a group purchasing organization, and ASD Healthcare, a distributor. The drug is usually purchased directly or indirectly by providers from entities such as INN's parent, Defendant AmerisourceBergen Corporation and its subsidiaries, Defendants AmerisourceBergen Specialty Group and ASD Healthcare. The medical provider then seeks reimbursement for the drug from federal and state governmental health insurance programs, such as Medicare and Medicaid.

6. As a direct, proximate and foreseeable result of Defendants' fraudulent course of conduct set forth herein and conducted on a national scale, the 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 drugs Aranesp from at least September 2002 through at least mid-March 2005, when Relator was actively employed by Defendant Amgen. On information and belief, and based on the Multi-State Complaint in Intervention incorporated herein by reference, the practices complained of herein are continuing. As detailed below and in the Multi-State Complaint in Intervention, Defendants' actions and omissions have caused improper and illegal billings to the United States and to the State Plaintiffs named herein. For the years 2001-2008, Amgen's aggregate United States revenues from Aranesp totals over \$11 billion, with approximately \$6 billion coming from federal and state health care programs such as Medicaid and Medicare.

7. By their actions, the Defendants have violated several laws, including without limitation, the Federal and State FCAs, the Medicare and Medicaid Patient Protection Act (also known as the Anti-Kickback Statute), and similar Anti-Kickback laws of the Plaintiff States.

8. The purpose of these unlawful activities was 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 – all of which was done by Defendants in order to increase reimbursement for Aranesp from governmental (and private) health insurance programs.

9. In addition to causing damage to programs such as Medicare and Medicaid, Defendants' actions have also put patient safety and health at risk. The population of patients for whom Aranesp is indicated is especially vulnerable. 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.

10. All of the foregoing unlawful practices are detailed in the pages below and in the Multi-State Complaint in Intervention, the allegations of which are incorporated herein by reference.

JURISDICTION AND VENUE

11. This Court has jurisdiction over this action under the Federal FCA causes of action pursuant to 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. §§ 3732(a) and 3730, and has supplemental jurisdiction over the State FCA causes of action pursuant to 28 U.S.C. § 1367.

12. 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).

13. 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 this Complaint and in the Multi-State Complaint in Intervention,

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).

THE PARTIES

14. The real parties in interest to the FCA *Qui Tam* claims herein are the sovereign governments of the United States of America and each of the named eighteen State Plaintiffs:

(a) Fifteen of the eighteen named State Plaintiffs have as of this date filed notices of intervention in this action, and are this date filing a Multi-State Complaint in Intervention.

Relator incorporates herein by reference that Complaint in Intervention;

(b) The United States of America has filed with this Court a Notice of Not Intervening at this Time (but is continuing its investigation); and

(c) Three of the eighteen State Plaintiffs (namely, Texas, Georgia and New Mexico) have not filed any notice (i.e. of intervention, declination, or not intervening at this time) with the Court as of this date (hereafter the “Uncommitted State Plaintiffs”).

Accordingly, at this time, the Relator is pursuing her Complaint on behalf of the United States and the Uncommitted State Plaintiffs on the FCA *Qui Tam* claims set forth herein pursuant to their respective FCAs. See, e.g., 31 U.S.C. § 3730(c) (3).

15. 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. In addition to pursuing *Qui Tam* claims on behalf of certain of the sovereign Plaintiffs, see supra, Relator is pursuing on her own behalf her claim against Defendant Amgen for unlawfully retaliating against her in her employment in violation of the FCA, 31 U.S.C. § 3730(h), and California law.

16. 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. (Aranesp is contraindicated in patients with uncontrolled hypertension).

17. Defendant International Nephrology Network ("INN") d/b/a Integrated Nephrology Network, is since 2004 a wholly owned subsidiary of Defendant AmerisourceBergen Specialty Group, with its principal place of business in Frisco, Texas. INN is purportedly a "group purchasing organization" ("GPO") that focuses on nephrology practices and physicians. It is now the country's largest such GPO (including in the Commonwealth of

Massachusetts) that sells pharmaceuticals to medical providers and physicians specializing in nephrology. INN originally was directed by Anthony Corrao (a former Amgen employee with close ties to other current Amgen employees--including upper management) and others. Amgen started doing business with INN in 2003. INN now is part of Defendant AmerisourceBergen Specialty Group, the specialty pharmaceutical business arm of Defendant AmerisourceBergen Corporation. INN does business throughout the United States, including in the Commonwealth of Massachusetts.

18. Defendant AmerisourceBergen Specialty Group (“ABSG”), headquartered in Frisco, Texas, is the specialty pharmaceutical business arm of Defendant AmerisourceBergen Corporation (“ABC”) headquartered in Chesterbrook, Pennsylvania (NYSE: ABC) (collectively referred to herein as “AmerisourceBergen”). AmerisourceBergen is one of the largest pharmaceutical service and distribution companies in the United States and serves both pharmaceutical manufacturers and health care providers. ABC does business through numerous subsidiaries including Defendants ABSG and ASD Healthcare, a drug wholesaler, also headquartered in Frisco, Texas. ABC and its subsidiaries operate and conduct business throughout the United States, including in the Commonwealth of Massachusetts.

FEDERAL AND STATE LAWS AND REGULATIONS

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

19. The Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (“AKS”), arose out of congressional concern that the remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and could 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 AKS 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.

20. In 1977, Congress amended the AKS 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 which “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, 3047.¹

21. In 1987, Congress again strengthened the AKS 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.

¹ 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 and the public purse.” 123 Cong. Rec. S31767 (daily ed. Sept 30, 1997)(statement of Sen. Talmadge).

22. The AKS 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).

23. The statute provides, in pertinent part:

(b) Illegal remunerations

* * *

(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.

42 U.S.C. § 1320a-7b(b).

24. In addition to criminal penalties, a violation of the AKS 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).

25. Concern about improper drug marketing practices prompted the Inspector General of the Department of Health and Human Services to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the AKS. *See* Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 29, 1994). In May 2003, the Inspector General of HHS 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.” 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)

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

27. Compliance with the AKS 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 AKS is a *condition of payment* for drug claims administered by physicians for which Medicare or Medicaid reimbursement is sought. *See supra*.

