

**UNITED STATES DISTRICT COURT
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; and 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.)
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CIVIL ACTION NO.
06-10972-WGY

**JURY TRIAL
DEMANDED**

MULTI-STATE COMPLAINT IN INTERVENTION

The Plaintiff States of California, Delaware, Florida, Hawaii, Illinois, Indiana, Louisiana, Michigan, Nevada, New Hampshire, New York, Tennessee, the Commonwealths of Massachusetts and Virginia and the District of Columbia (hereafter referred to as “the Intervening Plaintiff States”) bring this action to recover losses from false claims and fraudulent certifications submitted to the state Medicaid programs as a result of the fraudulent course of conduct of the defendants, Amgen, Inc. (“Amgen”), International Nephrology Network, and its parent corporations AmerisourceBergen Specialty Group, and AmerisourceBergen Corporation

(collectively “INN”), and ASD Healthcare, and its parent corporations AmerisourceBergen Specialty Group, and AmerisourceBergen Corporation (collectively “ASD Healthcare”) in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), the Intervening Plaintiff States’ False Claims Acts (the “FCAs”), the Intervening Plaintiff States’ anti-kickback laws and common law in selling and promoting Amgen’s anemia drug, Aranesp (darbepoetin alfa).

Beginning in at least 2002 and continuing to the present, Amgen illegally offered kickbacks to medical providers in the form of free Aranesp product so as to induce them to purchase and prescribe Aranesp. By knowingly offering these inducements to medical providers to increase its Aranesp sales, Amgen caused medical providers to submit false certifications to the state Medicaid programs that the providers were in compliance with state and federal laws, including the Anti-kickback Statute. Amgen’s kickbacks to providers caused at least thousands of ineligible Medicaid claims for Aranesp to be paid by the Intervening Plaintiff States.

In furtherance of its kickback scheme, in 2003, Amgen entered into a financial relationship with INN, a purported group purchasing organization for nephrology specialists, in which Amgen paid INN to market Aranesp to its customers and convert customers from the competing anemia drug, Procrit. INN conspired with Amgen and its preferred distributor, ASD Healthcare, to offer illegal inducements to its member-customers in order to increase sales of Aranesp. As a result of their conspiracy to offer kickbacks to medical providers to increase Aranesp purchases and prescriptions, Amgen, INN, and ASD Healthcare caused false provider certifications and non-payable claims for reimbursement to be submitted to the state Medicaid programs and Medicare program.

NATURE OF THE ACTION

1. The Intervening Plaintiff States bring this action to recover treble damages and civil penalties under the states' False Claims Act laws for violations of the federal and state Anti-Kickback laws, and to recover damages and other monetary relief under the common law or equitable theories of common law fraud and unjust enrichment.

2. The Intervening Plaintiff States base their claims on defendants Amgen, INN and ASD Healthcare causing the submission of false or fraudulent claims to the state Medicaid programs in violation of: the California False Claims Act, Cal. Govt. Code § 1265(a)(1) and (2); the Delaware False Claims and False Reporting Act, 6 Del C. § 1201(a)(1) and (2); the Florida False Claims Act, Fla. Stat. § 68.082(2); the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a); the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(1)-(3); the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-1, *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. R.S. 46:438.1, *et seq.* and 46:439.1, *et seq.*; the Michigan Medicaid False Claims Act, MCL § 400.601, *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.040(a)(a), (b); The New Hampshire Medicaid Fraud and False Claims Act, N.H. RSA § 167:61-b, *et seq.*; the New York False Claims Act Law, N.Y. St. Fin. Law §§ 187, *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a); the Massachusetts False Claims Act Law, Mass. Gen. Laws Ch. 12 § 5B(1) and (2); the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.3(a)(1) and (2); and the District of Columbia Procurement Reform Amendment Act, D.C. Official Code § 2-308.13, *et seq.*

3. Within the time frames detailed below, Amgen engaged in a fraudulent scheme to induce medical providers to purchase Aranesp by promoting free product in the form of

“overfill”—extra product in excess of the labeled fill volume dosages—contained in vials of Aranesp. Amgen employees offered this free product as a means for medical providers to increase their profits from Aranesp reimbursement at the expense of the Medicare and state Medicaid programs.

4. Amgen encouraged medical providers to bill the federal Medicare and state Medicaid programs for the free product—overfill amounts—in Aranesp vials. Amgen’s offer of free product was unlawful remuneration to providers prohibited by the federal and state anti-kickback laws, and some providers did, in fact, submit claims to the state Medicaid programs for the free Aranesp product they received from Amgen. As a result of these and other illegal kickbacks to medical providers, Amgen caused medical providers to submit false certifications of compliance with the anti-kickback laws and the states’ Medicaid program regulations, which are a condition of payment. Consequently, Amgen’s inducements tainted claims reimbursed by the Medicare and the state Medicaid programs, thereby rendering them non-payable.

5. As a direct, proximate and foreseeable result of Amgen’s fraudulent course of conduct as set forth above and herein, Amgen caused providers to submit false certifications to the Medicare and state Medicaid programs that they were in compliance with anti-kickback provisions, thereby causing thousands of false claims to be submitted to and paid by the Medicare and Medicaid programs for Aranesp prescriptions that were ineligible for payment as a result of illegal kickbacks.

6. Beginning in or about 2003, Amgen conspired with INN, a purported group purchasing organization (“GPO”), whereby Amgen paid INN to promote Aranesp to INN’s customers, which INN purchased from its sister-company, ASD Healthcare. INN and ASD Healthcare conspired with Amgen to offer inducements to Aranesp customers in the form of free

Aranesp product, sham consultancy payments, and all-expense paid weekends retreats, among other things. Amgen and INN also conspired to induce providers to purchase Aranesp by paying medical providers bogus “honoraria” for attending all expense paid junkets that Amgen and INN referred to as “Advisory Board” meetings or “weekend retreats.”

7. As a result of Amgen, INN and ASD Healthcare’s conspiracy to offer kickbacks to medical providers so as to increase Aranesp sales, Amgen, INN, and ASD Healthcare caused false medical provider certifications to be submitted to the state Medicaid programs, thereby causing thousands of false claims to be paid by the state Medicaid programs that were ineligible for payment as a result of illegal kickbacks.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1345, 1367(a) and under 31 U.S.C. § 3732(b).

9. The Court may exercise personal jurisdiction over Amgen pursuant to 31 U.S.C. § 3732(a) and because Amgen transacts business within the District of Massachusetts.

10. The Court may exercise personal jurisdiction over AmerisourceBergen Corporation and its subsidiaries, AmerisourceBergen Specialty Group, INN and ASD Healthcare pursuant to 31 U.S.C. § 3732(a) and because these defendants transact business within the District of Massachusetts.

11. Venue is proper in this District pursuant to 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Amgen transacts business in this District.

12. Venue is proper in this District pursuant to 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because AmerisourceBergen Corporation and its subsidiaries, AmerisourceBergen Specialty Group, INN and ASD Healthcare, transact business in this district.

PARTIES

13. The Intervening Plaintiff States bring this action on behalf of their respective Medicaid programs and on behalf of their respective State interests.

14. Relator Kassie Westmoreland (“Relator”) is a resident of California and a former employee of Amgen. Ms. Westmoreland is a registered pharmacist with a Bachelor of Science in Pharmacy and Biology and a Master of Business Administration. On or about June 5, 2006, Ms. Westmoreland filed a Complaint that was amended by a filing on or about July 2, 2007 (the “Amended Complaint”). The Amended Complaint alleges violations of the FCAs on behalf of herself, the United States, and the Named Plaintiff States, pursuant to the qui tam provisions of the federal FCA, 31 U.S.C. 3730(b)(1), and the state FCAs: Cal Govt. Code § 1265(a)(1) and (2); 6 Del C. § 1201(a)(1) and (2); Fla. Stat. § 68.082(2); Georgia Code Ann. § 49-4-168, *et seq.*; Haw. Rev. Stat. § 661-21(a); 740 Ill. Comp. Stat. § 175/3(a)(1)-(3); IC 5-11-5.5; Ind. Code § 5-11-5.5; 46 La. Rev. Stat. c. § 46:438.3; Mich. Comp L. § 400.603; Nev. Rev. Stat. Ann. § 357.040(a)(a), (b); N.H. Rev. Stat. Ann. §§ 167:61-b *et seq.*; N.M. L. Ch. 49 (H.B. 468); N.Y. St. Fin. Law §§ 187-194; Tenn. Code Ann. § 71-5-182(a)(1); Tex. Hum. Res. Code § 36.001 *et seq.*; Mass. Gen. Laws Ch. 12 § 5B(1) and (2); Va. Code Ann. §8.01-216.3(a)(1) and (2); D.C. Official Code § 2-308.14(a)(1) and (2).

15. Defendant Amgen is a publicly-traded diversified human therapeutics company in the biotechnology industry organized in 1986 under the laws of Delaware, with its principal place of business located in Thousand Oaks, California. Amgen transacts business in this District through its agents and employees. Amgen developed, manufactures, distributes, and markets darbepoetin alfa in the United States under the trademark name Aranesp. Amgen was the original developer of the drug Aranesp, which was approved by the United States Food and

Drug Administration (“FDA”) in 2001 for the treatment of anemia associated with chronic renal failure. In 2002, the FDA expanded Aranesp’s indication to include the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies.

16. Defendant International Nephrology Network, d/b/a Integrated Nephrology Network (“INN”), is a wholly owned subsidiary of AmerisourceBergen Specialty Group, with its principal place of business in Frisco, Texas. INN is a purported GPO that sells pharmaceuticals to medical providers and physician practices specializing in nephrology, and is the largest nephrology specialty GPO in the United States. Amgen began its business relationship with INN in 2003, after Anthony J. Corrao, then Amgen Segment Director of Sales, left Amgen’s employ and became the Vice President and General Manager of INN. Defendant INN is now a wholly-owned subsidiary of Defendant AmerisourceBergen Specialty Group, and its parent corporation, AmerisourceBergen Corporation, both of which are headquartered in Chesterbrook, Pennsylvania, and all of which do business throughout the United States, including in the Commonwealth of Massachusetts.

17. Defendant ASD Healthcare is a pharmaceutical distributor that is wholly owned by AmerisourceBergen Specialty Group (which is a part of AmerisourceBergen Corporation), with its principal place of business in Frisco, Texas. ASD Healthcare distributes drugs all over the United States, including the Commonwealth of Massachusetts, and is the preferred distributor for INN.

18. Defendant, AmerisourceBergen Specialty Group, is the specialty pharmaceutical business arm of its parent corporation, AmerisourceBergen Corporation, with its principal place of business in Chesterbrook, Pennsylvania. Amerisource Specialty Group is the parent

corporation of defendants INN and ASD Healthcare and transacts business throughout the United States, including in the Commonwealth of Massachusetts.

19. Defendant AmerisourceBergen Corporation is a pharmaceutical service company with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen Corporation does business through numerous subsidiaries, including Defendants AmerisourceBergen Specialty Group, ASD Healthcare, and INN. Defendant AmerisourceBergen Corporation and its subsidiaries operate and conduct business throughout the United States, including in the Commonwealth of Massachusetts.

THE LAW

A. The Anti-Kickback Statute

20. 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 the medical decision-making process 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.

21. 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.

22. 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.

23. 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).

24. 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).

25. 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).

26. 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 OIG 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)

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

28. Compliance with the AKS is a precondition to participation as a health care provider under the federally-funded healthcare programs and the state Medicaid programs. Indeed, compliance with the AKS is a *condition of payment* for drug claims for which Medicare or Medicaid reimbursement is sought by medical providers.

29. The following Intervening Plaintiff States also have similar anti-kickback laws under their respective state laws, which apply to medical providers and entities participating in their Medicaid programs: California, Cal. Welf. & Inst. Code § 14107.2; Delaware, Del. Code. Ann. Tit. 31, § 1005; 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-a; New York, N.Y. Soc. Serv. Law § 366-d; and Virginia, Va. Code Ann. § 32.1-315.

B. The State False Claims Act Laws

30. Each of the Intervening Plaintiff States has a parallel state False Claims Act law that is closely modeled on the federal False Claims Act, 31 U.S.C. §§ 3729-33. A violation of the state FCAs occurs, *inter alia*, when any person knowingly presents, or causes to be

presented, a false or fraudulent claim for payment or approval. Similar to the federal False Claims Act, any person who violates the state FCAs is liable for treble damages and civil penalties for knowingly causing the submission of false or fraudulent claims for payment to the state Medicaid programs. *See* 31 U.S.C. § 3729(a)(1); *see* state FCAs: Cal Govt. Code § 1265(a)(1) and (2); 6 Del. C. § 1201(a)(1) and (2); Fla. Stat. § 68.082(2); Haw. Rev. Stat. § 661-21(a); 740 Ill. Comp. Stat. § 175/3(a)(1)-(3); I.C. 5-11-5.5; 46 La. Rev. Stat. c. 3 § 438.3A - C; Mich. Comp. Laws § 400.612; Nev. Rev. Stat. Ann. § 357.040(a)(a), (b); N.H. RSA §§ 167:61-b et seq.; N.Y. St. Fin. Law §§ 187-194; Tenn. Code Ann. § 71-5-182(a)(1); Mass. Gen. Laws Ch. 12 § 5B(1) and (2); Va. Code Ann. §8.01-216.3(a)(1) and (2); D.C. Official Code § 2-308.14(a)(1) and (2).

C. Group Purchasing Organizations

31. Group purchasing organizations (GPOs) are buying consortiums or associations of hospitals and healthcare organizations designed to leverage the aggregate purchasing power of members by associating to negotiate contract terms with various suppliers of drugs, medical devices and other goods and services. GPOs do not typically purchase anything from the suppliers. But 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). 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.

32. Although GPOs are the agents of the hospitals and healthcare organizations that they negotiate on behalf of, they may also be compensated through administrative fees paid by the vendors or suppliers, which the GPO negotiates along with the other written contract terms. 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.* In 1986, Congress exempted these GPO administrative fees paid by vendors from the Anti-Kickback Act, 42 U.S.C. § 1320a-7b, *supra*, which otherwise makes it a felony to solicit or pay remuneration of any kind in exchange for any kind of referral or recommendation of purchases that are reimbursed, in part, by Medicare or Medicaid or other Federal health care programs. But regulations promulgated by the Office of Inspector General of the Department of Health and Human Services limit this exemption (known as a “safe harbor”) by imposing standards for the written agreement between the GPO and its members who are the purchasing entities. *See* 42 C.F.R. § 1001.952(j). The two standards imposed by the AKS GPO “safe harbor” for exemption of the “remuneration” paid by the vendor of goods or services to the GPO are:

(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.

THE STATE MEDICAID PROGRAMS

33. Medicaid is a joint federal-state program that provides health care benefits, including prescription drug coverage, for certain groups, including the poor and disabled. The Medicaid program was created in 1965 in Title XIX of the Social Security Act and covers approximately 47 million individuals, including children, the aged, blind, and/or disabled, and people who are eligible to receive federally assisted income maintenance payments. The most basic requirement for reimbursement eligibility under Medicare, Medicaid and other government healthcare programs is that the service provided must be 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.*

34. The funding for Medicaid is shared between the federal and state governments. To qualify for federal funding, state Medicaid programs must provide certain minimum basic services, such as in-patient hospital care to low-income individuals. 42 U.S.C. § 1396a. The federal portion of states' Medicaid payments, known as the Federal Medical Assistance Percentage, is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b).

35. The Intervening Plaintiff States are required to implement a State Plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a(a).

36. The Intervening Plaintiff States' Medicaid programs precondition payment of

Medicaid claims upon a Medicaid provider's certification of compliance with Medicaid rules and regulations, including the AKS. Every physician and pharmacist that participates in the Intervening Plaintiff States' Medicaid programs must sign an agreement with his or her state that certifies compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, their agreements typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished. Consequently, medical providers and pharmacists expressly certify to the Intervening Plaintiff States that they are in compliance with the AKS in submitting Aranesp claims for Medicaid reimbursement. This certification is a condition of payment by the Intervening Plaintiff States' respective Medicaid Programs. Sample provider enrollment agreements and/or provider certifications for each of the Intervening Plaintiff States are attached hereto as Exhibit A.

ANEMIA PRODUCTS MANUFACTURED BY AMGEN

A. Aranesp (*Darbepoetin Alfa*)

37. Aranesp (darbepoetin alfa) is an injectable prescription drug developed and manufactured by Defendant Amgen that is used to treat anemia associated with chronic kidney disease and chemotherapy-induced anemia. Aranesp is an erythropoiesis-stimulating agent (ESA) that boosts production of red blood cells. On or about September 17, 2001, the U.S. Food and Drug Administration ("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 patients not on dialysis. On or about July 17, 2002, the FDA approved the drug for treatment of chemotherapy-induced anemia in patients with non-myeloid malignances. The FDA has not

approved Aranesp for any other uses or in labeled dosages different from those on the approved label.