28. Many States also have anti-kickback laws similar to the AKS, which apply to

medical providers and entities participating in their Medicaid programs. E.g., California, Cal. Welf. & Inst. Code § 14107.2; Delaware, Del. Code. Ann. Tit. 31, § 1005; Florida, Fla. Stat. § 409.920(2)(a)(5); Illinois, 305 Ill. Comp. Stat. 5/8A; Louisiana, La. Rev. Stat. Ann. § 46:438.2; Massachusetts, Mass. Gen. Laws ch. 118E, § 41; Michigan, Mich. Comp. Laws § 400.604; New Hampshire, N.H. Rev. Stat. Ann. § 167.61; New York, N.Y. Soc. Serv. Law § 366-d; and Virginia, Va. Code Ann. § 32.1-315.

B. Federal and State False Claims Acts

29. The Federal 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.

30. The Federal 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.

31. The Federal 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.

32. The Federal FCA defines a “claim” to include any request or demand, whether under 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).

33. The Federal 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.”

34. The Federal 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.”

35. Furthermore, the Federal 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.

36. Several states have passed False Claims Act legislation, which in most instances closely tracks the Federal FCA: California False Claims Act, Cal. Gov’t Code § 12650 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, §§ 1201 *et seq.*, District of

Columbia Procurement Reform Amendment Act, D.C. Code §§ 2-308.13 *et seq.*, Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq.*, Official Code of Georgia Annotated, 49-4-168, *et seq.*, Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*, Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*, Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5, Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. c. 3, § 437.1 *et seq.*, Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, §§ 5A *et seq.*, Michigan Medicaid False Claims Act, MI ST Ch. 400, Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*, New Hampshire False Claims Act, N.H. RSA §§ 167:61-b, *et seq.*, New Mexico Medicaid False Claims Act, 2004 New Mexico Laws Ch. 49 (H.B. 468), 2007 New York Laws 58, section 39, Art. XIII, §189, *et seq.*, Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*, Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code §§ 36.001 *et seq.*, and Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.* These State False Claims Acts apply, *inter alia*, to the state portion of Medicaid fraud losses caused by false Medicaid claims to the jointly federal-state funded Medicaid program. Each of the statutes listed above contains *qui tam* provisions governing, *inter alia*, a relator's right to claim a share of the State's recovery.

C. Group Purchasing Organizations

37. 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).

38. 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.

39. 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. Regulations promulgated by the Office of Inspector General of the Department of Health and Human Services 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.

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 does not reflect the actual arrangement between the parties. See generally 42 C.F.R. § 414.802, infra (fees must be “bona fide” to be excluded from Average Sales Price calculations).

40. 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. As noted above, 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. Id.

“‘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.”

Id. When a manufacturer submits its ASP required information to CMS, the manufacturer 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

41. 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”). 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.

42. 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. 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.

43. 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.

44. 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. 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). The Relator incorporates herein by reference the allegations at paragraphs 33-36 of the Multi-State Complaint in Intervention.

45. 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.

46. 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.

47. 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 41-47, and any other government funded healthcare programs, shall be referred to as “Federal Health Care Programs” or “Government Health Care Programs”).

48. 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.

49. 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 (discussed infra) and with other federal laws governing the provision of health care services in the United States. In other words, if a provider tells CMS or its agent that it provided services in violation of the Anti-Kickback Statute or another relevant law, CMS will not pay the claim.

50. For example, 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; Form CMS-8551 (effective 2001). In addition, the claims themselves as submitted contain a similar certification. See, e.g., Form CMS-1500.

51. 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 Statute.

52. In the case of Medicaid, each State's Medicaid Program's applicable certifications also incorporate relevant state law, as detailed in the Multi-State Complaint in Intervention and incorporated herein by reference.

THE RELATOR

53. 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.

54. 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.

55. 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. Relator was Amgen’s Aranesp PSR for the State of Oregon and Southwest Washington. In that capacity she called on nephrology (kidney) practices 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.

56. 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 by phone. Relator had extensive contacts with upper-level Aranesp sales managers and directors through these seminars and staff meetings, as well as countless telephone conferences and emails.

57. Relator worked as an Aranesp PSR for about one and a half years from September 2002 to March 2004. She witnessed first hand and heard about promotion of “overfill” by Defendant Amgen and medical providers billing for Aranesp “overfill”. Defendant Amgen’s

promotion of “overfill” and billing therefor is discussed more fully below and in the Multi-State Complaint in Intervention, the allegations of which are incorporated herein by reference.

58. 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. 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 (GPO) that focused on nephrology practices and physicians. Defendant Amgen’s relationship with Defendants INN and its related entity ASD is discussed more fully below and in the Multi-State Complaint in Intervention, the allegations of which are incorporated herein by reference.

59. As detailed below and in the Multi-State Complaint in Intervention, 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. In the regular course of her employment, Relator had access to email and internal documents and data which describe, document, and reflect the conduct discussed herein. Relator 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 AND THE COMPANY’S
BUSINESS STRATEGY FOR THE ANEMIA MARKET**

60. Defendant Amgen manufactures three anemia products, as detailed herein: Aranesp; Procrit; and Epogen. As to each, the Relator incorporates herein by reference the allegations contained in the Multi-State Complaint in Intervention.

A. Aranesp (Darbepoetin Alfa)

61. 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. Aranesp is an erythropoiesis-stimulating agent (ESA) that stimulates or boosts the production of red blood cells, thereby lowering the risk of anemia.

62. Treatment of anemia is a vital and integral part of the medical care of nephrology and cancer patients. Indeed, left untreated in such patients, anemia can undermine the efficacy of a medical treatment plan, and/or it can lead to severe health consequences for the patient, including death. Aranesp is used 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.

63. 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. 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. 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 B to the Multi-State Complaint in Intervention and incorporated herein by reference. Medical providers who administer Aranesp outpatient use procedure codes as detailed in the Multi-State Complaint in Intervention and incorporated herein by reference.

64. 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. 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 (see below): 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.

65. 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. 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).

66. On or about March 9, 2007, the FDA issued a black box warning for Aranesp, the most serious warning available on 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.

67. 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.

68. 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 current Aranesp label, approved by the FDA on or about November 19, 2008, is attached as Exhibit C to the Multi-State Complaint in Intervention and is incorporated herein by reference.

B. Procrit and Epogen (Epoetin Alfa)

69. 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.

70. In 1985, Amgen contracted with a subsidiary of Johnson & Johnson, Ortho Pharmaceutical Corporation (“J&J”) 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.)

71. 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. 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%.

72. 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. 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 recapture the lost Procrit market. In certain situations, Amgen also has marketed Aranesp as an alternative to its own drug Epogen – i.e., cannibalizing its own Epogen sales – to lay the groundwork for patent and future reimbursement changes that could make Aranesp more profitable to providers than Epogen. As of 2003, approximately 90% of all dialysis patients were receiving Epogen; it was Amgen’s best selling drug with gross sales totaling \$2.4 billion.

73. Amgen, by its subsidiary Amgen Manufacturing, Limited, manufactures Epogen and Procrit, as well as Aranesp. As with Aranesp, Amgen is also responsible for the labeling of Epogen and Procrit and any submissions to the FDA relating to those two drugs

74. On or about March 9, 2007, the FDA issued a black box warning for Epogen and Procrit, the most serious warning available, warning of increased risk for death, of serious cardiovascular or thromboembolic events, and more rapid tumor progressions. The 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. Amgen issued a “Dear Healthcare Provider Letter” to medical providers advising of the revised Epogen and Procrit labeling.

75. 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 to should be individualized to “achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.” Amgen also issued a Dear Healthcare Provider Letter to medical providers advising of the revised Epogen and Procrit labeling.

76. On or about March 7, 2008, the FDA mandated new black box warnings for Epogen and Procrit 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 those cancer patients not receiving chemotherapy or radiation therapy. This revised black box warning clarified that Epogen and Procrit should only be used in cancer patients with anemia specifically caused by chemotherapy, not for other causes of anemia.

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

77. The Relator incorporates herein by reference the allegations contained in the Multi-State Complaint in Intervention, including regarding: “The Overfill Contained in Aranesp Single Dose Vials”; “Amgen’s Manipulation of the Overfill in Epoetin Alfa to Make Aranesp More Competitive”; “Amgen’s National Fraud Scheme to Offer Overfill as an Inducement”; “Claims for Free Aranesp Overfill Have Been Identified by the State Medicaid Programs”; and “Amgen’s Overfill Kickbacks Across New York State Exemplify The National Kickback Scheme”. In addition to her allegations above and those in the Multi-State Complaint, Relator alleges the following.

A. The Clinical Use of Aranesp

78. Aranesp is distributed by Amgen in single dose vials and single dose pre-filled syringes containing liquid solution with a predetermined concentration of the drug. However, not all patients require the same amount of Aranesp. For example, oncology patients typically require a larger 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. Aranesp is generally dosed according to the patient’s weight.

For nephrology patients, the starting dose is 0.45 mcg/kg once weekly and for oncology patients the starting dose is 2.25 mcg/kg once weekly or 500 mcg every three weeks. Approved nephrology dosing is once every two weeks for patients who have already been on EPO once weekly and are getting converted to Aranesp, and once a week for new patients. In each case, the volume of liquid solution 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 syringes – but the amount of Aranesp administered to the patient (*i.e.*, the total micrograms of medicine) varies depending on the drug concentration.

79. 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” and 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. For the entire time that Aranesp has been on the market the USP has recommend overfill *up to* 10%. That is to say 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. However, at all times relevant to this Complaint, each vial of Aranesp contained excessive overfill as detailed in the Multi-State Complaint in Intervention.

80. Aranesp purchasers are charged for the drug based upon the concentration and dosage. Purchasers are *not* charged for the overfill that they receive – *i.e.*, they are not charged for the extra micrograms of drug that are present in the overfill. 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 (and/or a third-party drug provider) for 60 mcg worth of the drug. The physician would 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. However, under Amgen's unlawful marketing scheme, providers were encouraged to and did indeed bill Government Health Care Programs for their free overfill.

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

81. As stated above, reimbursement for Aranesp is provided based on the number of micrograms of Aranesp that were actually administered to the patient; or, in some cases, based on the number of micrograms of Aranesp in the single-dose vial or prefilled syringe that were paid for (even if not all of the micrograms were administered).

82. However, Amgen and the other Defendants have conspired with each other, 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 three reasons:

- (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; and
- (c) when the overfill has been administered, it is unreasonable and medically unnecessary and may endanger patient health and safety (see black box warnings).

For these reasons, Defendants' fraudulent overfill scheme caused providers to seek additional reimbursement which constitutes false and fraudulent billing, or to purchase Aranesp over a

competing, sometimes less expensive drug such as Procrit.

83. 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

84. The Relator has spreadsheets which are examples of how the overfill was calculated and advocated by reps and management. Some of these spreadsheets are attached to the Multi-State Complaint in Intervention at Exhibit D.

85. Relator is aware of other PSRs and INN employees discussing with customers/providers how to fill out the Form CMS 1500---they told the customer to simply write down the dose they administered which would include the overfill, on the Form CMS 1500, even if they did not actually administer the overfill amount.

86. 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 reps 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 reps. For example, Chris Coates of Amgen reported to Relator that Balboa Nephrology of San Diego, CA had never before considered capturing the overfill, but had resolved to do so in the future. Between March and August 2004, Balboa Nephrology, 65% of whose patients used Medicare as their primary insurance, spent \$696,021.60 on Aranesp.

87. Moreover, Relator is aware that some Aranesp customers did, in fact, engage in “overfill billing.” Details of Aranesp overfill billings and purchases are contained in the Multi-

State Complaint in Intervention and are detailed below.