38. 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.

39. According to Amgen's public filings, aggregate United States revenues for Aranesp from the years 2001 through 2008 have totaled over \$11 billion dollars. Until recently, Aranesp sales in the United States had increased steadily and dramatically; 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.

40. According to data obtained from the Centers for Medicare & Medicaid Services, from the fourth quarter 2001 through the fourth quarter 2007, the state Medicaid programs together reimbursed providers for more than \$371 million dollars for Aranesp retail pharmacy claims. In addition, the state Medicaid programs have paid millions more for claims for provider-administered Aranesp billed to the state Medicaid programs under J and Q procedure codes listed in ¶ 43 below. The Medicare program has reimbursed Aranesp claims totaling more than \$5 billion dollars from 2003 through 2008.

41. Aranesp is manufactured in single-dose vials, meaning one vial per use per patient, in the following labeled dosages: 25 micrograms, 40 micrograms, 60 micrograms, 100 micrograms, 150 micrograms, 200 micrograms, 300 micrograms and 500 micrograms sizes. Amgen also manufacturers Aranesp in pre-filled, single-dose syringes in the same labeled dosages as the vials.

42. Each dose strength or formulation of Aranesp has its own unique National Drug Code (NDC), as set forth in Exhibit B. The first two segments of the NDC, sometimes referred to as the NDC-9, describe the drug’s labeler, i.e., the company that manufactures the drug, and the product code, i.e., the product’s specific strength, dosage form and formulation. See Exhibit B.

43. Pharmacists submit claims for Aranesp to the Medicare and state Medicaid programs using the NDCs for Aranesp. Medical providers who administer Aranesp to Medicare beneficiaries and Medicaid recipients on an outpatient treatment basis, however, submit claims to the Medicare and state Medicaid programs using procedure codes. The following procedure codes are used by medical providers to submit claims for reimbursement to Medicare and the state Medicaid programs for Aranesp that is administered by medical providers:

PROCEDURE CODE	PROCEDURE DESCRIPTION
J0881	INJECTION DARBEPOETIN ALFA 1 MICROGRAM (NON-ESRD USE)
J0882	INJECTION DARBEPOETIN ALFA 1 MICROGRAM (FOR ESRD ON DIALYSIS)
Q4054	INJECTION DARBEPOETIN ALFA 1 MCG (FOR ESRD ON DIALYSIS)
J0880	INJECTION DARBEPOETIN ALFA 5 MCG
Q0137	INJECTION DARBEPOETIN ALFA 1 MCG (NON-ESRD USE)

44. 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.

45. 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.

46. 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 hereto as Exhibit C.

B. Procrit and Epogen (*Epoetin Alfa*)

47. In September of 1985, long before Aranesp was introduced to the ESA market, 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, Epoetin Alfa, an Erythropoiesis-Stimulating Agent (ESA) designed to prevent the need for blood transfusions. The FDA first approved Epoetin Alfa in June 1989. Since Epoetin

Alfa is an anemia drug, when Amgen's product Aranesp was approved by the FDA in late 2001, it competed with Epoetin Alfa.

48. Epoetin Alfa is marketed and sold under two trademark names: "Epogen", which is marketed and sold by Amgen; and "Procrit", which is marketed and sold by J&J. Pursuant to the technology license agreement between Amgen and J&J, Amgen retained exclusive rights to market Epoetin Alfa in the United States for use with dialysis patients under the trademark name "Epogen." Under this agreement, J&J has exclusive rights to market Epoetin Alfa, under the trademark name "Procrit," for all other uses in the United States, including non-dialysis kidney patients. Further, J&J must pay Amgen royalties on its net sales of Procrit in the United States. J&J also has exclusive rights to market Epoetin Alfa outside of the United States (except China and Japan) for all uses.

49. Amgen's subsidiary, Amgen Manufacturing, Limited, is the sole manufacturer of *both* Epogen and Procrit. Amgen is also responsible for the labeling of Epogen and Procrit and making submissions to the FDA relating to Epogen and Procrit. Consequently, Amgen manufactures and manages labeling for Epogen and Procrit in addition to its own completing anemia drug, Aranesp. Epogen and Procrit are both manufactured in single dose vials that allow one patient dose to be drawn from the vial, and multi-dose vials that allow more than one patient dose to be drawn from the vial.

50. At the time Amgen and J&J entered into their agreement, Epoetin Alfa was primarily used to treat anemia in dialysis and chronic kidney disease patients. Amgen marketed Epogen to dialysis clinics, while J&J marketed Procrit to pre-dialysis patients with chronic kidney disease. Thereafter, Epoetin Alfa was approved by the FDA for anemia suffered by cancer patients, to which J&J maintained the exclusive marketing rights in the United States.

51. 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.

52. 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.

53. 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.

THE OVERFILL CONTAINED IN ARANESP SINGLE DOSE VIALS

54. The United States Pharmacopeia (“USP”) requires that injectable drug vials contain a volume overage in “slight excess” of the labeled volume fill amount in order to permit withdrawal and administration of the labeled fill volume amounts. *See* USP Reference

Standards, United States Pharmacopeia, XXXI, Rockville, MD: United States Pharmacopeial Convention, Inc. (2008) Chp. 1151, p. 619. This “slight excess” fill volume, or overage, is commonly referred to as “overfill.” For the entire time that Aranesp has been on the market, the USP has recommended *up to* an additional .1 milliliter, or 10% overfill, for a labeled fill volume of 1.0 milliliter. *See id.* (emphasis supplied).

55. All of Aranesp’s dose strengths (*see* Exhibit A) manufactured in single-dose vials contain 1.0 milliliter *or less* of solution for administration to patients according to the label. Amgen also manufactures Aranesp in pre-filled syringes, which contain 1.0 milliliter *or less* of solution, depending on the size of the dose.

56. When Aranesp single-dose vials were initially introduced to the market, the vials contained 19% overfill. By comparison, a 1.0 milliliter pre-filled syringe of Aranesp contained only 4% overfill, well within the recommended margin. As a result, the Aranesp vials contained 90% more overfill than the .1 milliliter recommended by the USP.

57. According to an Amgen PowerPoint presentation, entitled “Update to Executive Committee,” overfill in Aranesp vials was initially increased from 16.8% to 19% to “assure success for launch” of the Aranesp product in 2001. (The PowerPoint also recommended decreasing the Aranesp overfill back to 16.8% in 2002, citing legal, regulatory and manufacturing reasons for reducing the overfill, but further states that reductions in overfill volume may have “customer and reimbursement implications”).

58. The excessive 19% overfill was included in the vials to ensure Amgen’s success in selling Aranesp when it was first introduced into the market, *not* because such a high percentage of overage was necessary to extract the labeled dose from the Aranesp vial. As discussed below, the Amgen national sales force and management used the Aranesp overfill as

an economic incentive to induce medical providers to buy, administer, and bill for more Aranesp. According to Amgen company documents, the overfill amounts contained in vials of Aranesp were decreased from 19% to 16.8% sometime in 2002.

59. According to Amgen documents dated between 2002 and 2008, including, for example, a document dated March 18, 2004 entitled “Aranesp (darbepoetin alfa) Overfill Volume for Vials,” Amgen’s Aranesp vials included: “a ‘target’ fill volume of 0.168 ml.” In other words, each vial of Aranesp contained 16.8% excess concentration of drug above the labeled dosage amount—.168 milliliters or 68% more overfill than the USP recommended overfill amount—for the majority of the time Aranesp was being marketed and sold by Amgen.

60. Aranesp purchasers are not charged for the overfill amounts—the free drug product-- contained in the Aranesp vials. For example, if a medical provider purchased a 100 microgram vial of Aranesp in 2003, the vial actually contained 116.8 micrograms of Aranesp, which is 16.8% percent more drug than the labeled fill volume and 68% more overfill than the .1 milliliter overfill recommended by USP.

61. At some point in 2008, an internal company recommendation was made to decrease the overfill amounts contained in Aranesp vials. An Amgen PowerPoint dated April 3, 2008, entitled “Overfill Reduction: Aranesp 1.0mL vials” recommends that the overfill amounts contained in Aranesp vials be decreased in two phases in order to reduce overfill amounts from 16.8% to 13%.

62. Amgen purposefully manipulated the overfill amounts in Aranesp vials so as to ensure that Aranesp succeeded in the ESA marketplace when it was initially rolled out as a competing drug to Procrit. Amgen’s manufacture of Aranesp vials with excessive overfill amounts was designed to ensure that the Amgen’s sales force would succeed in getting medical

providers to convert from Procrit to Aranesp, by enabling medical providers to profit from the free product and thereby giving Aranesp an economic advantage over Procrit and Epogen.

63. By manufacturing Aranesp with excessive amounts of overfill per vial—68% more Aranesp fill volume than what was needed to draw out the labeled dosage—Aranesp vials had “built in” free samples that the sales force could offer to medical providers. Amgen knew that medical providers who billed Medicare, Medicaid and third-party payors for this free overfill product in the Aranesp vials could realize a greater profit than those who did not.

64. After the initial rollout of Aranesp, Amgen could have reduced the overfill amounts for Aranesp vials between 2003 and 2008 to more closely comply with the USP recommendations, but chose not to.

AMGEN’S MANIPULATION OF THE OVERFILL IN EPOETIN ALFA TO MAKE ARANESP MORE COMPETITIVE

65. In 2002, shortly after obtaining FDA approval for Aranesp, Amgen decreased the overfill amounts contained in vials of Aranesp’s competitors, Epogen and Procrit, which it also manufactures. An Amgen PowerPoint presentation dated June 2, 2005, entitled “EPO Fill Volume” reports that overfill amounts contained in EPO were decreased in the fourth quarter 2002 from 16.8% to 14.4% for both single-use and multi-use vials.

66. Overfill amounts contained in Epogen and Procrit vials were subsequently decreased again in second quarter 2004 from 14.4% to 11.1% for both the single-use and multi-use vials. Consequently, for at least four years, the overfill amounts contained in Aranesp single-dose vials were 51% greater than the overfill amounts contained in vials of its competing drugs, Epogen and Procrit. Notably, the multi-dose vials for Epogen and Procrit, from which more than one dose was intended to be drawn, contained *less* overfill than the single use Aranesp vials, which are only drawn once and administered to one patient.

67. Amgen knowingly decreased the overfill amounts contained in Epogen and Procrit vials, while knowingly maintaining the overfill amount in Aranesp vials at significantly higher levels, so as to put Aranesp at an economic pricing advantage over its competitor drugs Procrit and Epogen and make Aranesp more competitive in the ESA marketplace. Aranesp vials contained a larger percentage of overfill than Procrit and Epogen vials, thereby enabling medical providers to realize higher profit margins than could be realized with Procrit or Epogen.

68. The overfill amounts contained in Amgen's ESA products, Aranesp and Epoetin Alfa (Epogen and Procrit), and the changes to the Epoetin Alfa overfill amounts, were issues of import at the highest level within the company. By example, an email dated January 6, 2006 from Edwin Mar, Senior Manager of Medical Information, to Helen Torley, Vice President and General Manager of Nephrology, and Leslie Mirani, Vice President of Sales, states: "In regards to your request to provide EPOGEN overfill historical information to [CEO] Kevin Sharer, these are the information I have available so far regarding EPOGEN 1.0 mL vial fill volumes." The email goes on to provide the overfill amounts for Epogen from 1993 through January 2006:

(1993-Q4/2002) – 1.168 mL
(Q4/2002-Q1/2004) – 1.144 mL
(Q1/2004 – present) – 1.111 mL

Accordingly, when Aranesp was first introduced into the market, Epogen vials contained 16.8% overfill, which was then reduced in two phases to 11.1% overfill.

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

69. The Amgen national sales force and management used the excessive overfill amounts contained in Aranesp vials as an inducement to medical providers nationwide to buy and prescribe Aranesp. The Amgen sales force touted the overfill contained in Aranesp vials as a means for medical providers to increase their profits—by getting reimbursements for the free

product. To promote Aranesp, the Amgen sales force often included overfill amounts, usually in the ten percent (10%) to fifteen percent (15%) percent range, in calculating a medical provider's potential profits.

70. Documents relating to the overfill amounts contained in Aranesp vials were circulated at all levels within the Amgen sales department, including to the Vice President of Sales, the Regional Sales Directors, District Managers and the sales representatives. Often, these communications reflected insincere warnings: "For Your Information Only. Not for Promotional Use," or "[D]o not distribute, not for promotional use" or "FOR YOUR EYES ONLY!" The sales force, including Relator Westmoreland, understood these warnings to be superficial since Amgen management was training her and others how to show medical providers the overfill and other economic incentives without leaving any documentation behind.

71. Amgen's sales force took full advantage of the "built in" free samples in Aranesp vials. The sales force utilized economic analyses including "overfill credits" or "overfill discounts" to aid their promotion of the overfill inducements to medical providers nationally. These economic analyses—often referred to as "cost revenue models"—assessed how Aranesp overfill would impact potential profits that a medical provider, clinic or hospital could realize in billing for free Aranesp overfill.

72. Relator Westmoreland first became aware of sales representatives offering overfill kickbacks shortly after joining Amgen as a sales representative in 2002. Relator Westmoreland was an Aranesp sales representative for nephrology practices, multi-specialty clinics and hospitals in the State of Oregon and Southwest Washington. She had extensive contacts with other Aranesp sales representatives (including in the oncology business unit) from around the country through training seminars and Aranesp sales staff meetings, which were held

at least six times per year. She also had weekly contact with other district sales representatives and district managers as well as other representatives around the country by telephone. She had extensive contacts with upper-level Aranesp sales managers and directors through these seminars and staff meetings, as well as many telephone conferences and emails.

73. Relator Westmoreland learned that Amgen sales representatives would promote the increased profits that could be realized if the customers sought reimbursement for the “overfill micrograms” contained in Aranesp single-dose vials. Relator Westmoreland had numerous communications with other sales representatives confirming that overfill inducements were being offered and that Aranesp purchasers were billing for the free overfill amounts. Amgen sales representatives and management prepared spreadsheets calculating potential revenues from overfill billings. The sales force showed these spreadsheets to their customers during office visits as a means to increase sales of Aranesp. Examples of the overfill revenue analyses that Ms. Westmoreland received from Julie Modesti-Skopp, her district trainer (and currently an Amgen Hospital Systems Manager), are attached hereto as Exhibit D. Relator Westmoreland has specific recollections of conversations with sales representatives who created or used these overfill spreadsheets with their customer medical providers, including sales representatives whose territories included California, Texas, and Florida.

74. These types of economic analyses for Aranesp purchases including “overfill discounts” or “overfill credits” were used *nationally* by the Amgen sales force to calculate potential profits for medical providers. For example, an Amgen document entitled “WAP to AWP Pricing”, which was authored by a sales representative based in Tennessee, contains an Aranesp and Procrit cost and revenue comparison and reflects an “Overfill at 10%” credit for Aranesp purchases of 100 microgram vials. The analysis calculates a medical provider’s

potential profit in purchasing Aranesp based on Medicare reimbursement rates, and includes a dollar credit for “Overfill at 10%.” This economic worksheet was electronically mailed on September 16, 2003 to Amgen sales representatives located in Louisiana, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Tennessee, Vermont and the District of Columbia.

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

a. An excel spreadsheet entitled “2006 Comprehensive Reimbursement Worksheet,” calculated Aranesp overfill in its reimbursement calculations. This excel spreadsheet was electronically mailed from a California-based Amgen Hospital Systems Manager to multiple sales representatives based in Atlanta, Georgia.

b. An economic cost and revenue analysis completed for Balboa Nephrology Medical Group, a nephrology group with 14 clinical offices in San Diego, California, reflects a 16.8% overfill “all units” credit versus a 11.1% overfill credit for Procrit.

c. An email dated February 7, 2005 to Northeast Regional Sales Director Mark Papineau from a New York City based sales representative attaching a “clinic spreadsheet” tool comparing Aranesp to Procrit costs and reimbursements. The spreadsheet compares reimbursements for the Aranesp vials at 10% overfill and at 15% overfill against Procrit. Northeast Regional Sales Director Mark Papineau electronically forwarded this clinic reimbursement spreadsheet tool to the entire Northeast Management

Team with the admonition: “This is truly an FYI. DO NOT SHARE WITH CUSTOMERS.”

d. A “Neu Era Plus” Aranesp contract analysis for St. Luke’s Hospital in New York, New York reflects an overfill “credit” for Aranesp purchases.

e. An email dated August 2, 2005 from an Oklahoma-based sales representative to a District Sales Manager referencing conversations “at a couple of hospitals” and that there is “more overfill with the vial. There is no overfill with the Singleject [Aranesp syringe]... 3 mcgs for free for Aranesp and they can bill for it.”