88. Furthermore, upper management of Amgen – including the National Sales Director (“NSD”) for Aranesp and the Director of Marketing for Aranesp – 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 some spreadsheets that included overfill, and Relator witnessed conversations in meetings regarding overfill with the NSD and Marketing Director (among other management).

89. The PSRs would often complain about overfill because they said J&J was actively marketing Procrit with such promotional materials and the Amgen reps wanted some similar materials to market Aranesp overfill. Management would always say Amgen could not come out with official company materials, but instead to talk about it in private with customers and to let Defendant INN discuss it with customers.

90. Nevertheless, in order to have some materials, some Aranesp sales reps 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. As such, the “overfill spreadsheets” typically would compare the reimbursement amounts and spreads for Aranesp + overfill to the reimbursement amounts and spreads for Procrit + overfill. Amgen management saw these spreadsheets and did nothing to prevent the Amgen sales force from using them with their Aranesp accounts.

91. Defendant Amgen (and the other Defendants as discussed below) knew they

could influence the purchaser's choice of drug by using the "overflow" profit contained in each vial of Aranesp compared to that for Procrit or Epogen. Amgen also knew it could manipulate the "overflow" economics because Amgen manufactured all three drugs.

92. This practice of advocating "overflow 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 overflow found in every Aranesp vial were provided by Amgen without any reporting requirement. When Amgen advocated to, and conspired with other Defendants and their customers to engage in "overflow billing," however, the unlawful effect was no different than it would be had Amgen provided its customers with free Aranesp samples and then encouraged them to seek reimbursement for them from Government Health Care Programs.

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

94. If anything, one would reasonably expect there to be more overflow 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.

95. As discussed in more detail below and in the Multi-State Complaint in Intervention, Defendants INN and ASD also improperly advocated and encouraged its/Amgen's customers to seek reimbursement for Aranesp overflow. For example, on March 26-27, 2004 Relator attended a weekend seminar in Carmel, CA that was put on by INN at which the INN representatives openly pushed physicians and office managers to bill for overflow 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.

96. The unlawful “overfill billing” discussed above with respect to Aranesp should be distinguished from how the issue arises with respect to the competing drug Procrit of which Amgen’s PSRS sometimes complained. Specifically, whereas Aranesp is marketed in single-dose vials, Procrit is marketed in multi-dose vials which contemplate that more than one dose will be drawn from the vial.

97. Amgen was aware of the ability of Procrit customers to benefit from administering and billing for the overfill in the *multi-dose* Procrit vials which could even result in an extra dose available from the larger multi-dose vials. Indeed, Amgen did the same with Epogen from the time it was launched in 1993. But, once Aranesp was launched, Amgen improperly condoned and/or encouraged its Aranesp sales force to market the overfill found in the *single-dose vials* of Aranesp, as explained herein and in the Multi-State Complaint in Intervention.

98. Defendant Amgen was aware that promoting billing of “overfill” in Aranesp vials was unlawful, but did it anyway. The Multi-State Complaint in Intervention contains numerous specific examples of communications, meetings, emails and other documents reflecting Amgen’s overfill scheme and Amgen’s knowledge. Those allegations are incorporated herein by reference. Further examples are detailed below.

**AMGEN’S CONSPIRACY WITH INN AND ASD HEALTHCARE TO OFFER
KICKBACKS TO MEDICAL PROVIDERS**

99. Relator incorporates herein by reference the allegations of the Multi-State

Complaint in Intervention, including in particular, the allegations regarding “Amgen’s Conspiracy With INN And ASD Healthcare To Offer Kickbacks To Medical Providers”. In addition to those allegations and the ones above, the Relator alleges as follows.

100. 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. As alleged above, INN originally was directed by Anthony Corrao (a former Amgen employee with close ties to other current Amgen employees--including upper management) and others.

101. 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. 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). In essence, INN’s role was to do the things Amgen could not do and comply with the AKS because INN, as a GPO, purportedly enjoyed a “safe harbor” under the AKS, 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, supra).

102. 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. 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. 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 email 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.”

103. At the same time, INN’s related entity, wholesaler Defendant ASD (which is part of Defendants ABC and ABSG) was knowingly helping Amgen reps and INN get customers and vice versa. For example, the ASD rep would “buddy up” with the Amgen rep and tell the Amgen rep that he would give an important customer a better price on Aranesp. The Amgen rep would then use various means and spreadsheets to let this important customer know that if they switched to ASD, they would get a better price on Aranesp. These targets included those already using Aranesp but buying it from another wholesaler (not ASD) or it could be a customer who was using all Procrit and the rep (and INN) were trying to convert their office to Aranesp. (The customer may have been buying Procrit from ASD or another wholesaler). Sometimes ASD would even offer a customer a slight discount on Procrit just to lure them in to ASD, with the main objective being to then convert the account to Aranesp once the customer had switched to

ASD. Defendant ASD was using Aranesp as a “loss leader” for getting the business it really wanted—oncology drugs. As one ASD employee told Relator, he quoted pricing to customers based on how important the customer was to Amgen. Basically, the Defendants were triangulating customers: ASD, Amgen and INN were all targeting the customer from slightly different angles and the customer had no idea that the different reps were talking to each other and sharing information, and that each company was attempting to direct business to the other(s).

104. 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. 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.

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

Procrit and at times Epogen.

106. At or about the same time, 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. 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.

107. Nevertheless, INN reps 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.

108. INN would prepare Practice Assessment Forms and then, unbeknownst to the physician, would share the results with Amgen and the Defendants would formulate a plan to get the doctor to switch to Aranesp. As part of their conspiracy with Amgen, INN would audit target clinics and, under the pretense of acting as an independent GPO, prepare "Practice Assessment" forms providing management advice. Unbeknownst to the target clinic, INN would share the results with Amgen and the Defendants would then formulate a plan to have the clinic switch to Aranesp. 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. In a side report, INN prepared for Amgen,

there was an “immediate opportunity” to “Expand CKD program and shift to Aranesp.” This is the practice whom Chris Coates reported to Relator had never before considered capturing the overflow but had resolved to do so in the future (see supra);

(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 5 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 and spent \$231,240.00 on Aranesp in the month of October 2004. Rockland Renal is one of the specific provider examples detailed in the Multi-State Complaint in Intervention, and below under “Claims Submitted and Damages Caused to Government Health Care Programs”.

109. In an email 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 “These 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 email of November 26, 2004 Gary Inglese sent Ray Chow three documents 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®”

The INN Growth Report, also attached to the email, 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 is 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.”

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

- (i) “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
- (ii) “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. 126. An email from Eric Price, Aranesp Team Product Manager before Relator took over

the position, on February 13, 2004 set out the cost of some of the services which 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

	<i>2003</i>	<i>2004</i>	<i>Program Total</i>
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	<u>\$1,944,400</u>	<u>\$1,912,565</u>	<u>\$3,856,965</u>
	budget	\$1,800,000	
	current spend	\$1,734,565	
	remainder	<u>\$65,435</u>	

In addition, Amgen employees and INN reps would do “chart audits” of patient records/charts in offices and clinics in an attempt to find additional patients who might be “candidates” for Aranesp.

111. In addition to the conduct alleged above which operated as illegal inducements or kickbacks, 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 Defendant INN. These seminars and retreats ostensibly were done 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.

112. 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.

113. 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.

114. Amgen’s internal documents show, and Relator knows from first hand 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.

115. The Multi-State Complaint in Intervention contains numerous specific examples of communications, meetings, emails and other documents reflecting Amgen's conspiracy with INN and ASD Healthcare. Those allegations are incorporated herein by reference. By way of further example, Relator offers the following:

(a) Relator has notes of several meetings or conversations where representatives of Amgen, INN, and/or ASD discussed the overfill in Aranesp single use vials, how it compared to the overfill in multi-dose Procrit vials and to the overfill in Aranesp prefilled syringes, marketing and billing of the Aranesp overfill, and customers' reactions to this marketing. Among her notes are the following: 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 email 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, Corrao) discussed changing the INN administrative fee and the purpose or use to be made of the fee. From these meetings, as well as evidence cited in the Multi-State Complaint in Intervention and in this Complaint, it is apparent Amgen, INN, and ASD were using the administrative fee to fund additional discounts of between at least 1-3% that were to be passed through to certain customers (through INN and/or ASD) to obtain or retain their business, as well as to enable INN to fund medical education programs and the other activities detailed herein. In these conversations, there are also references to assertions that INN was in a “safe harbor” but Amgen was not. Among these meetings are: June 21, 24, 25-28, and July 19 and 21, 2004.

(d) There is an email from Frank Messana of Amgen on November 3, 2004, to Chuck Halstenson, Executive Director of the National Renal Administrators Association, stating “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.”

**CLAIMS SUBMITTED AND DAMAGES CAUSED TO GOVERNMENT
HEALTH CARE PROGRAMS**

116. The Defendants’ actions described above and in the Multi-State Complaint in Intervention 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. Claims filed with the Government Health Care Programs have contained false and fraudulent statements and material omissions and Amgen caused medical providers who accepted their to file false certifications with Government Health Care Programs that they were in compliance with the AKS. 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 under the guise of a GPO agreement. Moreover, Aranesp is expensive. According to an Amgen document dated August 10, 2004, Aranesp was 43% more expensive than Procrit.

117. By Defendant Amgen directing business to Defendants INN and ASD, and INN and ASD 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.

118. 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 AKS. 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.”

119. 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.

120. Relator incorporates herein by reference the allegations of the Multi-State Complaint in Intervention, including in particular the “Claims for Free Aranesp Overfill Have Been Identified by the State Medicaid Programs”, “Amgen’s Overfill Kickbacks Across New York State Exemplify The National Kickback Scheme”, and the “Damages to the State Medicaid Programs” allegations.

121. Defendants’ overfill and other inducements caused medical providers to submit false provider certifications that they were in compliance with the federal and state anti-kickbacks laws. Compliance with the anti-kickback laws is a precondition to payment by the Medicare and Intervening Plaintiff State Medicaid programs, and by other Government Health Care Programs. By virtue of Defendants’ overfill inducements to medical providers, the Medicare program, the Plaintiff States’ Medicaid programs, and other Government Health Insurance Programs: (1) reasonably and foreseeably paid medical providers for free 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.

122. By way of example, and in addition to the examples of Medicare and Medicaid billing alleged in the Multi-State Complaint in Intervention, Relator offers the following Tables I, II, and III 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; and

(d) **Table IV** shows Medicare Part A and Part B Aranesp claims submitted and reimbursement amounts for one of the practices (Rockland Renal Associates) discussed in the Multi-State Complaint in Intervention and in Table II.

TABLE I

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

	<u>Claims</u>	<u>Disbursements</u>
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	<u>\$413,708,136.54</u>	<u>\$147,465,866.00</u>
	\$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 5353 Mission 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 72 nd Street Suite 200 Miami, FL 33173	6 physicians	December 23, 2003	Primarily nephrology but it also has a significant portion of internal	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
			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 91205	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.
Milwaukee	11 physicians,	December	Nephrology	80% of the	Spent \$11,060.28 on

Practice	Details	Date of Assessment	Specialty	Medicare Population	Purchase
Nephrologists, SC St. Luke's Health Science Building 2901 W. Kinnickinnic River Prkwy Ste. 405 Milwaukee, WI 53215	2 nurse practitioners (hospital based), 4 nurses (dialysis center based), 1.5 billing staff, 5.5 receptionist/se c, 1.0 Other Office Staff	11, 2003		patients have Medicare as their primary insurance.	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 Named Plaintiff States:

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,	Spent \$ 118,316.40 on Aranesp between March and

CA	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,	Spent \$50,194.20 on Aranesp between September 1,

Las Vegas, NV	2003 and August 31, 2004.
NEW MEXICO²	
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,

² The New Mexico accounts may not be INN members.

	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.
MONTANA	
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	Spent \$8,618.40 on Aranesp in May 2004.