76. In addition to the tools created and used by the Amgen sales force and management relating to the overfill kickbacks, Amgen’s Medical Affairs Department maintained letters that contained information as to the overfill amounts contained in each of the labeled fill dosages of Aranesp vials. If a medical provider requested information on overfill amounts contained in Aranesp vials, then the Medical Affairs Department would send an “overfill letter” that stated:

Thank you for your inquiry regarding overfill in Aranesp (darbepoetin alfa) vials.

Taking into account the Aranesp vial-closure system and the filling variance in the vial-filling equipment, Amgen has determined a “target” fill volume of 0.168 mL to ensure that the label fill volume of Aranesp can be readily withdrawn using standard dead-space needle and syringe combinations. Amgen is continuously investigating and evaluating the most appropriate measures. **It is important to emphasize that Amgen cannot and will not condone unsafe practices that may be utilized to capture any overfill, such as the pooling of unused portions of single-dose preservative-free vials of Aranesp** (emphasis in original).

Importantly, this letter did not suggest that medical providers should *not* capture or bill for the free overfill amounts, but only suggests that Amgen does not condone *unsafe* practices to capture

overfill, offering only one example—pooling overfill from more than one vial—but not mentioning administering all of the overfill from one vial, a practice Amgen promoted.

77. Although the Medical Affairs Department purportedly distributed these overfill letters to medical providers, not the sales force, the sales force had access to these “overfill letters.” An Amgen document, entitled “Aranesp/Epogen/Sensipar Tools, Benefits and Strategies”, lists the Aranesp overfill guidelines as “economic” tools that were accessible to the sales force in Microsoft Word format.

78. Indeed, Amgen’s Vice President of Sales, Leslie Mirani, maintained these overfill letters on the computer server. In emails dated October 17 and October 18, 2004, Vice President Leslie Mirani requested information relating to the overfill amounts contained in vials of Aranesp and Epogen from Gabriel Mesa, in Amgen’s Medical Affairs Department. Upon receiving the overfill letters from Mr. Mesa, Ms. Mirani emailed the following instruction to her administrative assistant: “Keep on [sic] server.”

79. Other high level sales executives at Amgen also maintained electronic copies of these Aranesp overfill letters, including: Mark Papineau, Executive Director of Regional Sales (Nephrology) for the Northeast Region, and Steven Terreri, Executive Director of Regional Sales (Oncology) for the Northeast Region.

80. Amgen’s management was well aware that their sales force offered these overfill inducements to medical providers to increase Aranesp purchases. By example, a former Amgen sales representative, “Sales Representative 1”, whose territory included New York City, stated that District Manager Patrick Campbell used the “overfill profit” in his sales pitch to physicians. Patrick Campbell was subsequently promoted to Executive Director of Regional Sales.

81. Another former sales representative, “Sales Representative 2”, whose territory included Westchester and Long Island, New York, stated that District Manager, Eric Hedge, used the overfill amounts contained in Aranesp vials to convert hospitals from buying Procrit to buying Aranesp. During a meeting with Long Island hospitals, at which Sales Representative 2 and Amgen Regional Hospital Manager, Carol Sheridan, were present, District Manager Eric Hedge overtly promoted Aranesp by emphasizing the overfill profit benefit to the hospitals.

82. Another former sales representative, “Sales Representative 3”, who was employed with Amgen as a senior sales representative until 2007 and whose territory included New York City, admitted that sales representatives would make physicians “aware” of overfill in Aranesp vials, but were not supposed to tell physicians that the overfill could be used as an extra dose or that the physician could bill for it. Sales Representative 3 stated that doctors routinely used the overfill on patients because it created additional profit for the administering physicians.

83. Indeed, Relator Westmoreland witnessed numerous conversations about Aranesp overfill among high-level Amgen management including: Robert Azelby, Executive Marketing Director for the Nephrology Business Unit (then Senior Director of the Anemia Business Unit), Ray Chow, Executive Director of Global Marketing (then Director of CRI), Laurence “Matt” Skelton, Associate Director of Marketing for Aranesp, George Esgro, Senior Director of Sales and Marketing, Kevin Carlin, Associate Director of Marketing for the Nephrology Business Unit Strategic Planning and Operations, and Michael Sullivan, then Senior Marketing Manager of Hospitals. Management trained and instructed the sales force in how to promote the overfill as a profit incentive without leaving any written documentation with the medical provider.

84. In offering the overfill inducement to medical providers, Amgen’s sales force encouraged medical providers to administer higher doses of Aranesp to patients without any

clinical need for that higher dose. For example, and as discussed *infra*, a nurse practitioner based in a Central New York chronic kidney disease clinic, Nephrology Associates of Syracuse, reported that she administered the Aranesp overfill “because it was there,” *not* because a patient needed to receive additional micrograms of Aranesp. The nurse practitioner went on to explain that when her practice began billing for the free overfill amounts, she changed the physician orders for *all* patients receiving Aranesp to increase the administration dosage to include the free overfill. Consequently, the practice began administering the overfill amounts in Aranesp vials to its patients solely to profit from billing for the free product.

85. Amgen then paid that Central New York nurse practitioner to promote Aranesp to other nephrology practices by telephone and in person with its sales representatives. According to Amgen-issued IRS forms 1099, this nurse practitioner was paid \$31,600 from 2004 through 2007 as an Amgen consultant. She instructed medical providers, on behalf of Amgen, how to bill the overfill in Aranesp vials and circulated her nephrology practice’s overfill “Conversion Chart” to other practices so that they would know how to bill Medicare, Medicaid and third-party payors for free overfill. *See infra* ¶¶ 100-107, 112.

86. Amgen’s overfill kickbacks caused medical providers to administer Aranesp dosages in excess of what patients may have required and submit claims for that free product to third party payors, including Medicare and the state Medicaid programs. The sales force’s promotion of free overfill was nothing more than a means for medical providers to profit from Medicare and Medicaid reimbursements. It was not only a violation of the federal and state anti-kickback and false claims acts laws, but also implicated patient safety because of its inconsistency with the black box label warning that medical providers should administer the *lowest* dose of Aranesp possible.

**CLAIMS FOR FREE ARANESP OVERFILL HAVE BEEN IDENTIFIED
BY THE STATE MEDICAID PROGRAMS**

87. Medicaid claims for Aranesp administered by medical providers (J and Q code billings) reflect that providers submitted claims for the free overfill at least between April 1, 2004 and September 9, 2009. To date, state Medicaid programs across the United States, including California, Illinois, Indiana, Michigan, Oregon, New York, Nevada and Texas, have identified fraudulent Aranesp claims paid by their respective programs to medical providers for the free overfill offered by Amgen, and the other Intervening Plaintiff States continue to analyze claims data to identify billings for free overfill. Amgen's violation of the AKS in offering inducements to medical providers caused the state Medicaid programs to pay for Aranesp claims that were not eligible for payment, and caused the Intervening Plaintiff States to pay Aranesp claims submitted by medical providers that would not have otherwise been submitted.

88. Additionally, the state Medicaid programs have paid false claims as the secondary insurer for beneficiaries dually eligible under the Medicare and Medicaid programs, where overfill claims were presented to Medicare as the primary insurer, and a state Medicaid program as the secondary insurer. The Intervening Plaintiff States have identified instances where state Medicaid reimbursements were made to providers for free Aranesp overfill for dually-eligible Medicare and Medicaid beneficiaries. Consequently, for the dually eligible beneficiary population of claims, both the Medicare and state Medicaid programs have paid claims that were ineligible for payment by virtue of Amgen's kickbacks to medical providers.

89. To exemplify how Amgen's illegal kickback scheme was executed nationally by its sales force and the far-reaching effects of Amgen's kickbacks on the Intervening Plaintiff States' Medicaid and Medicare programs, Amgen's kickbacks to medical providers across the State of New York and the resulting harm to its Medicaid program are described below.

**AMGEN'S OVERFILL KICKBACKS ACROSS NEW YORK STATE
EXEMPLIFY THE NATIONAL KICKBACK SCHEME**

90. Amgen's kickback scheme was expertly executed in the State of New York, resulting in thousands of false claims being submitted to the New York Medicaid program. In New York State alone, Amgen's overfill inducements caused medical providers to submit more than 6,500 ineligible claims for Aranesp overfill to the New York Medicaid program for reimbursement between April 1, 2004 and July 28, 2009. For the aforementioned time period, Medicaid claims for overfill amounts contained in Aranesp vials accounted for at least \$1,797,000 in fraudulent reimbursements paid by the New York Medicaid program that have so far been identified. This paid claims figure only represents claims identified which included free overfill, however, and does not include the entirety of the false claims reasonably and foreseeably caused by Amgen's fraud scheme. In addition to the figure above, Amgen's kickback scheme caused damages to the New York Medicaid program resulting from: (1) Aranesp claims caused by other types of illegal kickbacks Amgen extended to medical providers; (2) renewed, reoccurring, continuing or future Aranesp claims caused by Amgen's inducing providers to convert their patients to Aranesp including the free overfill product; and (3) claims paid for Aranesp that instead could have been paid for the less costly alternative, Procrit.

91. Amgen's blatant promotion of the overfill—resulting in overfill billings to New York Medicaid totaling nearly 13% of all provider-administered Aranesp in the State of New York—caused medical providers to submit false certifications to the New York Medicaid program that the Aranesp claims that they were submitting were in compliance with New York State anti-kickback laws and the federal AKS. As a result of Amgen's fraudulent course of conduct, the New York Medicaid program paid more than \$1,797,000 for ineligible claims

submitted by medical providers which included free Aranesp overfill amounts allegedly administered to New York Medicaid recipients.

92. Amgen employees offered kickbacks of free product to medical providers across the state of New York so as to increase Aranesp sales. Some examples of Amgen employees offering kickbacks to medical providers serving Medicare beneficiaries and Medicaid recipients located in various parts of the State of New York are as follows:

A. Terence Cardinal Cooke Health Care Center

93. In 2005, Amgen offered inducements in the form of free Aranesp to Terence Cardinal Cooke Health Care Center (“TCC”), located at 1249 Fifth Avenue, New York, New York 10029, in order to get TCC to switch from buying and administering Epogen to buying and administering Aranesp. TCC treated patients in an outpatient dialysis setting and on an outpatient chronic kidney disease (non-dialysis) basis with Aranesp.

94. The Amgen sales representative, whose territory included Upper Manhattan, advised the Administrator of the TCC End Stage Renal Disease (ESRD) Clinic and the Quality Assurance Nurse for the TCC ESRD Clinic that Aranesp vials contained overfill amounts above the labeled dosages. She further advised them that TCC could capture an extra 15% of the Aranesp drug in the overfill and bill third-party payors for this free product.

95. The Amgen sales representative further instructed TCC employees that, in order to capture the overfill amounts contained in the Aranesp vials, TCC employees should utilize dead space syringes.

96. TCC converted from purchasing and administering Amgen’s Epogen drug to purchasing and administering Aranesp in 2005.

97. Following TCC’s conversion to Aranesp in 2005, and at the direction of Amgen

representatives, TCC employees administered Aranesp overfill amounts to TCC patients.

98. Following TCC's conversion to Aranesp in 2005, and at the direction of Amgen representatives, TCC billed third-party payors, including the New York State Medicaid Program and the Medicare program, for the free overfill it received from Amgen. TCC billed the Medicaid program for 15% more than each Aranesp vial's labeled dosage. For example, for each 100 microgram vial of Aranesp it purchased from Amgen, TCC billed 115 micrograms, or 15% over the labeled dosage, to the New York Medicaid program.

99. From June 15, 2005 to March 28, 2008, TCC submitted claims for reimbursement for the overfill amounts contained in Aranesp vials to the New York Medicaid program. For the aforementioned time period, TCC submitted at least 3,445 separate claims which included the free overfill amounts. The New York Medicaid Program paid at least \$1,290,000 in reimbursements to TCC that were ineligible for payment, due to Amgen's inducement.

100. For the aforementioned time period, Amgen caused TCC and its medical providers to submit false certifications to the New York Medicaid and Medicare Programs that TCC and its medical providers were in compliance with state and federal laws, including the New York State and federal anti-kickback laws.

B. Nephrology Associates of Syracuse

101. Amgen offered inducements, in the form of free Aranesp to Nephrology Associates of Syracuse ("NAS"), located at 1304 Buckley Road, Ste. 2, Syracuse, New York 13212-4311. The Amgen sales representative, whose territory included the Syracuse area, offered overfill as an inducement to NAS to prevent NAS from switching from Aranesp to Procrit. A November 2004 PowerPoint by an Amgen employee reflects that NAS was a top 20 Aranesp account, as measured by volume of purchases. The PowerPoint also suggests that NAS

maintained a 100% market share in favor of Aranesp in November of 2004.

102. In 2004, an Amgen sales representative informed the Chief Operating Officer for NAS, that the discounts that NAS had been receiving for Aranesp pre-filled syringes would be terminated. The sales representative further explained that although NAS would be losing those discounts, NAS could receive “discounts” by instead purchasing Aranesp in vials, rather than purchasing Aranesp pre-filled syringes. The Amgen sales representative explained that the vials of Aranesp contained free product, in the form of overfill, that NAS could use to bill third-party payors.

103. The Amgen sales representative told NAS how much overfill was included in each labeled dose vial of Aranesp, and even showed NAS employees how to bill for the overfill amounts to third-party insurers, Medicare and Medicaid.

104. Thereafter, NAS began purchasing Aranesp in vials, rather than in pre-filled syringes, and administered the overfill amounts contained in Aranesp vials to its patients. As previously noted, a nurse practitioner at NAS administered the overfill amount “because it was there,” regardless of whether the patient required the additional medication. Consequently, NAS administered extra Aranesp to its patients in order to profit by billing for that extra product, not because patients required the additional medication.

105. At Amgen’s direction, NAS billed for the overfill, at 10% above each labeled fill dose of Aranesp to Medicare, Medicaid and private insurers. For example, for each 200 microgram vial of Aranesp NAS purchased from Amgen, NAS would bill 220 micrograms, or 10% over the labeled dosage, to the New York Medicaid program.

106. NAS went so far as to establish a “Conversion Chart” for its billing staff, so that they would know how to bill for the free product. The Conversion Chart, for example, reflected

that: “100 mcg. = 110 mcg. / 5 = 22 units to be billed” (where one unit equals 5 mcgs). The Amgen sales representative reviewed this Conversion Chart and proceeded to use the Conversion Chart to promote the overfill to other nephrology practices.

107. From November 17, 2004 to January 9, 2008, physicians affiliated with NAS submitted claims for reimbursement for the overfill amounts contained in Aranesp vials to the New York Medicaid program for 10% over the labeled fill volume doses of Aranesp. For the aforementioned time period, physicians affiliated with NAS submitted at least 690 separate claims for the overfill amounts contained in Aranesp vials. The New York Medicaid Program paid at least \$81,500 in Medicaid reimbursements to NAS for claims that were ineligible for payment, due to Amgen’s free product inducement.

108. For the aforementioned time period, Amgen’s overfill inducements caused physicians affiliated with NAS to submit false certifications to the New York Medicaid and Medicare Programs that they were in compliance with state and federal laws, including the New York State and federal anti-kickback laws.

C. Nephrology Associates of Western New York

109. During 2005 and 2006, Amgen offered inducements, in the form of free overfill, to Nephrology Associates of Western New York (“NAWNY”), located at 4223 Maple Rd., Amherst, New York 14226.

110. A NAWNY billing clerk identified an Amgen sales representative, whose sales territory covered the Buffalo area, as the person who “pushed the idea of billing for overfill to NAWNY.”

111. The Amgen sales representative initially approached the NAWNY Office Manager with the idea of billing for the overfill. In fact, when the sales representative first

approached the Office Manager about overfill, he told her that “he was not supposed to tell her this.”

112. On multiple occasions, the Amgen sales representative explained to NAWNY employees the concept of overfill amounts contained in Aranesp vials, the amounts of overfill contained in the various labeled doses of Aranesp, how NAWNY could capture overfill and administer it to patients, and instructed NAWNY employees how to bill for the overfill amounts.

113. In a meeting with NAWNY employees, the Amgen sales representative presented the idea of billing overfill and reviewed with the staff the overfill amounts contained in the Aranesp vials. The nurse practitioner from the NAS practice also participated in the meeting with NAWNY employees and provided them with the Aranesp overfill “Conversion Chart” from the nurse practitioner’s Syracuse practice. The Amgen sales representative reviewed this “Conversion Chart” from the NAS practice with the NAWNY employees and provided NAWNY’s billing staff with specific instructions on how to bill overfill amounts.