Lehigh Valley, Easton, PA	
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
Centerrock 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
					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

JONATHAN S WOLF
STEVEN B YABLON
KENNETH S SHAPIRO

UPIN	year of Data					
	2006		2007		2008	
	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt
	177	\$471,583	231	\$699,640	93	\$234,847
	95	\$225,889	124	\$293,315	51	\$107,631
	992	\$2,355,107	1,452	\$3,576,475	484	\$1,177,431

DEFENDANT AMGEN'S UNLAWFUL RETALIATION AGAINST RELATOR

123. 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.

124. 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.

125. At or about the same time, Relator learned that INN's related entity, wholesaler Defendant ASD (which is part of Defendants 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. This "marketing" technique was employed both with respect to purchasers who already were using Aranesp but buying it from another wholesaler (not ASD), and with respect to

prospective customers who were using Procrit, which the sales representative (and INN) were trying convert to Aranesp. Relator learned that ASD would even offer prospective customers discounts on Procrit to lure that customer to become affiliated with ASD, with the main objective being to convert the account to Aranesp once the customer had switched to ASD. ASD, 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.

126. 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. 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. 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.

127. 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. In conjunction with Amgen, INN sold this “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.

128. 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 with 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. 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. INN 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. In addition, Amgen employees and INN representatives together would conduct “chart audits” of patient records/charts in doctor’s offices and clinics.

129. 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.

130. In Fall 2004, Relator approached her immediate supervisor, Laurence “Matt” Skelton (“Skelton”), and told 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. At about the same time, Relator communicated these same concerns to another of her supervisors, Ray Chow (“Chow”). Relator had multiple discussions with both Skelton and 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.

131. 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. 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 Skelton and/or Chow to “stay out of it,” that it “wasn’t Relator’s problem anymore because INN was now being handled by someone else.” The more Relator continued to express her concerns regarding INN, the more Skelton and Chow became nervous and uncomfortable being around Relator. Indeed, 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.”

132. 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 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. 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. 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.

133. Despite the fact that Relator had followed company policy and directives regarding her expense account, Skelton and Chow advised Relator that she would be expected to reimburse Amgen for certain items that were deemed inappropriate business expenses. Relator complained to Skelton and Chow that she was the only Project Manager being singled out in that fashion, and that Relator's expense accounting procedures were no different from any of the other Product Managers. Relator was particularly concerned about her expense audit, because 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. When Relator told Skelton and Chow that she expected any expense audit to be conducted by the appropriate finance department supervisors, Plaintiff was subjected to verbal threats and abuse by Skelton and Chow. Relator thereafter was told by 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.

134. 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.

135. 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., section 3730(h), as set forth below.

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

LEGAL CLAIMS FOR RELIEF

137. Relator alleges that Defendants' conduct detailed above (including the allegations of the Multi-State Complaint in Intervention that are also incorporated in this Second Amended Complaint by reference) violates the False Claims Act ("FCA") of the United States, 31 U.S.C. §§ 3729-3733, as amended (Counts One and Two) and the FCAs of the three Uncommitted State Plaintiffs (Counts Four through Ten). In addition, she brings personal claims against Defendant Amgen for retaliating against her in violation of 31 U.S.C. § 3730(h) and California law (Counts Eleven and Twelve).

CLAIMS ON BEHALF OF THE UNITED STATES OF AMERICA

COUNT ONE

FEDERAL FALSE CLAIMS ACT

(Presentation of False and/or Fraudulent Statements, Records, Certifications and Claims in Connection with Violation of Anti-Kickback Laws),
31 U.S.C. § 3729 (a)(1)(A) and (B)

138. 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 137 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

139. This is a claim for treble damages and monetary penalties pursuant to the False

Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

140. Through the above-described acts and omissions, and from at least on or before September, 2001 to the present, the Defendant Amgen knowingly caused to be presented for payment and approval false and/or fraudulent claims to officers of the United States Government, in that Amgen caused to be presented claims to obtain reimbursement for Aranesp when the Defendant knew such items were not eligible for reimbursement or not eligible in part. Aranesp prescriptions would not have been presented but for the unlawful promotional activities made by Defendant and the kickback activity and resulted in claims which failed to disclose the material violations of the AKS 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) and (B)

141. From at least 2003 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.

142. From at least 2003 to present, Amgen, INN and ASD Healthcare knowingly offered kickbacks to medical providers, including sham consultancy agreements, weekend retreats, and/or other services, to induce Aranesp sales and prescriptions.

143. Defendants knowingly caused to be presented and/or caused to be made or used false certifications to Government Health Care Programs, including the Medicare and Medicaid Programs, that the medical providers were in compliance with state and federal laws, including the Anti-Kickback Statute.

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

145. 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.

146. The Defendants, through the means described above, 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.

147. 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.

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

COUNT TWO
FEDERAL FALSE CLAIMS ACT
(Conspiring to Violate the False Claims Act),
31 U.S.C. § 3729 (a)(1)(C)

149. 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 148 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

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

151. Through the above-described acts and omissions, and from on or before at least 2003 to the present, the Defendants, with each other and with persons known and unknown, knowingly agreed and conspired to defraud the federal and state governments by having false

and fraudulent statements, certifications, and claims for Aranesp submitted to, paid and approved by Government Health Care Program officials, their contractors, carriers, intermediaries and agents.

152. From 2003 to present, Defendants Amgen, INN and ASD Healthcare conspired to defraud the United States by knowingly offering kickbacks to medical providers in the form of overfill contained in vials of Aranesp, sham consultancy agreements, weekend retreats, and/or other services, and encouraging medical providers to present, make and/or use claims for payment that were ineligible for reimbursement.

153. From 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.

154. From 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.

155. 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, Government Health Care Programs, including the Medicare and Medicaid Programs, causing the United States to suffer damages.

156. 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.

CLAIMS ON BEHALF OF THE STATE OF GEORGIA

**COUNT THREE
GEORGIA STATE FALSE MEDICAID CLAIMS ACT**

(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
Article 7B, Chapter 4, Title 49 of the Official Code of Georgia Annotated

157. Relator restates and realleges the allegations contained in Paragraphs 1 through 156 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

158. The Georgia State False Medicaid Claims Act, Official Code of Georgia Annotated, 49-4-168, *et seq.*, specifically provides, in part at 49-4-168.1, that:

(a) Any person who:

- (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program ...

shall be liable to the State of Georgia for a civil penalty of not less than \$5,500.00 and not more than \$11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

159. From 2002 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.

160. From 2003 to present, Amgen, INN and ASD Healthcare knowingly offered kickbacks to medical providers, including sham consultancy agreements, weekend retreats, and/or other services, to induce Aranesp sales and prescriptions.

161. Defendants knowingly caused to be presented and/or caused to be made or used false certifications to the Medicaid program that the medical providers were in compliance with state and federal laws, including the Anti-Kickback Statute.

162. Defendants knowingly caused to be presented and/or caused to be made or used claims for the overfill amounts contained in Aranesp vials thereby causing the Medicaid program to reimburse ineligible claims.

163. By virtue of the false or fraudulent claims, and/or false records or statements, including provider certifications, presented and caused to be presented, the State of Georgia suffered damages.

164. Therefore, the State of Georgia is entitled to recover from Defendants treble damages under the Georgia FCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT FOUR
GEORGIA STATE FALSE MEDICAID CLAIMS ACT

(Conspiring to Cause the Submission of False Claims)
Article 7B, Chapter 4, Title 49 of the Official Code of Georgia Annotated

165. Relator restates and realleges the allegations contained in Paragraphs 1 through 164 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

166. The Georgia State False Medicaid Claims Act, Official Code of Georgia Annotated, 49-4-168, *et seq.*, specifically provides, in part at 49-4-168.1, that:

(a) Any person who:

(3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid...

shall be liable to the State of Georgia for a civil penalty of not less than \$5,500.00 and not more than \$11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

167. From 2003 to present, Amgen, INN, and ASD Healthcare conspired to defraud the State of Georgia by knowingly offering kickbacks to medical providers in the form of overfill contained in vials of Aranesp, sham consultancy agreements, weekend retreats, and/or other services, and encouraging medical providers to present, make and/or use claims for payment that were ineligible for reimbursement.

168. From 2003 to present, Defendants conspired to defraud the State of Georgia by knowingly causing medical providers to submit false certifications to the Medicaid program that the provider was in compliance with state and federal laws, including the Anti-Kickback Statute.

169. From 2003 to present, Defendants conspired to defraud the State of Georgia by knowingly causing medical providers to present, make and/or use claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

170. 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 the Medicaid program, causing the State of Georgia to suffer damages. The State of Georgia is therefore entitled to recover from Defendants treble damages under the Georgia FCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

CLAIMS ON BEHALF OF THE STATE OF NEW MEXICO

COUNT FIVE

NEW MEXICO FALSE CLAIMS ACT

(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)

N.M. Legis 49 (2004) Chapter 4

171. Relator restates and realleges the allegations in paragraphs 1 through 170 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

172. The New Mexico Medicaid False Claims Act, N.M. Legis 49 (2004) Chapter 4, specifically provides, in part, that by certain acts “a person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains because of the act if that person [including]:

4A. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent claim;

4B. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program;

4C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

173. From 2003 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.

174. From 2003 to present, Amgen, INN and ASD Healthcare knowingly offered kickbacks to medical providers, including sham consultancy agreements, weekend retreats, and/or other services, to induce Aranesp sales and prescriptions.

175. Defendants knowingly caused to be presented and/or caused to be made or used false certifications to the Medicaid program that the medical providers were in compliance with state and federal laws, including the Anti-Kickback Statute.

176. Defendants knowingly caused to be presented and/or caused to be made or used claims for the overfill amounts contained in Aranesp vials thereby causing the Medicaid program to reimburse ineligible claims.

177. By virtue of the false or fraudulent claims, and/or false records or statements, including provider certifications, presented and caused to be presented, the State of new Mexico suffered damages and therefore is entitled to recover from Defendants treble damages under the DCFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT SIX
NEW MEXICO STATE FALSE MEDICAID CLAIMS ACT
(Conspiring to Cause the Submission of False Claims)
sN.M. Legis 49 (2004) Chapter 4

178. Relator restates and realleges the allegations in paragraphs 1 through 177 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

179. The New Mexico Medicaid False Claims Act, N.M. Legis 49 (2004) Chapter 4, specifically provides, in part, that by certain acts “a person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains because of the act if that person [including]:

4D. conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent; [and/or]

180. From 2003 to present, Amgen, INN, and ASD Healthcare conspired to defraud the State of New Mexico by knowingly offering kickbacks to medical providers in the form of overfill contained in vials of Aranesp, sham consultancy agreements, weekend retreats, and/or other services, and encouraging medical providers to present, make and/or use claims for payment that were ineligible for reimbursement.

181. From 2003 to present, Defendants conspired to defraud the State of New Mexico by knowingly causing medical providers to submit false certifications to the Medicaid program that the provider was in compliance with state and federal laws, including the Anti-Kickback Statute.

182. From 2003 to present, Defendants conspired to defraud the State of New Mexico by knowingly causing medical providers to present, make and/or use claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

183. 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 the Medicaid program, causing the State of New Mexico to suffer damages. The State of New Mexico is therefore entitled to recover from Defendants treble damages under the Georgia FCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

CLAIMS ON BEHALF OF THE STATE OF TEXAS

COUNT SEVEN

TEXAS MEDICAID FRAUD PREVENTION ACT

Tex. Hum. Res. Code § 36.002(1)-(2)

(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)

184. Relator restates and realleges the allegations in paragraphs 1 through 183 above as

if each were stated herein in their entirety and said allegations are incorporated herein by reference.

185. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001(1), specifically provides, in part, that a person commits an unlawful act if the person:

- (1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized.

The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001(2), specifically provides, in part, that a person commits an unlawful act if the person:

- (2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the payment or benefit that is authorized.