114. The Amgen sales representative provided the NAWNY physicians with information about overfill claims for payment made by the NAS practice in Syracuse, New York and promoted the financial benefits of billing overfill amounts to the NAWNY physicians.

115. At the direction of Amgen’s sales representative, NAWNY billed third-party payors, including Medicare and the New York State Medicaid Program, for 10% overfill over each Aranesp labeled dose. For example, for each 100 microgram vial of Aranesp it purchased from Amgen, NAWNY billed 110 micrograms, or 10% over the labeled dosage, to the New York Medicaid program.

116. From April 19, 2005 to August 21, 2006, physicians affiliated with NAWNY submitted claims for reimbursement for the overfill amounts contained in Aranesp vials to the

New York Medicaid program. For the aforementioned time period, physicians affiliated with NAWNY submitted at least 52 separate claims for the overfill amounts contained in Aranesp vials. The New York Medicaid Program paid at least \$2,420 in reimbursement for claims to NAWNY that were ineligible for payment, due to Amgen's illegal inducement.

117. For the aforementioned time period, Amgen's overfill inducement caused physicians affiliated with NAWNY to submit false certifications to the New York Medicaid and Medicare Programs that they were in compliance with state and federal laws, including the New York State and federal anti-kickback laws.

D. Winthrop University Hospital

118. In 2006, Amgen offered inducements in the form of free Aranesp to Winthrop University Hospital, located at 259 First Street, Mineola, New York 11501 to get Winthrop University Hospital to administer Aranesp to its dialysis patients.

119. Amgen employees, including District Manager Eric Hedge, offered free Aranesp product, in the form of overfill, to induce Winthrop University Hospital to purchase and administer Aranesp. During a meeting with Long Island hospitals, at which Sales Representative 2 and Amgen Regional Hospital Manager, Carol Sheridan, were present, District Manager Eric Hedge outwardly promoted Aranesp by emphasizing the overfill profit benefit to Winthrop University Hospital.

120. The Director of Pharmaceutical Services at Winthrop University Hospital stated that they switched from Epogen to Aranesp in 2006, in part, because Amgen employees indicated that Aranesp would have a beneficial dosing advantage over Epogen. He acknowledged that Winthrop University Hospital administers the overfill contained in Aranesp vials to its patients, noting that "the overfill dosages provide the hospital with more of the drug

than it paid for and therefore the hospital saves money by having to buy less drug.”

121. The ESRD Clinic Administrator for Winthrop University Hospital reported that 10% overfill was administered to the patients and billed to New York Medicaid and the Medicare programs. She reported that approximately 5% of their patient population is Medicaid, while approximately 77% is Medicare. She further reported that Winthrop University Hospital created a dosing protocol for Aranesp that included the overfill amounts in the physician’s orders. Therefore, a physician would order that 110 micrograms be administered to a patient, so as to capture the 10% overfill.

122. Winthrop University Hospital billed third-party payors, including the New York State Medicaid Program and the Medicare Program, for 10% overfill amount above each Aranesp labeled dose. For example, for each 100 microgram vial of Aranesp it purchased from Amgen, Winthrop University Hospital would bill 110 micrograms, or 10% over the labeled dosage, to the New York Medicaid and Medicare programs.

123. From March 3, 2006 to December 28, 2008, provider Winthrop Hospital submitted claims for reimbursement for the overfill amounts contained in Aranesp vials to the New York Medicaid program. For the aforementioned time period, Winthrop Hospital submitted at least 179 separate claims for the overfill contained in Aranesp vials, amounting to at least \$30,000 in Medicaid reimbursements paid by the New York Medicaid program for claims that were ineligible for payment.

124. For the aforementioned time period, Amgen’s overfill inducements caused Winthrop University Hospital to submit false certifications to the New York Medicaid and Medicare Program that Winthrop University Hospital was in compliance with state and federal laws, including the New York State and federal anti-kickback laws.

E. North Shore University Hospital

125. Amgen offered inducements in the form of free Aranesp to North Shore University Hospital (“NSUH”), located at 300 Community Drive, Manhasset, New York 11030, in order to get NSUH to switch from purchasing Procrit to purchasing Aranesp.

126. Amgen employees, including District Manager Eric Hedge, used overfill amounts in Aranesp vials to induce NSUH to convert from purchasing and administering Procrit to purchasing and administering Aranesp. District Manager Eric Hedge outwardly promoted the “overfill profit benefit” as a means for NSUH to make additional profit on the administration of Aranesp.

127. Following NSUH’s conversion to Aranesp, and at the direction of Amgen representatives, NSUH billed third-party payors, including the New York State Medicaid Program, for the free product it received from Amgen, in the amount of 20% overfill over each Aranesp labeled dose. For example, for each 100 microgram vial of Aranesp it purchased from Amgen, NSUH would bill 120 micrograms, or 20% over the labeled dosage, to the New York Medicaid program.

128. From September 5, 2005 to December 12, 2008, provider NSUH submitted claims for reimbursement for the overfill amounts contained in Aranesp vials to the New York Medicaid program. Specifically, NSUH submitted at least 131 separate claims for the overfill amounts contained in Aranesp vials, amounting to at least \$13,000 in Medicaid reimbursements paid by the New York Medicaid program for claims that were ineligible for payment.

129. For the aforementioned time period, Amgen’s overfill inducements caused NSUH to submit false certifications to the New York Medicaid and Medicare Programs that NSUH was in compliance with state and federal laws, including the New York State and federal anti-

kickback laws.

F. Bronx Westchester Medical Group

130. In 2004 and continuing into 2009, Amgen offered inducements, in the form of free overfill, to Bronx Westchester Medical Group, located at 1521 Jarret Place, Bronx, New York 10461-2606. Amgen representatives offered the overfill to Bronx Westchester Medical Group so as to prevent it from buying and administering Procrit.

131. Amgen employees told a physician affiliated with the Bronx Westchester Medical Group about the overfill amounts contained in Aranesp vials. The Amgen sales representatives told the physician that the practice could bill for the free overfill as a means to profit from administering Aranesp. The overfill was a “selling point” for Bronx Westchester Medical Group and dissuaded the practice from buying Procrit. The physician was shown economic analyses comparing Aranesp and Procrit and potential overfill profits by Amgen sales representatives. Amgen sales representatives never allowed the physician to keep those economic analyses but would only permit him to view them while the Amgen sales representative was present. During the time that Bronx Westchester Medical Group was considering converting to Procrit, Amgen sales representatives also facilitated telephone calls or meetings between other medical providers, INN representatives and Bronx Westchester Medical Group employees to pitch Aranesp as being the lower cost alternative to Procrit.

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

133. At the direction of Amgen’s sales representatives, physicians associated with the Bronx Westchester Medical Group billed third-party payors, including Medicare and the New

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

134. From August 10, 2004 to May 29, 2009, physicians affiliated with Bronx Westchester Medical Group submitted claims for reimbursement for the overfill contained in Aranesp vials to the New York Medicaid program. For the aforementioned time period, physicians affiliated with Bronx Westchester Medical Group submitted at least 139 separate claims for the overfill contained in Aranesp vials, amounting to at least \$21,000 in Medicaid reimbursements paid by the New York Medicaid program for claims that were ineligible for payment.

135. For the aforementioned time period, Amgen's overfill inducements caused physicians affiliated with Bronx Westchester Medical Group to submit false certifications to the New York Medicaid Program that they were in compliance with state and federal laws, including the New York State and federal anti-kickback laws.

DAMAGES TO THE STATE MEDICAID PROGRAMS

136. Amgen offered the free overfill in Aranesp vials to medical providers so as to induce medical providers to buy Aranesp and so as to gain the market share over the competing drugs, Procrit and Epogen. In pitching the "overfill profit" a medical provider could earn in billing for the free Aranesp product, Amgen caused medical providers to use and seek reimbursement for free product from the Medicare and the Intervening Plaintiff States' Medicaid programs. These overfill claims were not reimbursable, however, because they were ineligible for payment as a result of the illegal kickbacks. Additionally, the Intervening Plaintiff States

also paid non-payable claims, as the secondary insurer, for dually-eligible Medicare and Medicaid recipients and for Medicare patients on dialysis, where overfill claims were presented to Medicare as the primary insurer, and a state Medicaid program paid an amount (also referred to as a “cross-over claim”) as the secondary insurer.

137. Amgen’s overfill 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. By virtue of Amgen’s overfill inducements to medical providers, the Medicare program and the Intervening Plaintiff States’ Medicaid 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 medical providers and pharmacies for renewed and continuing treatments of Aranesp for patients who might not have otherwise received that treatment; and (4) reasonably and foreseeably paid medical providers and pharmacies for the more expensive drug, Aranesp, rather than the less costly alternatives, Procrit and Epogen.

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

138. In 2003, Amgen began discussions with representatives from the International Physician Network (IPN) about marketing Aranesp to Amgen’s nephrology customers. IPN, a company that owned GPOs, such as International Oncology Network, created the International Nephrology Network to target nephrology specialists and work with Amgen to promote Aranesp. Shortly after IPN/INN and Amgen began discussions about working together to promote Aranesp, a high-level Amgen employee left Amgen to join the newly-formed INN. In July 2003,

Anthony J. Corrao, the Director of Sales in Amgen's Physician Practice Management Group, left Amgen and became the Executive Vice President and General Manager of INN. Not surprisingly, in September of 2003, Amgen executed contracts with INN whereby INN would plan "Advisory Board" meetings for Amgen-targeted medical providers. Separately, Amgen entered into a "GPO agreement" with INN providing the conditions under which INN would purchase Aranesp on behalf of its GPO members.

The INN Advisory Board Contracts

139. In June of 2003, Amgen began negotiations with IPN/INN concerning INN's proposal to plan and execute dozens of regional and practice "Advisory Board" meetings for potential Aranesp nephrology customers including: "nephrologists, nurse and office manager consultants" in a "comfortable and enjoyable environment" on behalf of Amgen. INN submitted a formal proposal to Amgen on or about June 10, 2003 (the "INN Proposal"). The INN Proposal was then edited and revised by Amgen personnel, including Eric Price, Aranesp Team Product Manager, and Sherry Danese, Associate Director of Global Marketing. Several rounds of revisions were made to the INN Proposal by Amgen and INN employees.

140. A June 25, 2003 memorandum from Aranesp Team Product Manager Eric Price to INN proposed further changes to INN's proposal for Advisory services dated June 24, 2003. Mr. Price asked that the INN proposal be revised to "include specific measurement criteria" to "assess the performance of INN initiatives." Notably, the memorandum requests that Amgen measure INN's performance quarterly based upon the change in Aranesp sales and Aranesp market share for the advisory board attendees. Specifically, Mr. Price requested that INN's performance would be based on the following quantitative measures: "Overall growth" of the ESA market; "Change in Aranesp sales"; and "Aranesp market share" for the "advisory board

attendees versus a control group of other Amgen targets.” Amgen’s quantitative metrics from the memorandum were then incorporated into the revised INN Proposal verbatim.

141. Pursuant to the INN Proposal, Amgen was to select the nephrologists who were to participate in these Advisory Board meetings, provide a list of speakers for the events, approve the final program content for these meetings, and pay honoraria and all expenses (travel, accommodations) for the speakers and attendees. Both INN and Amgen employees would attend these meetings, which were intended to target a total of 220 nephrologists, nurses and office managers nationally.

142. In addition to being reimbursed for travel expenses, the INN Proposal states that every nephrologist, nurse or office manager attendee would be paid an honorarium by Amgen to *attend* the meeting. These “consulting fees” would allegedly be paid to attendees for their “services” in providing “perspectives on emerging information in this therapeutic area” of anemia of chronic kidney disease. The INN Proposal further required that every Advisory Board meeting attendee be sent an Amgen consultant agreement once they registered to attend the meeting.

143. Pursuant to the INN Proposal, Amgen was responsible for paying for the travel, hotel, and meal expenses for all Advisory Board meeting attendees and attendees were also provided with “an expense reimbursement form from Amgen submitting expenses associated with travel and incidentals” including such incidentals as: “movies, spa or gift shop purchases.”

144. Based on the negotiated INN Proposal, in September of 2003, Amgen executed two contracts with INN (the “INN Contracts”), whereby Amgen agreed to pay INN a total of \$975,600, plus expenses, to plan twenty-eight (28) advisory board meetings for Amgen-selected Aranesp customers.

145. The INN Contracts provided that Amgen would pay honoraria to the speakers and attendees of the advisory board meetings. Speakers would receive \$1000, and attending nephrologists would receive \$500 each from Amgen to attend the meetings. Amgen also paid/reimbursed attendees for all travel expenses, weekend lodging, meals and incidentals related to these meetings. Even business related entertainment was reimbursed by Amgen for its guest attendees. All attendees were required to enter into “consultant agreements” with Amgen prior to attending the meetings in order to receive their “honoraria” payments.

146. Pursuant to the INN Contracts, advisory board meetings were held in: Washington, D.C. on October 3-4, 2003; Dallas, Texas on October 24-25, 2003; Miami, Florida on November 21-22, 2003 and Los Angeles, California on December 13-14, 2003. INN also coordinated 24 practice advisory board meetings based on target attendees lists supplied by the Amgen sales force. Amgen provided lists of medical providers that INN should target for the weekend advisory board meetings. These weekend advisory board meetings were held at lavish hotels, with Friday night receptions and dinners and only included a Saturday meeting schedule. In addition to having all expenses, meals and entertainment paid by Amgen, attendees were paid “consulting fees” by Amgen to attend these Saturday meetings.

147. These INN Contracts were a conduit for Amgen and INN to provide kickbacks, including sham consultancy fee payments and all expense paid weekend trips, to Aranesp nephrology-specialty customers. Amgen’s metrics, which evaluated INN’s performance on the attendees’ “change in Aranesp sales” and “Aranesp market share,” very clearly denoted that the purpose of these meetings was to increase Aranesp sales and market share for the Amgen-selected attendees. The sole purpose of these advisory board meetings was to ingratiate a targeted group of nephrologists and their staff, who were invited and paid by Amgen to attend

the meetings. Even the INN sales force referred to these advisory board meetings as “weekend retreats” in their nephrology practice assessments, as discussed *infra* ¶ 175. By currying favor with these medical providers, Amgen and INN intended to induce them to buy more Aranesp and less Procrit.

148. In January 2004, Amgen and INN entered into a third consulting agreement whereby INN would be paid \$354,750, plus expenses, to plan three additional advisory board meetings for Amgen-selected medical providers. Like the prior advisory board meeting agreements, this agreement required Amgen to approve final program content, generate a list of invitees, pay all honoraria and incidental expenses for all attendees and speakers, and pay for all travel and meals.

149. According to a PowerPoint presentation dated June 2004 and presented by Amgen employee Eric Price at a Los Angeles District Meeting, the INN program objectives included: an increase in the anemia of chronic kidney disease treatment penetration in the “current patient base”; an increase in the “number of patients treated for anemia of chronic kidney disease”; and to “further establish goodwill with the Nephrology community.” Indeed, Amgen and INN’s efforts to “establish goodwill” by these Advisory Board meetings were nothing more than kickbacks to medical providers designed to induce Aranesp sales. To be sure, Amgen estimated that it paid \$264,000 in “honoraria” for these 2003 advisory board meetings and an additional \$186,000 in “honoraria” for 2004 advisory board meetings according to a 2004 PowerPoint by Amgen employee Eric Price entitled “INN Reference Slides.” The 2004 PowerPoint presentation states that the total program costs for the INN planned advisory board meetings were \$3.56 million for 2003 and 2004, excluding INN’s fees and costs of \$3.1 million to plan the meetings.

150. In addition to conspiring with Amgen to offer sham consultancy fees and weekend junkets to medical providers, Defendant INN also improperly advocated and encouraged medical providers to seek reimbursement for Aranesp overfill at these advisory board meetings. For example, on March 26 and 27, 2004, Relator Westmoreland attended a weekend INN advisory board meeting at The Carmel Valley Ranch in Carmel, California. At this meeting, Amgen, INN and ASD Healthcare representatives were in attendance. INN representatives openly pushed physicians and office managers to seek reimbursement for free Aranesp overfill. 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 if they were *not* actually administered to patients – then the overfill claims to third-party insurers, Medicare and Medicaid would supposedly pass an audit. According to an Amgen Conference Agenda for this meeting, one of the potential breakout sessions was “billing and reimbursement simplified.” An INN registration roster dated March 25, 2004 for the Carmel, California meeting reflects that medical providers were invited to attend from the following states: Arizona, California, Colorado, Florida, Idaho, Illinois, Iowa, Kansas, Maryland, Michigan, Montana, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Texas, Utah, and Washington.

151. Amgen and INN conspired to offer and offered and paid kickbacks to medical providers to induce Aranesp sales and prescriptions by offering medical providers weekend junkets, sham honoraria and overfill inducements. Amgen and INN's fraudulent scheme reasonably and foreseeably caused medical providers: (1) to submit false certifications with the Medicare and Intervening States' Medicaid programs of their compliance with the anti-kickback laws; (2) to submit ineligible claims for Aranesp to the Medicare and Intervening Plaintiff States' Medicaid programs for provider-administered or retail pharmacy claims for Aranesp that

otherwise would not have been ordered and/or prescribed; (3) to submit Aranesp claims relating to the renewal, reorder or continuing course of treatment for their patients by virtue of kickbacks; and (4) to submit Aranesp claims to the Medicare and Intervening Plaintiff States' Medicaid programs that instead could have been for the less costly alternatives, Procrit and Epogen.

The INN GPO Agreement

152. Shortly after entering into the INN advisory board meeting contract, Amgen and INN entered into a "strategic partnership" arrangement. On or about September 15, 2003, Amgen and INN entered into a Group Purchasing Organization Agreement ("INN GPO Agreement") relating to the purchase of Aranesp for INN's GPO customers. INN was the sole GPO partner with Amgen in the chronic kidney disease (non-dialysis) market. At some point in 2004, INN was acquired by AmerisourceBergen Specialty Group.

153. In March of 2004, Relator Westmoreland was promoted from a sales position to Amgen's marketing department in headquarters and was assigned responsibility for Amgen's relationship with INN. Relator became privy to certain information and documentation that caused Relator to believe that INN was not an independent GPO, but rather, an entity that essentially functioned as a *de facto* marketing arm for Amgen to promote Aranesp.

INN's GPO Administrative Fee from Amgen

154. The term of the initial INN GPO Agreement was extended by amendments to run from at least September 15, 2003 through December 31, 2006. In or about December 2006, Amgen entered into a second group purchasing agreement with INN specific to dialysis centers and providers (the "Dialysis GPO Agreement") relating to the purchases of Epogen and Aranesp. Similar to the INN GPO Agreement, discussed *infra*, the Dialysis GPO Agreement required Amgen to pay INN a volume-based performance administrative fee of up to two percent (2%),

plus an “Affiliate Information Program” (“AIP”) performance-based administration fee of up to one percent (1%). The AIP program required that INN customers submit their clinical patient data in order for INN to qualify for this performance administrative fee.

155. Amgen made more than twenty amendments to the INN GPO Agreement, many of which changed the purchase or rebate terms for specific INN customers. By example, a July 18, 2006 amendment by Amgen to the INN GPO Agreement (Amendment 15) extends an additional 2% supplemental rebate, over and above the 4% supplemental rebate then available from INN to a nephrology practice located in Orlando, Florida. Another amendment to the INN GPO Agreement dated September 18, 2006 (Amendment 18) requires INN to extend “Tier D” rebates to a nephrology practice based in Richmond, Virginia. Although the practice didn’t qualify for Tier D rebates based on its volume purchases and market share from INN, Amgen required INN to extend those rebates. Many of Amgen’s amendments to the INN GPO Agreement were made to extend more favorable terms to its customers than otherwise available to that customer by virtue of INN membership.

156. The INN GPO Agreement required that Amgen pay INN an administrative fee based on qualified net purchases less “any discounts, rebates or other incentives” (“Net Purchases”) to participating physician practices. The INN GPO Agreement provided that the total of all administrative fees paid by Amgen to INN was three percent (3%) or less of the Net Purchases of Aranesp provided to INN’s GPO customers.

157. Pursuant to the INN GPO Agreement and subsequent amendments, Amgen paid INN a three percent (3%) administrative fee on Net Purchases, with the exception of April 1, 2004 through August 14, 2004. For that period, Amgen paid INN a one percent (1%)

administrative fee on all Net Purchases of Aranesp by INN's customers, plus a performance based administrative fee of 2%.

158. A PowerPoint presentation entitled "INN GPO Amendment Analysis" dated August 2004, and created by Hani Sefain, Amgen Associate Director of Corporate Pricing (the "August 2004 INN PowerPoint"), contains a slide describing the 3% administrative fee structure as follows:

- Originally set up to provide oversight and management of the INN GPO
 - 3% of total Aranesp sales through the GPO paid to INN quarterly through March 31, 2004
 - INN passed through 1% of the sales to ASD, the preferred vendor
 - This provides INN with 2% for operations, to deploy a sales and practice management team of eight, to target loyal Procrit customers

The August 2004 INN PowerPoint is annexed hereto as Exhibit E.

159. The August 2004 INN PowerPoint presentation (Exhibit E) also addresses the performance-based administrative fee that INN could earn for April 1, 2004 through August 14, 2004 pursuant to the INN GPO Agreement. The PowerPoint states that INN requested an extension of the 3% non-performance administrative fee because INN had not been "able to meet performance measures in the current contract due to a multitude of historical reasons and may not be able to receive the full 3% (1% base + 2% performance)". See Exhibit E, p. 2. The Amgen PowerPoint recommends extending a "grace" period from August 15, 2003 through February 28, 2005 to INN "so that they receive the 3% Admin fee with a requirement to work with Amgen to alleviate current ASD (Wholesaler) chargeback issues." *Id.* Consequently, INN and Amgen were concerned about INN's viability because it could not meet the performance

measures Amgen had established. Amgen planned to use an increase in the administrative fee to negotiate with ASD Healthcare, INN's distributor, over Aranesp pricing discrepancies.

160. Indeed, an Amgen PowerPoint presentation dated April 29, 2005 entitled "National Account Business Review Corporate Accounts, GPOs, Key CAM Initiatives", states at slide 44 that INN's performance-based administrative fee "was dropped in August due to concern for survival of INN under new ownership" [AmerisourceBergen Specialty Group]. Consequently, from August 15, 2004 through December 31, 2006, Amgen paid INN a fixed three percent (3%) administrative fee on all Net Purchases of Aranesp by INN's customers.

161. Pursuant to the INN GPO Agreement, INN provided Amgen with a complete membership list of its GPO customers. According to a list of INN GPO members annexed to the INN GPO Agreement in September 2003, INN had only roughly 35 different nephrology practices listed as GPO members.

162. Amgen subsequently provided INN with "target lists" of practices that it wished INN to convert from Procrit to Aranesp. By example, Aranesp Team Product Manager Eric Price circulated an excel spreadsheet, entitled "INN targeting accounts", dated November 4, 2003, for the Amgen sales representatives "to supply a list of accounts for George [Esgro] to communicate to INN. The list is unlimited, so please supply all difficult and important unpenetrated accounts where INN can make an impact." Mr. Price added the following, "PSRs [Professional Sales Representatives] should not be promoting or discussing INN services with their accounts. If a PSR wishes to have INN call on an account they must submit the account on this list. We can direct INN to accounts but can not direct accounts to INN." As a result, INN's membership grew rapidly over the next year.

163. A March 16, 2004 PowerPoint created by INN for Amgen suggests that INN had already grown to 750 physician members. The PowerPoint states that INN's Aranesp sales for 2003 totaled \$870,299, which was surpassed by its January 2004 sales of \$898,727 and February 2004 sales of \$1.3 million. In that PowerPoint, INN lists its business strategy as including: "converting Procrit users to Aranesp"; "expanding the treatment of CRI in nephrologists' offices"; and "building fidelity with nephrologists by developing their awareness and competencies of diversified revenue opportunities."

INN's Administrative Fee Failed to Meet Safe Harbor Exceptions

164. The administrative fees that Amgen paid to INN did not comply with the safe harbor exceptions to the AKS for group purchasing organizations. *See* 42 C.F.R. § 1001.952(j). HHS-OIG Advisory Opinion No. 01-6, issued May 22, 2001, explicitly states that the "GPO fee must be paid as part of an agreement to furnish good or services to the group of individuals or entities for which the GPO is the authorized agent." The safe harbor provisions expressly require that "the GPO must have a written agreement with each hospital or health care provider." *See* 42 C.F.R. § 1001.952(j), and by definition, a GPO's membership consists "solely of hospitals and health care entities bound by written contract with the entity." *See* 21 CFR § 203.3.

165. Here, Amgen paid INN an administrative fee "to deploy a sales and practice management team of eight, to target loyal Procrit customers"—not to furnish services to customers for whom INN was the authorized agent. *See* Exhibit E. Indeed, INN provided services funded through Amgen's administration fee, such as practice assessments, to medical providers who *were not* its GPO members and not covered by a written agreement as required for safe-harbor protection. INN failed to have written agreements with medical providers for which it provided services funded through the Amgen administration fee. By example, on December 8,

2003, INN completed a detailed practice assessment for Rockland Renal Associates of West Nyack, New York. At the time that INN completed that practice assessment, Rockland Renal Associates was utilizing Procrit and was not enrolled as an INN GPO member.

166. As evidenced by INN's diminutive customer list at the time the INN GPO Agreement was executed and Amgen's provision of "target" Procrit accounts to INN for conversion to Aranesp, the fixed GPO administrative fee was not designed to cover operational costs or services to GPO members for which INN was the authorized agent. In actuality, the GPO administrative fee was a payment to INN for marketing Aranesp to Procrit accounts.

The INN "Pass Through" Payment to ASD Healthcare

167. INN purchased Aranesp exclusively from wholesaler ASD Healthcare, which became its sister-company once it also became a wholly owned subsidiary of AmerisourceBergen Specialty Group, to wit, in 2004. Exhibit 3 to the INN GPO Agreement lists ASD Specialty Healthcare as its authorized wholesaler and provides Evan Gremont as the ASD Healthcare contact. Currently, INN's website lists ASD Healthcare as its "preferred distribution partner." See <https://www.inn-online.com/display.aspx?cid=711.cms> (viewed October 15, 2009).

168. A PowerPoint that Anthony Corrao, INN Executive Vice President of Global Sales and Development, presented to Amgen marketing employees, including Relator Westmoreland by email dated July 21, 2004, explains how INN passed through part of Amgen's administrative fee to ASD Healthcare. The July 21, 2004 PowerPoint (and cover email to Relator Westmoreland) is annexed hereto as Exhibit F. The PowerPoint states that INN passes through 1% of the GPO administrative fee for Aranesp purchases to ASD Healthcare. See Exhibit F, p. 1; *see also* Exhibit E.

169. INN's pass through payment of Amgen's administrative fee to ASD Healthcare, its distributor, further illustrates that Amgen's administrative fee to INN fell outside the AKS "safe harbor" exceptions for GPOs. As previously noted, HHS-OIG Advisory Opinion No. 01-6, issued May 22, 2001, explicitly states that the "GPO fee must be paid as part of an agreement to furnish goods or services to the group of individuals or entities for which the GPO is the authorized agent." Part of Amgen's administrative fee was not used by INN for operational expenses or to furnish goods or services to INN's GPO members, rather it was funneled to its sister-company, ASD Healthcare.

170. In addition to distributing Aranesp to INN's members, ASD Healthcare also worked closely with Amgen. ASD Healthcare even shared its confidential Aranesp pricing spreadsheets for INN customers with Amgen's marketing department by email dated June 28, 2004 from Evan Gremont, ASD Healthcare Nephrology Account Manager, to Relator Westmoreland. ASD Healthcare shared this proprietary information with Amgen, even though that permitted Amgen to then calculate ASD's profit margin.

171. ASD Healthcare's sales force even attended and presented at INN advisory board meetings. At the advisory board meeting that Relator Westmoreland attended in Carmel, California, ASD Healthcare Account Manager Evan Gremont was in attendance and presented during some of the breakout sessions.

172. ASD sales representatives, such as Evan Gremont, would "buddy up" with Amgen sales representatives in order to get a large Aranesp account to buy the drug from ASD Healthcare. After the ASD Healthcare representative and the Amgen sales representative discussed pricing, the Amgen sales representative would then convey to a customer that if they switched to ASD, they would get a better price on Aranesp. Specifically, ASD Healthcare

account manager Mr. Gremont told Relator Westmoreland that he quoted pricing to customers based on “how important of a customer they were to Amgen.”

173. ASD Healthcare had good reason to assist Amgen and INN in promoting and selling Aranesp, because ASD Healthcare profited from all net purchases of Aranesp under the INN GPO Agreement, receiving INN’s “pass through” payment of 1% of the Aranesp Net Purchases.

Amgen and INN’s Conspiracy to Offer Inducements

174. After entering the INN GPO Agreement, INN hired five Strategic Account Managers (“SAMs”) to call on nephrology accounts to sell Aranesp, including Angela Miele, a former Amgen sales representative, and Dan Smitley, a registered nurse who worked as an independent consultant and speaker for Amgen (and was formerly employed as the Director of Clinical Services, San Antonio Kidney Disease Center, San Antonio, Texas). The Amgen sales force was encouraged to develop relationships and share information with the INN SAMs and coordinate their efforts to pitch Aranesp to medical providers. By email dated July 15, 2004, Amgen provided INN Director of Sales and Marketing, Gary Inglese, with the sales force roster and contact information for the nephrology sales force.

175. By example, an Amgen memorandum dated February 12, 2004 from Louis Deppe, Executive Director of Regional Sales (Nephrology), to the Miami nephrology sales force states, “We will work in lock step with INN to have **no** unpenetrated Target Accounts in your territories and maximize opportunities with our advocates.” (emphasis in original).

176. Among other things, INN provided sales reports, reports for accounts it successfully converted from Procrit to Aranesp, narrative reports specific to accounts, and practice assessments to the Amgen marketing and sales employees. INN SAMs and the Amgen

sales force shared information about target nephrology accounts, including account updates and practice assessments that INN completed for its GPO members as a “service”. These practice assessments contained proprietary information specific to the practice, including: the practice’s operating expenses, patient population payor mix, Procrit contract pricing, billing function, Medicare billing compliance, and ESA purchases. INN also made recommendations in the practice assessments of programs and services that it could provide the practices, such as “weekend retreats” and dinner meetings. Nowhere in the practice assessment did INN disclose that it was sharing the practice assessment with Amgen or that INN’s services, including “weekend retreats” and dinner meetings would be funded by Amgen. Moreover, the INN GPO enrollment forms do not disclose that Amgen was paying INN 3% on net purchases of Aranesp.

177. By example, a physician affiliated with Rockland Renal Associates of Nyack, New York, confirmed that INN prepared a practice assessment for his nephrology practice. The physician was surprised, however, that INN would have shared that practice assessment with Amgen. He stated that INN represented itself as a separate entity operating at arm’s length from Amgen. Rockland Renal Associates was not a member of INN at the time the practice assessment was conducted.

178. A November 2004 INN PowerPoint, entitled “INN Capabilities Presentations for Amgen 11-04”, proposed, among other things, that Amgen pay INN to conduct additional practice assessments. The practice assessments required INN to be on site to gather data and interview for two days and would cost Amgen \$30,000 per practice assessment. Thus, the practice assessments conducted by INN were of significant value to the nephrology practices.

179. INN shared its practice assessments with Amgen to give Amgen a competitive advantage in trying to undercut Procrit pricing and to provide the Amgen sales force with an

understanding of the practice's financials and dynamics. This in turn increased INN's earnings under the administrative fee provision. Similarly, INN conspired with Amgen to offer "weekend retreats" to practices to gain Aranesp sales. By example, INN provided Amgen with practice assessments for the following practices, among others, located within the Intervening Plaintiff States: Balboa Nephrology Medical Group, San Diego, CA; Carabello Nephrology, Los Angeles, CA; Central Nephrology Group, Bakersfield, CA; Vita Medical Center, Los Angeles, CA; Nephrology Medical Associates, Tarzana, CA; Washington Hospital Center, Washington, DC; Nephrology Associates of South Miami, Miami, FL; Nephrology Hypertension Clinic, PC, Dearborn, MI; Mid Michigan Kidney and Hypertension Clinic, Flint, MI; Nephrology and Internal Medicine of Flint, Flint, MI; Nephrology Associates of Michigan, Ypsilanti, MI; Queens/Nassau Nephrology, Garden City, NY; and Rockland Renal, West Nyack, NY.

180. In addition to collaborating on target Procrit accounts, the Amgen sales representatives and the INN SAMs actually met with medical providers together to pitch Aranesp. For example, an email exchange dated January 7, 2005, between Claes Hornstrand, Regional Sales Director for the Western Region (now Executive Director of Marketing), and Jeremy Jaggi, then District Sales Manager (now Senior Manager of Sales and Planning Operations), reflects how closely the Amgen sales force was working with INN SAM, Shelley Huttar, to pitch accounts in Idaho:

Jaggi: "FYI, because we received this feedback from Tanya [about INN representative Shelley Huttar], we spent 1.5 hours with Shelley [INN SAM] Thursday before a meeting with Idaho nephrology. All went well, and after all these years, may indeed win Idaho Nephrology next week."