The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.0011, specifically provides, in part, that a person acts “knowingly” with respect to information if the person:

- (1) has knowledge of the information;
- (2) acts with conscious indifference to the truth or falsity of the information; or
- (3) acts in reckless disregard of the truth or falsity of the information.

186. Defendants knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Texas Medicaid program, and knowingly concealed or failed to disclose information on claims for payment in violation of Tex. Hum. Res. Code § 36.002 (1)-(2).

187. The State of Texas paid said claims and has sustained damages, to the extent of its

portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendants.

COUNT EIGHT
TEXAS MEDICAID FRAUD PREVENTION ACT
(Conspiring to Cause the Submission of False Claims)
Tex. Hum. Res. Code § 36.002(4)(B)

188. Relator restates and realleges the allegations in paragraphs 1 through 187 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

189. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(4)(B), specifically provides, in part, that a person commits an unlawful act if the person:

(4) knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

...

(B) Information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program.

190. Defendants by knowingly causing to be made, inducing, and seeking to induce the making of false statements and misrepresentations of material facts concerning information required to be provided by state and federal law, rule, regulation and provider agreements pertaining to the Medicaid program, are in violation of Tex. Hum. Res. Code § 36.002(4)(B).

191. The State of Texas paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINE
TEXAS MEDICAID FRAUD PREVENTION ACT
(Kickbacks)
Tex. Hum. Res. Code § 36.002(5)

192. Relator restates and realleges the allegations in paragraphs 1 through 191 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

193. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(5), specifically provides, in part, that a person commits an unlawful act if the person:

(5) except as authorized under the Medicaid program, knowingly charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program

194. Defendants knowingly and intentionally paid and received kickbacks, gifts, money, or other consideration as a condition of service to a Medicaid recipient, in violation of Tex. Hum. Res. Code §36.002(5).

195. The State of Texas paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TEN
TEXAS MEDICAID FRAUD PREVENTION ACT
(Conspiracy to Defraud)
Tex. Hum. Res. Code § 36.002(9)

196. Relator restates and realleges the allegations in paragraphs 1 through 195 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

197. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(9), specifically provides, in part, that a person commits an unlawful act if the person:

(9) knowingly enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program

198. Defendants knowingly and intentionally conspired to defraud the State of Texas by aiding another person in obtaining an unauthorized payment from the Medicaid program, in violation of Tex. Hum. Res. Code § 36.002(9).

199. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendants.

CLAIMS ON BEHALF OF THE RELATOR PERSONALLY

**COUNT ELEVEN
FEDERAL FALSE CLAIMS ACT
(Defendant Amgen's Unlawful Retaliation Against Relator),
31 U.S.C. § 3730(h)**

200. Relator restates and realleges the allegations in paragraphs 1 through 199 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

201. 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).

202. 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.

203. 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 TWELVE
CALIFORNIA LAW**

(Defendant Amgen's Wrongful Termination of Relator),
Violation of Public Policy Under California Law

204. By this reference, Relator hereby incorporates paragraphs 1 through 203 above, inclusive, as though set forth fully herein.

205. 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.

206. 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.

207. 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.

208. 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.

209. 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 Section 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 the Not Intervening at this Time State Plaintiffs, and on her own behalf, demands and prays that judgment be entered as follows against the Defendants under the Federal FCA Counts and under supplemental State FCA Counts and on her personal claims, 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 pursuant to 31 U.S.C. § 3730(d) to include reasonable expenses, attorney fees and costs incurred by Relator;
- (d) For all costs of the Federal FCA civil action;
- (e) In favor of the Relator and the United States for such other and further relief as this Court deems to be just and equitable;
- (f) In favor of the Relator and the State of Georgia against Defendants jointly and severally in an amount equal to three times the amount of damages that Georgia has sustained, respectively, as a result of the Defendants' actions, as well as the statutory maximum civil penalty against the Defendants for each violation of Georgia's State's FCA;
- (g) In favor of the Relator and the Plaintiff State of Texas against Defendants jointly and severally in an amount equal to two times the amount of damages that Texas has sustained as a result of the Defendants' actions, as well as a civil penalty against the Defendants of a statutory maximum for each violation of Tex. Hum. Res. Code § 36.002;
- (h) In favor of the Relator and the State of New Mexico against the Defendants jointly and severally in an amount equal to three times the amount of damages that New Mexico has sustained, respectively, as a result of the Defendants' actions, as well as the statutory maximum civil penalty against the Defendants for each violation of New Mexico's State's FCA;

- (i) 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;
- (j) In favor of the Relator for all costs and expenses associated with the supplemental State claims, including attorney's fees and costs;
- (k) In favor of the State Plaintiffs and the Relator for all such other relief as the Court deems just and proper; and
- (l) In favor of Relator Westmoreland against Defendant Amgen under Counts Eleven and Twelve for all available damages and relief under 31 U.S.C. section 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

Dated: October 30, 2009

Respectfully submitted,

/s/ Suzanne E. Durrell

Suzanne E. Durrell
(Mass. BBO #139280)
DURRELL LAW OFFICE
180 Williams Avenue
Milton, Massachusetts 02186
(617) 333-9681
Fax: (617) 333-0014
Email: Suzanne.durrell@verizon.net

/s/ Robert M. Thomas, Jr.

Robert M. Thomas, Jr.
(Mass. BBO #645600)
THOMAS & ASSOCIATES
280 Summer Street, 5th Floor
Boston, MA 02210-1131
(617) 371-1072
Fax: (888) 676-7420
Email: rmt@thomasandassoc.net

/s/ Rory Delaney

Rory Delaney (BBO #655666)
33 Broad Street, 5th Floor
Boston, MA 02109
(857) 498-0384
Email: rory@rorydelaney.com

/s/ Charles F. Kester

Charles F. Kester

(CA Bar #157763)

Lawrence M. Isenberg

(CA Bar #137339)

KESTER & ISENBERG

Encino Financial Center

16133 Ventura Boulevard, Suite 260

Encino, California 91436

(818) 728-3300

Fax: (818) 728-3311

Emails ckester@kesterisenberg.com

lisenberg@kesterisenberg.com