Hornstrand: "I am keeping my fingers crossed for you on the Idaho Neph [sic] situation. Is Shelley going to talk "brass tax" [sic] there? If so we need to make sure Amgen people are not in

the room (it needs to be orchestrated). We should probably talk about this live.”

Jaggi: “It was an orchestrated approach. Stephanie [Amgen representative] left the room when they got down to brass tacks. It was helpful. They liked the possibility of injecting Iron for economic purposes. They liked the 5.5% they get from INN to get to 16.5% off invoice. I think we’ll get them. We’ll find out by Wed. next week.”

181. In a January 11, 2005 email to Claes Hornstrand and Jeremy Jaggi regarding this meeting, the Amgen sales representative, Stephanie, advised:

“I do believe that having INN join me did tip the scale in our favor after gaining the agreement that they felt Aranesp would be more clinically efficient. I am planning to proactively have Shelley [INN SAM] join me in a few more clinics to secure the partnership already established with Amgen in regards to Aranesp in CKD [Chronic Kidney Disease]. I believe by doing that, I will be bringing them a resource that Ortho [Biotech] hasn’t and it shows our proactiveness at bring [sic] to them GPO benefits like we have in the iFSDC [Free Standing Dialysis Clinics].

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

183. This sales technique permitted the INN sales representatives to present economic analyses and offer overfill inducements on behalf of the Amgen sales force, without the appearance of Amgen offering financial incentives or marketing the economics of Aranesp. In

reality, INN was being paid administrative fees that were based on the Procrit accounts it successfully converted to Aranesp, much the same as a sales representative would be paid a salary and bonuses.

184. Relator Westmoreland 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. She learned that INN would prepare practice assessment forms and then, unbeknownst to the physician, would share the results with Amgen. Then Amgen and INN could formulate a plan to get the physician practice to switch to Aranesp.

185. By example, a physician associated with Rockland Renal Associates, referenced *supra*, reported participating in a dinner meeting with an Amgen sales representative and INN sales representative before his practice converted from Procrit to Aranesp in 2004. He stated that at one point during the dinner, the Amgen sales representative left the table and the comment was made that the INN and Amgen sales representatives "can't talk in front of each other." INN and Amgen won the Rockland Renal Associates account. As can be seen from the August 2004 PowerPoint concerning the INN GPO, annexed at Exhibit E, Rockland Renal was listed as a \$1.2 million dollar account.

186. Amgen further used this faux GPO relationship to conspire with INN to offer overfill inducements to medical providers. By example, a New York-based nephrologist affiliated with Bronx Westchester Medical Group reported that he met with an INN SAM who promoted Aranesp. He reported that the INN SAM promoted the free overfill in Aranesp vials as a means for his practice to make profits. This nephrologist further stated that he believed INN to be affiliated with Amgen and that the INN SAMs to be Amgen employees because of how

heavily they pushed him to buy Aranesp. An INN PowerPoint dated July 19, 2004 entitled “INN Update” confirms that an INN SAM and Amgen sales representative jointly called on this Bronx Westchester Medical Group nephrologist to pitch Aranesp.

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

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

188. Accordingly, even the Vice President of Sales, Leslie Mirani, was aware that INN was offering overfill inducements and marketing the spread to accounts that Amgen wished INN to target.

189. An Amgen PowerPoint dated October 19, 2005 by Corporate Account Manager Chris Coates provides insights into the Amgen and INN relationship. The PowerPoint states that INN members accounted for 54% of Aranesp nephrology clinic sales, and that the Aranesp market share was 20 points higher for INN members than the market share for non-INN Aranesp accounts. The kickbacks to the nephrology community had paid off for Amgen.

190. Accordingly, Defendants’ inducements, in the form of sham consultancy agreements, weekend retreats, and other services offered by INN stemming from the GPO “administrative fee”, 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. By virtue of Defendants' inducements to medical providers, the Medicare program and the Intervening Plaintiff States' Medicaid programs: (1) reasonably and foreseeably paid medical providers for free Aranesp product; (2) reasonably and foreseeably paid medical providers for provider-administered and prescribed Aranesp that those medical providers would not have otherwise ordered or prescribed; (3) reasonably and foreseeably paid medical providers and pharmacies for renewed and continuing treatments of Aranesp for patients who would not have otherwise received that treatment; and (4) reasonably and foreseeably paid medical providers and pharmacies for the more expensive drug, Aranesp, rather than the less costly alternatives, Epogen and/or Procrit.

CLAIMS OF THE STATE OF CALIFORNIA

COUNT ONE

CALIFORNIA FALSE CLAIMS ACT

(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
Cal. Gov't Code § 12651(a)(1), (2)

191. The State of California repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

192. The California False Claims Act (“CAFCA”), specifically provides, in pertinent part, that any person who:

(a)(1) Knowingly presents or causes to be presented to an officer or employee of the state or of any political subdivision thereof, a false 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 claim paid or approved by the state or by any political subdivision; [or] (3) Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.

Shall be liable to the state for three times the amount of damages which the state sustains because of the act . . . and shall also be liable to the state for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state for a civil penalty of not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000) for each false claim.

193. The CAFCA defines the terms “knowing” and “knowingly” to mean that a person, with respect to information: “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.” Cal. Gov't Code § 12650(b)(2).

194. From 2002 to present, Amgen 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.

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

196. 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.

197. Defendants knowingly caused to be presented and/or caused to be made or used claims for Aranesp resulting from the kickbacks and thereby causing the Medicaid program to reimburse ineligible claims.

198. 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 California suffered damages and therefore is entitled to recover from Defendants treble damages under the CAFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT TWO
CALIFORNIA FALSE CLAIMS ACT
(Conspiring to Cause the Submission of False Claims)
Cal. Gov't Code § 12651(a)(1), (2)

199. The State of California repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

200. From 2003 to present, Defendants Amgen, INN and ASD Healthcare conspired to defraud the State of California 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.

201. From 2003 to present, Defendants conspired to defraud the State of California 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.

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

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

CLAIMS OF THE DISTRICT OF COLUMBIA

COUNT THREE

PROCUREMENT REFORM AMENDMENT ACT (Presentation of False Certifications/Claims in Connection with Violation of Anti-kickback Laws) D.C. Code § 2-308.14(a)(1), (2)

204. The District of Columbia repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

205. The Procurement Reform Amendment Act (“DCFCA”), specifically provides, in pertinent part, that any person who:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false 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 claim paid or approved by the District; (3) Conspires to defraud the District by getting a false claim allowed or paid by the District

shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person [and] . . . acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than \$5,000, and not more than \$10,000, for each false claim . . .

206. The DCFCA defines the terms “knowing” and “knowingly” to mean that a person, with respect to information: “(i) has actual knowledge of the falsity of the information; or (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.” D.C. Official Code § 2-308.13(3)(A).

207. From 2002 to present, Amgen 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.

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

209. 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.

210. 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.

211. By virtue of the false or fraudulent claims, and/or false records or statements, including provider certifications, presented and caused to be presented, the District of Columbia 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 FOUR
PROCUREMENT REFORM AMENDMENT ACT
(Conspiring to Cause the Submission of False Claims)
D.C. Code § 2-308.14(a)(3)

212. The District of Columbia repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

213. From 2003 to present, Amgen, INN, and ASD Healthcare conspired to defraud the District of Columbia 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.

214. From 2003 to present, Defendants conspired to defraud the District of Columbia 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.

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

216. 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 District of Columbia to suffer damages. The District of Columbia is therefore 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 FIVE
COMMON LAW FRAUD**

217. The District of Columbia repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

218. From 2003 to present, Defendants caused fraudulent claims and false provider certifications to be made to the United States and the District of Columbia relating to Aranesp.

219. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

220. Defendants intended that the District of Columbia act or refrain from acting in justifiable reliance on these misrepresentations.

221. District of Columbia did, in fact, rely upon Defendants' fraudulent claims and false provider certifications. As a result, between 2003 and present District of Columbia paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

222. As a result of Defendants' conduct, the District of Columbia suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

**COUNT SIX
UNJUST ENRICHMENT**

223. The District of Columbia repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

224. The District of Columbia Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

225. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the District of Columbia, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the District of Columbia.

CLAIMS OF THE STATE OF DELAWARE

**COUNT SEVEN
DELAWARE FALSE CLAIMS AND REPORTING ACT
(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
Del. Code Ann. Tit. 6 §1201(a)**

226. The State of Delaware repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

227. The Delaware False Claims and Reporting Act ("DEFCRA"), specifically provides, in pertinent part, that any person who:

(a)(1) knowingly presents, or causes to be presented to an officer or employee of the Government 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 Government; [or] (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

shall be liable to the Government for a civil penalty of not less than \$ 5,500 and not more than \$ 11,000 for each act constituting a violation of this section, plus three times the amount of actual damages which the Government sustains because of the act of that person.

228. The DEFCRA defines the terms “knowing” and “knowingly” to mean that a person, with respect to information: “(a) has actual knowledge of the information; (b) acts in deliberate ignorance of the truth or falsity of the information; or (c) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.” Del. Code Tit. 6 § 1202(3).

229. From 2002 to present, Amgen 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.

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

231. 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.

232. Defendants knowingly caused to be presented and/or caused to be made or used claims for Aranesp resulting from kickbacks, thereby causing the Medicaid program to reimburse ineligible claims.

233. 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 Delaware suffered damages and therefore is entitled to recover from Defendants treble damages under the

DEFCRA, in an amount to be proved at trial, plus a civil penalty of at least \$5,500 for each violation.

COUNT EIGHT
DELAWARE FALSE CLAIMS AND REIMBURSEMENT ACT
(Conspiring to Cause the Submission of False Claims)
Del. Code Ann. Tit. 6 §1201(a)(3)

234. The State of Delaware repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

235. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the State of Delaware 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 by virtue of the kickbacks.

236. From 2003 to present, Defendants conspired to defraud the State of Delaware 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.

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

238. 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 Delaware to suffer damages. The State of Delaware is therefore entitled to recover from Defendants treble damages

under the DEFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,500 for each violation.

**COUNT NINE
COMMON LAW FRAUD**

239. The State of Delaware repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

240. From 2003 to present Defendants caused fraudulent claims and false provider certifications to be made to the United States and the State of Delaware relating to Aranesp.

241. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

242. Defendants intended that the State of Delaware act or refrain from acting in justifiable reliance on these misrepresentations.

243. Delaware did, in fact, rely upon Defendants' fraudulent claims and false provider certifications. As a result, between 2003 and present Delaware paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

244. As a result of Defendants' conduct, the State of Delaware suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

**COUNT TEN
UNJUST ENRICHMENT**

245. The State of Delaware repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

246. The Delaware Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

247. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the State of Delaware, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Delaware.

CLAIMS OF THE STATE OF FLORIDA

**COUNT ELEVEN
FLORIDA FALSE CLAIMS ACT
(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
Fla. Stat. 68.082(2)(a), (b)**

248. The State of Florida repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

249. The Florida False Claims Act (“FLFCA”) provides in pertinent part that any person who:

(a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false claim for payment or approval; (b) 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 an agency; [or] (c) conspires to submit a false or fraudulent claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid . . .

is liable to the state for a civil penalty of not less than \$5,000 and not more than \$10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person. Fla. Stat. 68.082(a).

250. The FLFCA defines the terms “knowing” and “knowingly” to mean that a person, with respect to information “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.” Fla. Stat. § 68.082(c).

251. From 2002 to present, Amgen 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.

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

253. 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.

254. Defendants knowingly caused to be presented and/or caused to be made or used claims for Aranesp resulting from the kickbacks, thereby causing the Medicaid program to reimburse ineligible claims.

255. 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 Florida suffered damages and therefore is entitled to recover from Defendants treble damages under the FLFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT TWELVE
FLORIDA FALSE CLAIMS ACT
(Conspiring to Cause the Submission of False Claims)
Fla. Stat. 68.082(2)(c)

256. The State of Florida repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

257. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the State of Florida 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

258. From 2003 to present, Defendants conspired to defraud the State of Florida 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.

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

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

**COUNT THIRTEEN
COMMON LAW FRAUD**

261. The State of Florida repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

262. From 2003 to present, Defendants caused fraudulent claims and false provider certifications to be made to the United States and the State of Florida relating to Aranesp.

263. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

264. Defendants intended that the State of Florida act or refrain from acting in justifiable reliance on these misrepresentations.

265. Florida did, in fact, rely upon Defendants' fraudulent claims and false provider certifications. As a result, between 2003 and present, Florida paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

266. As a result of Defendants' conduct, the State of Florida suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

**COUNT FOURTEEN
UNJUST ENRICHMENT**

267. The State of Florida repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

268. The Florida Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

269. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the State of Florida, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Florida.

CLAIMS OF THE STATE OF HAWAII

COUNT FIFTEEN

HAWAII FALSE CLAIMS ACT

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

Haw. Rev. Stat. § 661-21(a)

270. The State of Hawaii repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

271. The Hawaii False Claims Act (“HIFCA”), specifically provides, in pertinent part, that any person who:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the State 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 State; (3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

shall be liable to the State for a civil penalty of not less than \$5,000 and not more than \$10,000 for each act constituting a violation of this section, plus three times the amount of actual damages which the State sustains because of the act of that person.

272. The HIFCA defines the terms “knowing” and “knowingly” to mean that a person, with respect to information “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or

falsity of the information, and no proof of specific intent to defraud is required.” Haw. Rev. Stat. §661-21(e)

273. From 2002 to present, Amgen 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.

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

275. 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.

276. Defendants knowingly caused to be presented and/or caused to be made or used claims for Aranesp resulting from the kickbacks, thereby causing the Medicaid program to reimburse ineligible claims.

277. 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 Hawaii suffered damages and therefore is entitled to recover from Defendants treble damages under the HIFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT SIXTEEN
HAWAII FALSE CLAIMS ACT
(Conspiring to Cause the Submission of False Claims)
Haw. Rev. Stat. § 661-21(a)

278. The State of Hawaii repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

279. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the State of Hawaii 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

280. From 2003 to present, Defendants conspired to defraud the State of Hawaii 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.

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

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

**COUNT SEVENTEEN
COMMON LAW FRAUD**

283. The State of Hawaii repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

284. From 2003 to present Defendants caused fraudulent claims and false provider certifications to be made to the United States and the State of Hawaii relating to Aranesp.

285. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

286. Defendants intended that the State of Hawaii act or refrain from acting in justifiable reliance on these misrepresentations.

287. Hawaii did, in fact, rely upon Defendants' fraudulent claims and false provider certifications. As a result, between 2003 and present Hawaii paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

288. As a result of Defendants conduct, the State of Hawaii suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

COUNT EIGHTEEN UNJUST ENRICHMENT

289. The State of Hawaii repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

290. The Hawaii Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

291. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the State of Hawaii, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Hawaii.

CLAIMS OF THE STATE OF ILLINOIS

COUNT NINETEEN
ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT
(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
740 ILCS 175/3(a)(1)

292. The State of Illinois repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

293. The Illinois Whistleblower Reward and Protection Act provides, in pertinent part, that any person who:

(a)(1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard 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 State; [or] (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid . . .

is liable to the State for a civil penalty of not less than \$5,500 and not more than \$11,000 plus three (3) times the amount of damages which the State sustains because of the act of that person . . . and shall also be liable to the State for the costs of a civil action brought to recover any such penalty or damages.

740 ILCS 175/3(a).

294. The Illinois Whistleblower Reward and Protection Act defines the terms “knowing” and “knowingly” to mean that a person, with respect to information “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.” 740 ILCS 175/3(b).

295. From 2002 to present, Amgen 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.

296. For 2003 to present, Amgen, INN and ASD Healthcare also offered kickbacks to medical providers, including overfill in Aranesp vials, sham consultancy agreements, weekend retreats, and/or other services, to induce Aranesp sales and prescriptions.

297. 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.

298. Defendants knowingly caused to be presented and/or caused to be made or used claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

299. By virtue of the false or fraudulent claims, and/or false records or statement, including provider certifications, presented and caused to be presented, the State of Illinois suffered damages and therefore is entitled to recover from Defendants treble damages under the ILFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,500 for each violation.

COUNT TWENTY
ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT
(Conspiring to Cause the Submission of False Claims)
740 ILCS 175/3(a)(3)

300. The State of Illinois repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

301. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the State of Illinois 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

302. From 2003 to present, Defendants conspired to defraud the State of Illinois 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.

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

304. 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 Illinois to suffer damages. The State of Illinois is therefore entitled to recover from Defendants treble damages under the Illinois Whistleblower Reward and Protection Act, in an amount to be proved at trial, plus a civil penalty of at least \$5,500 for each violation.

**COUNT TWENTY ONE
COMMON LAW FRAUD**

305. The State of Illinois repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

306. From 2003 to present, Defendants caused fraudulent claims and false provider certifications to be made to the United States and the State of Illinois relating to Aranesp.

307. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual

knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

308. Defendants intended that the State of Illinois act or refrain from acting in justifiable reliance on these misrepresentations.

309. Illinois did, in fact, rely upon Defendants' fraudulent claims and false provider certifications. As a result, between 2003 and present, Illinois paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

310. As a result of Defendants' conduct, the State of Illinois suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

COUNT TWENTY TWO UNJUST ENRICHMENT

311. The State of Illinois repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

312. The Illinois Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

313. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the State of Illinois, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Illinois.

CLAIMS OF THE STATE OF INDIANA

COUNT TWENTY THREE
INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT
(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
Ind. Code § 5-11-5.5-2(b)(8)

314. The State of Indiana repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

315. The Indiana False Claims and Whistleblower Protection Act (“INFCA”), Ind. Code § 5-11-5.5-2(b), *et seq.*, provides in pertinent part, that any person who:

knowingly or intentionally: (1) presents a false claim to the state for payment or approval; (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state; (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state; (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true; (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property; (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state; (7) conspires with another person to perform an act described in Ind. Code. § 5-11-5.5-2(b)(1) or (2); or (8) cause or induces another person to perform an act described in subdivisions (1) through (6);

is liable to the state for a civil penalty of at least five thousand dollars (\$5,000.00) and for up to three (3) times the amount of damages sustained by the state. In addition, a person who violates this section is liable to the state for the costs of a civil action brought to recover a penalty or damages. Ind. Code. § 5-11-5.5-2(b).

316. The INFCA defines the terms “knowing”, “knowingly” and “known” to mean that a person, regarding information relating to a claim, “(a) has actual knowledge of the

information; (b) acts in deliberate ignorance of the truth or falsity of the information; or (c) acts in reckless disregard of the truth or falsity of the information.” Ind. Code § 5-11-5.5-1(4).

317. From 2002 to present, Amgen 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.

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

319. Defendants knowingly and/or intentionally caused medical providers to make and/or submit false certifications to the Medicaid program that the medical providers were in compliance with state and federal laws, including the Anti-Kickback Statute.

320. Defendants knowingly and/or intentionally caused medical providers to make and/or submit claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

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

COUNT TWENTY FOUR
INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT
(Conspiring to Cause the Submission of False Claims)
Ind. Code § 5-11-5.5-2(b)(8)

322. The State of Indiana repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

323. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the State of Indiana 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

324. From 2003 to present, Defendants conspired to defraud the State of Indiana by knowingly and/or intentionally 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.

325. From 2003 to present, Defendants conspired to defraud the State of Indiana by causing medical providers to submit claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

326. By virtue of their conspiratorial agreement, Defendants caused to be submitted false or fraudulent claims, and/or false records or statements, including provider certifications, to the Medicaid program, causing the State of Indiana to suffer damages. The State of Indiana is therefore entitled to recover from Defendants treble damages under the INFCRA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

**COUNT TWENTY FIVE
COMMON LAW FRAUD**

327. The State of Indiana repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

328. From 2003 to present, Defendants caused fraudulent claims and false provider certifications to be made and submitted to the State of Indiana for Aranesp claims that were ineligible for payment.

329. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

330. Defendants intended that the State of Indiana act or refrain from acting in justifiable reliance on these misrepresentations.

331. Indiana did, in fact, rely upon the fraudulent claims and false provider certifications that Defendants caused to be submitted to the Medicaid program. As a result, between 2003 and present, Indiana paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

332. As a result of Defendants' conduct, the State of Indiana suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

COUNT TWENTY SIX UNJUST ENRICHMENT

333. The State of Indiana repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

334. The Indiana Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

335. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the State of Indiana, and are liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Indiana.

CLAIMS OF THE STATE OF LOUISIANA

COUNT TWENTY SEVEN
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
La. R.S. § 46:438.3

336. The State of Louisiana repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

337. The Louisiana Medical Assistance Programs Integrity Law (“MAPIL”), La. R.S. § 46:438 et seq., provides in pertinent part, that:

(A) No person shall knowingly present or cause to be presented a false or fraudulent claim . . . (C) No person shall knowingly make, use, or cause to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs. La. R.S. § 46:438.3.

Shall be subject to a civil fine in an amount not to exceed three times the amount of actual damages sustained by the medical assistance programs as a result of the violation. La. R.S. § 46:438.6(B)(2)

[and] not less than five thousand dollars but not more than ten thousand dollars for each false or fraudulent claim . . . La. R.S. § 46.438.6(C)(1)(a).

338. The MAPIL defines “knowing” or “knowingly” to mean “that the person has actual knowledge of the information or acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.” La. R.S. §46:437.3(12).

339. From 2002 to present, Amgen 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.

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

341. Defendants knowingly caused medical providers to make and/or submit false certifications to the Medicaid program that the medical providers were in compliance with state and federal laws, including the Anti-Kickback Statute.

342. Defendants knowingly caused medical providers to make and/or submit claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

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

COUNT TWENTY EIGHT
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
(Conspiring to Cause the Submission of False Claims)
La. R.S. § 46:438.3(D)

344. The State of Louisiana repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

345. The Louisiana Medical Assistance Programs Integrity Law (“MAPIL”), La. R.S. § 46:438 et seq., provides in pertinent part, that:

(D) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by

obtaining, or attempting to obtain, payment for a false or fraudulent claim. La. R.S. § 46:438.3(D).

346. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the State of Louisiana 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

347. From 2003 to present, Defendants conspired to defraud the State of Louisiana 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.

348. From 2003 to present, Defendants conspired to defraud the State of Louisiana by causing medical providers to submit claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

349. By virtue of their conspiratorial agreement, Defendants caused to be submitted false or fraudulent claims, and/or false records or statements, including provider certifications, to the Medicaid program, causing the State of Louisiana to suffer damages. The State of Louisiana is therefore entitled to recover from Defendants treble damages under the MAPIL, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT TWENTY NINE
VIOLATION OF MEDICAID ANTI-KICKBACK STATUTE

La. R.S. § 46:438.2

350. The State of Louisiana repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein

351. The Louisiana MAPIL provides, in pertinent part, that:

No person shall solicit, receive, offer, or pay any remuneration, including but not limited to kickbacks, bribes, rebates . . . directly or indirectly, overtly or covertly, in cash or in kind, for any of the following: (1) In return for . . . the furnishing or arranging to furnish any good, supply, or service for which payment may be made, in whole or in part, under the medical assistance programs; [or] (2) in return for purchasing ,leasing , or ordering , or for arranging for or recommending purchasing, leasing, or ordering, any good, supply or service or facility for which payment may be made, in whole or in part under the medical assistance programs. La. R.S. § 46:438.2.

Any person who is found to have violated R.S. 46:438.2 shall be subject to a civil fine in an amount not to exceed ten thousand dollars per violation, or an amount equal to three times the value of the illegal remuneration, whichever is greater. La. R.S. § 438.6(B)(1).

[and] Not less than five thousand dollars but not more than ten thousand dollars for each false or fraudulent claim, misrepresentation, illegal remuneration or other prohibited act. . . La. R.S. § 438.6(C)(1)(a).

352. From 2003 to present Amgen, INN and ASD offered medical providers remuneration, in the form of free Aranesp product, sham consultancy agreements, weekend retreats, and/or other services, so as to induce those medical providers to purchase Aranesp, a drug eligible for reimbursement through the Medicaid program. As a result of those inducements, the Medicaid program paid claims for Aranesp that were not reimbursable because of Defendants' illegal inducements.

353. The State of Louisiana is entitled to treble damages, of an amount to be determined at trial, for the illegal kickbacks that Defendants offered to medical providers.

COUNT THIRTY FRAUD

354. The State of Louisiana repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

355. From 2003 to present, Defendants caused fraudulent claims and false provider certifications to be made and submitted to the State of Louisiana for Aranesp claims that were ineligible for payment.

356. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

357. Defendants intended that the State of Louisiana act or refrain from acting in justifiable reliance on these misrepresentations.

358. Louisiana did, in fact, rely upon the fraudulent claims and false provider certifications that Defendants caused to be submitted to the Medicaid program. As a result, between 2003 and present, Louisiana paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

359. As a result of Defendants' conduct, the State of Louisiana suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

COUNT THIRTY ONE UNJUST ENRICHMENT

360. The State of Louisiana repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

361. The Louisiana Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

362. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the State of Louisiana, and are liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Louisiana.

CLAIMS OF THE COMMONWEALTH OF MASSACHUSETTS

COUNT THIRTY TWO
MASSACHUSETTS FALSE CLAIMS ACT
(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
Mass. G.L. ch. 12 § 5(B)(1),(2)

363. The Commonwealth of Massachusetts repeats and realleges the allegation contained in paragraphs 1 through 190 as if fully set forth herein.

364. The Massachusetts False Claims Act (“MAFCA), Mass. G.L. ch. 12 § 5B, et seq. provides in pertinent part that, any person who:

(1) Knowingly presents, or causes to be presented, 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 obtain payment or approval of a claim by the commonwealth or any political subdivision thereof; [or] conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim . . .

Shall be liable to the commonwealth for a civil penalty of not less than \$5,000 and not more than \$10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person . . . [and] shall also be liable to the commonwealth for the expenses of the civil action brought to recover any such penalty or damages . . .”

365. The MAFCA defines the terms “knowing” and “knowingly” to mean that a person, regarding information relating to a claim “possesses actual knowledge of relevant information, acts with deliberate ignorance of the truth of the falsity of the information or acts in

reckless disregard of the truth or falsity of the information and no proof of specific intent to defraud is required.” Mass. G.L. ch. 12 § 5A(a).

366. From 2002 to present, Amgen 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.

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

368. 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.

369. Defendants knowingly caused to be presented and/or caused to be made or used claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

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

COUNT THIRTY THREE
MASSACHUSETTS FALSE CLAIMS ACT
(Conspiring to Cause the Submission of False Claims)
Mass. G.L. ch. 12 § 5B(3)

371. The Commonwealth of Massachusetts repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

372. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the Commonwealth of Massachusetts 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

373. From 2003 to present, Defendants conspired to defraud the Commonwealth of Massachusetts 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.

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

375. 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 Commonwealth of Massachusetts to suffer damages. The Commonwealth of Massachusetts is therefore entitled to recover from Defendants treble damages under the MAFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT THIRTY FOUR
VIOLATION OF MEDICAID ANTI-KICKBACK STATUTE
Mass. G.L. 118E §§ 41, 44

376. The Commonwealth of Massachusetts repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

377. The Massachusetts Medicaid Anti-Kickback Statute provides, in pertinent part, that:

Whoever offers or pays any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind to induce such person to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this chapter shall be punished by a fine of not more than ten thousand dollars, or by imprisonment in the state prison for not more than five years or in a jail or house of correction for not more than two and one-half years, or by both such fine and imprisonment.

Mass. G.L. ch. 118E § 41.

378. The Massachusetts Medicaid Anti-Kickback Statute further provides that if any person violates the Medicaid Anti-Kickback Statute, the attorney general “may bring a civil action, either in lieu of or in addition to a criminal prosecution, and recover three times the amount of damages sustained including the costs of investigation and litigation.” Mass. G.L. ch. 118E §44.

379. From at least 2003 to present Amgen, INN and ASD offered medical providers remuneration, in the form of free Aranesp product, sham consultancy agreements, weekend retreats, and/or other services, so as to induce those medical providers to purchase Aranesp, a drug eligible for reimbursement through the Medicaid program. As a result of those inducements, the Medicaid program paid claims for Aranesp that were not reimbursable because of Defendants’ illegal inducements.

380. The Commonwealth of Massachusetts is entitled to treble damages, of an amount to be determined at trial, for the illegal kickbacks that Defendants offered to medical providers.

**COUNT THIRTY FIVE
COMMON LAW FRAUD**

381. The Commonwealth of Massachusetts repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

382. From 2003 to present Defendants caused fraudulent claims and false provider certifications to be made to the United States and the Commonwealth of Massachusetts relating to Aranesp.

383. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

384. Defendants intended that the Commonwealth of Massachusetts act or refrain from acting in justifiable reliance on these misrepresentations.

385. Massachusetts did, in fact, rely upon Defendants' fraudulent claims and false provider certifications. As a result, between 2003 and present Massachusetts paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

386. As a result of Defendants' conduct, the Commonwealth of Massachusetts suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

**COUNT THIRTY SIX
UNJUST ENRICHMENT**

387. The Commonwealth of Massachusetts repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

388. The Massachusetts Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

389. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the Commonwealth of Massachusetts, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the Commonwealth of Massachusetts.

CLAIMS OF THE STATE OF MICHIGAN

COUNT THIRTY SEVEN MICHIGAN MEDICAID FALSE CLAIMS ACT (Presentation of False Certifications/Claims in Connection with Violation of Anti-kickback Laws) Mich. Comp. Laws § 400.603

390. The State of Michigan repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

391. The Michigan Medicaid False Claims Act (“MIFCA”), specifically provides, in pertinent part, that:

A person shall not make or present or cause to be made or presented to an employee or officer of this state a claim under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, upon or against the state, knowing the claim to be false. MCL 400.607(1)
* * *

A person who receives a benefit that the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact, or who engages in any conduct prohibited by this statute, shall forfeit and pay to the state the full amount received, and for each claim a civil penalty of not less than \$5,000.00 or more than \$10,000.00 plus triple the amount of damages suffered by the state as a result of the conduct by the person. MCL 400.612

392. The MIFCA defines the terms “knowing” and “knowingly” to mean that a person, "is in possession of facts under which he or she is aware or should be aware of the nature of his

or her conduct and that his or her conduct is substantially certain to cause the payment of a Medicaid benefit. Knowing or knowingly includes acting in deliberate ignorance of the truth or falsity of facts or acting in reckless disregard of the truth or falsity of facts. Proof of specific intent to defraud is not required." MCL 400.602(f)

393. The MIFCA defines the terms "claim" to mean "any attempt to cause the department of community health to pay out sums of money under the social welfare act."

394. The MIFCA defines the terms "false" to mean "wholly or partially untrue or deceptive." MCL 400.602(d).

395. From 2002 to present, Amgen 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.

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

397. 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.

398. Defendants knowingly caused to be presented and/or caused to be made or used claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

399. 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 Michigan suffered damages and therefore is entitled to recover from Defendants restitution and treble

damages under the MIFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT THIRTY EIGHT
MICHIGAN MEDICAID FALSE CLAIMS ACT
(Conspiring to Cause the Submission of False Claims)
MCL 400.606

400. The State of Michigan repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

401. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the State of Michigan 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

402. From 2003 to present, Defendants conspired to defraud the State of Michigan 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.

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

404. 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 Michigan to suffer damages. The State of Michigan is therefore entitled to recover from Defendants restitution and

treble damages under the MIFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

**COUNT THIRTY NINE
COMMON LAW FRAUD**

405. The State of Michigan repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

406. From 2003 to present Defendants caused fraudulent claims and false provider certifications to be made to the United States and the State of Michigan relating to Aranesp.

407. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

408. Defendants intended that the State of Michigan act or refrain from acting in justifiable reliance on these misrepresentations.

409. Michigan did, in fact, rely upon Defendants' fraudulent claims and false provider certifications. As a result, between 2003 and present Michigan paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

410. As a result of Defendants' conduct, the State of Michigan suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

**COUNT FORTY
UNJUST ENRICHMENT**

411. The State of Michigan repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

412. The Michigan Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

413. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the State of Michigan, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Michigan.

CLAIMS OF THE STATE OF NEVADA

**COUNT FORTY ONE
NEVADA FALSE CLAIMS ACT
(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
Nev. Rev. Stat. § 357.040(1)**

414. The State of Nevada repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

415. The Nevada False Claims Act (“NVFCA”), specifically provides, in pertinent part, that any person who:

(a) Knowingly presents or causes to be presented a false claim for payment or approval; (b) Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim; (c) Conspires to defraud by obtaining allowance or payment of a false claim.

is liable to the State or a political subdivision, whichever is affected, for three times the amount of damages sustained by the State or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than \$5,000 or more than \$10,000 for each act.

416. The NVFCA defines the term “knowingly” to mean that a person, with respect to information: “(a) has knowledge of the information; (b) acts in deliberate ignorance of whether the information is true or false; or (c) acts in reckless disregard of the truth or falsity of the information.” Nev. Rev. Stat. § 357.040(2).

417. From 2002 to present, Amgen 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.

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

419. 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.

420. Defendants knowingly caused to be presented and/or caused to be made or used claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

421. 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 Nevada suffered damages and therefore is entitled to recover from Defendants treble damages under the NVFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT FORTY TWO
NEVADA FALSE CLAIMS ACT
(Conspiring to Cause the Submission of False Claims)
Nev. Rev. Stat. § 357.040(1)(c)

422. The State of Nevada repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

423. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the State of Nevada 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

424. From 2003 to present, Defendants conspired to defraud the State of Nevada 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.

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

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

**COUNT FORTY THREE
COMMON LAW FRAUD**

427. The State of Nevada repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

428. From 2003 to present Defendants caused fraudulent claims and false provider certifications to be made to the United States and the State of Nevada relating to Aranesp.

429. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

430. Defendants intended that the State of Nevada act or refrain from acting in justifiable reliance on these misrepresentations.

431. Nevada did, in fact, rely upon Defendants' fraudulent claims and false provider certifications. As a result, between 2003 and present Nevada paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

432. As a result of Defendants' conduct, the State of Nevada suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

**COUNT FORTY FOUR
UNJUST ENRICHMENT**

433. The State of Nevada repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

434. The Nevada Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

435. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the State of Nevada, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Nevada.

CLAIMS OF THE STATE OF NEW HAMPSHIRE

COUNT FORTY FIVE
NEW HAMPSHIRE FALSE CLAIMS ACT
(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
N.H. Rev. Stat. Ann. § 167:61-b

436. The State of New Hampshire repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

437. The New Hampshire Medicaid False Claims Act (“NHFCA”), specifically provides, in pertinent part, that any person who:

(a) Knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval; (b) 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 department; (c) Conspires to defraud the department by getting a false or fraudulent claim allowed or paid. . .

shall be liable to the state for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages that the state sustains because of the act of that person.

438. The NHFCA defines the terms “knowing” and “knowingly” to mean that a person, with respect to information: “(a) has actual knowledge of the information; (b) acts in deliberate ignorance the truth or falsity of the information; or (c) acts in reckless disregard of the truth or falsity of the information.” N.H. Rev. Stat. Ann. § 167:61-b(V)(b).

439. From 2002 to present, Amgen 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.

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

441. 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.

442. Defendants knowingly caused to be presented and/or caused to be made or used claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

443. 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 Hampshire suffered damages and therefore is entitled to recover from Defendants treble damages under the NHFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT FORTY SIX
NEW HAMPSHIRE MEDICAID FALSE CLAIMS ACT
(Conspiring to Cause the Submission of False Claims)
N.H. Rev. Stat. Ann. § 167:61-b

444. The State of New Hampshire repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

445. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the State of New Hampshire 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

446. From 2003 to present, Defendants conspired to defraud the State of New Hampshire 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.

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

448. 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 Hampshire to suffer damages. The State of New Hampshire is therefore entitled to recover from Defendants treble damages under the NHFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT FORTY SEVEN COMMON LAW FRAUD

449. The State of New Hampshire repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

450. From 2003 to present Defendants caused fraudulent claims and false provider certifications to be made to the United States and the State of New Hampshire relating to Aranesp.

451. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

452. Defendants intended that the State of New Hampshire act or refrain from acting in justifiable reliance on these misrepresentations.

453. New Hampshire did, in fact, rely upon Defendants' fraudulent claims and false provider certifications. As a result, between 2003 and present New Hampshire paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

454. As a result of Defendants' conduct, the State of New Hampshire suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

COUNT FORTY EIGHT UNJUST ENRICHMENT

455. The State of New Hampshire repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

456. The New Hampshire Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

457. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the State of New Hampshire, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of New Hampshire.

CLAIMS OF THE STATE OF NEW YORK

COUNT FORTY NINE
VIOLATION OF THE NEW YORK FALSE CLAIMS ACT
(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
N.Y. St. Fin. Law § 189(1)

458. The State of New York repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

459. The New York False Claims Act (“NYFCA”), N.Y. St. Fin. Law § 189(1), provides, in pertinent part, that any person who:

(a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval; (b) 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 state or a local government; (c) conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid . . .

shall be liable: (i) to the state for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of damages which the state sustains because of the act of that person. . . .

N.Y. St. Fin. Law § 189(1).

460. The NYFCA defines the terms “knowing” and “knowingly” to mean that a person, with respect to a claim or information relating to a claim, “(a) has actual knowledge of such claim or information; (b) acts in deliberate ignorance of the truth or falsity of such claim or information; or (c) acts in reckless disregard of the truth or falsity of such claim or information.”

N.Y. St. Fin. Law § 188(3).

461. From 2002 to present, Amgen 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.

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

463. 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.

464. Defendants knowingly caused to be presented and/or caused to be made or used claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

465. 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 York suffered damages and therefore is entitled to recover from Defendants treble damages under the NYFCA, in an amount to be proved at trial, plus a civil penalty of at least \$6,000 for each violation.

COUNT FIFTY
NEW YORK FALSE CLAIMS ACT
(Conspiring to Cause the Submission of False Claims)
N.Y. St. Fin. Law § 189(1)(c)

466. The State of New York repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

467. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the State of New York 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

468. From 2003 to present, Defendants conspired to defraud the State of New York 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.

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

470. 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 York to suffer damages. The State of New York is therefore entitled to recover from Defendants treble damages under the NYFCA, in an amount to be proved at trial, plus a civil penalty of at least \$6,000 for each violation.

COUNT FIFTY ONE
VIOLATION OF NEW YORK SOCIAL SERVICES LAW § 145-b

471. The State of New York repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

472. N.Y. Soc. Serv. Law § 145-b provides, in pertinent part, that:

It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or any other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payments from public funds for services or supplies furnished or purportedly furnished pursuant to this chapter.

473. As set forth above, Amgen knowingly, or acting in deliberate ignorance or in reckless disregard for the truth, made, used, and caused to be made and used, false claims to be submitted for Aranesp product in order to attempt to obtain or to obtain payments from the New

York Medicaid Program. In so doing, Amgen improperly obtained or attempted to obtain payments from the Medicaid Program.

474. By reason of the foregoing, Amgen is liable, pursuant to N.Y. Soc. Serv. Law § 145-b, to the State of New York for treble damages, penalties, and costs.

**COUNT FIFTY TWO
COMMON LAW FRAUD**

475. The State of New York repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

476. From 2003 to present Defendants caused fraudulent claims and false provider certifications to be made to the United States and the State of New York relating to Aranesp.

477. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

478. Defendants intended that the State of New York act or refrain from acting in justifiable reliance on these misrepresentations.

479. New York did, in fact, rely upon Defendants' fraudulent claims and false provider certifications. As a result, between 2003 and present New York paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

480. As a result of Defendants' conduct, the State of New York suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

**COUNT FIFTY THREE
UNJUST ENRICHMENT**

481. The State of New York repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

482. The New York Medicaid program paid substantially more for Aranesp claims that it would have had Amgen not offered kickbacks to medical providers.

483. As a consequence of the acts set forth above, Amgen was unjustly enriched at the expense of the State of New York, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of New York.

CLAIMS OF THE STATE OF TENNESSEE

**COUNT FIFTY FOUR
TENNESSEE FALSE CLAIMS ACT
(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
Tenn. Code. Ann. § 71-5-182(a)**

484. The State of Tennessee repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

485. The Tennessee False Claims Act (“TNMFCA”), specifically provides, in pertinent part, that any person who:

(1)(A) presents, or causes to be present, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent; (B) makes, uses or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false; [or] (C) conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent . . .

is liable to the state for a civil penalty of not less than \$5,000 and not more than \$25,000, plus three times the amount of actual damages which the state sustains because of the act of that person.

486. The TNMFCA defines the terms “knowing” and “knowingly” to mean that a person, with respect to information: “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.” Tenn. Code. Ann. § 71-5-182(b).

487. The TNMFCA defines "claim" to include "any request or demand for money, property, or services made to any employee, officer, or agent of the state, or to any contractor, grantee, or other recipient, whether under contract or not, if any portion of the money, property, or services requested or demanded was issued from, or was provided by, the state." Tenn. Code. Ann. § 71-5-182(c).

488. From 2002 to present, Amgen 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.

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

490. Amgen and INN 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.

491. Amgen and INN knowingly caused to be presented and/or caused to be made or used claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

492. 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 Tennessee suffered damages and therefore is entitled to recover from Amgen and INN treble damages under the TNMFCA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT FIFTY FIVE
TENNESSEE MEDICAID FALSE CLAIMS ACT
(Conspiring to Cause the Submission of False Claims)
Tenn. Code. Ann. § 71-5-182(a)

493. The State of Tennessee repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

494. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the State of Tennessee 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

495. From 2003 to present, Defendants conspired to defraud the State of Tennessee 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.

496. From 2003 to present, Amgen and INN conspired to defraud the State of Tennessee by knowingly causing medical providers to present, make and/or use claims for the overfill amounts contained in Aranesp vials thereby causing the Medicaid program to reimburse ineligible claims.

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

COUNT FIFTY SIX
TENNESSEE MEDICAID FALSE CLAIMS ACT
(Presentation of False Certifications/Claims in Connection
with Violation of Anti-kickback Laws)
Tenn. Code. Ann. § 71-5-182(a)

498. The State of Tennessee repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

499. The Tennessee Medicaid False Claims Act (“TNMFCA”), specifically provides, in pertinent part, that any person who:

(1)(A) presents, or causes to be present, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent; (B) makes, uses or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false; [or] (C) conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent . . .

is liable to the state for a civil penalty of not less than \$5,000 and not more than \$25,000, plus three times the amount of actual damages which the state sustains because of the act of that person.

500. The TNMFCA defines the terms “knowing” and “knowingly” to mean that a person, with respect to information: “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.”
Tenn. Code. Ann. § 71-5-182(b).

501. From 2002 to present, Amgen 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.

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

503. 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.

504. Defendants knowingly caused to be presented and/or caused to be made or used claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

505. 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 Tennessee suffered damages and therefore is entitled to recover from Defendants treble damages under the TNMFCRA, in an amount to be proved at trial, plus a civil penalty of at least \$5,000 for each violation.

COUNT FIFTY SEVEN
TENNESSEE MEDICAID FALSE CLAIMS ACT
(Conspiring to Cause the Submission of False Claims)
Tenn. Code. Ann. § 71-5-182(a)

506. The State of Tennessee repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

507. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the State of Tennessee 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

508. From 2003 to present, Defendants conspired to defraud the State of Tennessee 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.

509. From 2003 to present, Defendants conspired to defraud the State of Tennessee by knowingly causing medical providers to present, make and/or use claims for the overfill amounts contained in Aranesp vials thereby causing the Medicaid program to reimburse ineligible claims.

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

COUNT FIFTY EIGHT COMMON LAW FRAUD

511. The State of Tennessee repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

512. From 2003 to present Defendants caused fraudulent claims and false provider certifications to be made to the United States and the State of Tennessee relating to Aranesp.

513. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual

knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

514. Defendants intended that the State of Tennessee act or refrain from acting in justifiable reliance on these misrepresentations.

515. Tennessee did, in fact, rely upon Defendants' fraudulent claims and false provider certifications. As a result, between 2003 and present Tennessee paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

516. As a result of Defendants' conduct, the State of Tennessee suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

COUNT FIFTY NINE UNJUST ENRICHMENT

517. The State of Tennessee repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

518. The Tennessee Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

519. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the State of Tennessee, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of Tennessee.

CLAIMS OF THE COMMONWEALTH OF VIRGINIA

COUNT SIXTY

VIRGINIA FRAUD AGAINST TAXPAYERS ACT

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

Va. Code Ann. § 8.01-216.3(A)

520. The Commonwealth of Virginia repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

521. The Virginia Fraud Against Taxpayers Act (“VFATA”), specifically provides, in pertinent part, that any person who:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth 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 Commonwealth; (3) Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid. . .

shall be liable to the Commonwealth for a civil penalty of not less than \$5,500 and not more than \$ 11,000, plus three times the amount of damages sustained by the Commonwealth.

522. The VFATA defines the terms “knowing” and “knowingly” to 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 no proof of specific intent to defraud is required.” Va. Code Ann. § 8.01-216.3(C).

523. From 2002 to present, Amgen 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.

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

525. 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.

526. Defendants knowingly caused to be presented and/or caused to be made or used claims for Aranesp thereby causing the Medicaid program to reimburse ineligible claims.

527. By virtue of the false or fraudulent claims, and/or false records or statements, including provider certifications, presented and caused to be presented, the Commonwealth of Virginia suffered damages and therefore is entitled to recover from Defendants treble damages under the VFATA, in an amount to be proved at trial, plus a civil penalty of at least \$5,500 for each violation.

COUNT SIXTY ONE
VIRGINIA FRAUD AGAINST TAXPAYERS ACT
(Conspiring to Cause the Submission of False Claims)
Va. Code Ann. § 8.01-216.3(A)

528. The Commonwealth of Virginia repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

529. From 2003 to present, Amgen, INN and ASD Healthcare conspired to defraud the Commonwealth of Virginia 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 encouraged medical providers to present, make and/or use claims for payment that were ineligible for reimbursement by virtue of the kickbacks.

530. From 2003 to present, Defendants conspired to defraud the Commonwealth of Virginia 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.

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

532. 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 Commonwealth of Virginia to suffer damages. The Commonwealth of Virginia is therefore entitled to recover from Defendants treble damages under the VFATA, in an amount to be proved at trial, plus a civil penalty of at least \$5,500 for each violation.

**COUNT SIXTY TWO
MEDICAID FRAUD VIOLATION**

(Fraudulently obtaining excess or attempting to obtain excess benefits or payments)

Va. Code Ann. § 32.1-312

533. The Commonwealth of Virginia repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

534. Virginia Code § 32.1-312 provides in pertinent part:

(A) No person, agency or institution, but not including an individual medical assistance recipient of health care, on behalf of himself or others, whether under a contract or otherwise, shall obtain or attempt to obtain benefits or payments where the Commonwealth directly or indirectly provides any portion of the benefits or payments pursuant to the Plan for Medical Assistance and any amendments thereto as provided for in § 32.1-325,

hereafter referred to as “medical assistance” in a greater amount than that to which entitled by means of:

1. A willful false statement;
2. By willful misrepresentation, or by willful concealment of any material facts; or
3. By other fraudulent scheme or device

535. From 2003 to the present, Defendants caused fraudulent claims and false provider certifications to be made to the United States and the Commonwealth of Virginia relating to Aranesp.

536. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose materials facts that it had a duty to disclosure, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

537. Defendants intended that the Commonwealth of Virginia act in justifiable reliance on these misrepresentations.

538. The Commonwealth of Virginia did, in fact, rel upon Defendants’ fraudulent claims and false provider certifications. As a result, between 2003 and present, Virginia paid for Aranesp claims that were ineligible for reimbursement.

539. As a result of Defendants’ conduct, the Commonwealth of Virginia suffered harm and is entitled to repayment of any excess benefit or payments received, plus interest at the rate of 1 1/2 percent each month for the period from the date upon which payment was made to the date upon which repayment is made to the Commonwealth, and civil penalties in an amount not to exceed three times the amount of such excess benefits or payments.

**COUNT SIXTY THREE
COMMON LAW FRAUD**

540. The Commonwealth of Virginia repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

541. From 2003 to present Defendants caused fraudulent claims and false provider certifications to be made to the United States and the Commonwealth of Virginia relating to Aranesp.

542. Defendants made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

543. Defendants intended that the Commonwealth of Virginia act or refrain from acting in justifiable reliance on these misrepresentations.

544. Virginia did, in fact, rely upon Defendants' fraudulent claims and false provider certifications. As a result, between 2003 and present Virginia paid substantially more for Aranesp claims than it should have and paid for Aranesp claims that were ineligible for reimbursement.

545. As a result of Defendants' conduct, the Commonwealth of Virginia suffered harm and is entitled to recovery of actual damages plus prejudgment interest.

**COUNT SIXTY FOUR
UNJUST ENRICHMENT**

546. The Commonwealth of Virginia repeats and realleges the allegations contained in paragraphs 1 through 190 as if fully set forth herein.

547. The Virginia Medicaid program paid substantially more for Aranesp claims than it would have had Defendants not offered kickbacks to medical providers.

548. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the Commonwealth of Virginia, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the Commonwealth of Virginia.

PRAYER FOR RELIEF

WHEREFORE, the undersigned Intervening Plaintiff States respectfully request this Court to enter judgment for the Intervening Plaintiff States and against Defendants on each count of this Complaint, to impose damages and penalties as described above and to the full extent allowed by law, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The Intervening Plaintiff States demand a jury trial in this case.

Dated: October 30, 2009

Respectfully Submitted:

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