UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *ex rel*. MARK EUGENE DUXBURY and DEAN McCLELLAN Relators, v. ORTHO BIOTECH PRODUCTS, L.P., Defendant.	CIVIL ACTION: 03-CV-12189-RWZ **(LEAVE TO FILE AMENDED COMPLAINT GRANTED 10-24-06)**

FIRST AMENDED COMPLAINT

AND

DEMAND FOR JURY TRIAL

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I. SUMMARY OF CLAIM

1. This is a three (3) count action to recover damages and civil penalties on behalf of the United States of America under the Federal Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq*., as amended ("The Act"). The violations of the Act involve claims for Medicare reimbursement ("reimbursement claims") that Defendant "caused to be presented" by physicians, hospitals, and other health care providers (referred to collectively herein as "Providers") that Defendant knew were false and fraudulent.

2. The false and fraudulent reimbursement claims were for the administration of Defendant's drug that is commonly known as Procrit® ("Procrit"). Procrit is the brand name for the drug epoetin alfa which is used in the treatment of anemia, especially dialysis and chemotherapy patients. Procrit is responsible for the second largest total annual reimbursement amount of any drugs by Medicare. Procrit accounts for over $1 billion per year in federal prescription drug payments.

3. In order to induce Providers to administer Procrit to their patients, Defendant engaged in a common nationwide scheme to enable Providers to unlawfully profit from the Medicare system through the submission of false and fraudulent reimbursement claims. Defendant's unlawful scheme with Providers consisted of, among other things: (1) fraudulently inflating the spread between the "Average Wholesale Price" (AWP) benchmark used by the government to calculate reimbursement rates and actual acquisition cost to Providers, thus creating a significantly inflated spread between what the Providers actually paid for the drug and what they were reimbursed by the government; (2) fraudulently inducing and causing Providers to submit false claims for reimbursement to Medicare for Procrit that Defendant had given to Providers at no cost; and (3) unlawfully inducing Providers to administer and submit claims for reimbursement to Medicare for Procrit to chemotherapy patients at the "off-label" dosing rate of 40,000 IU one times a week instead of the approved rate of 10,000 IU three times a week.

4. Defendant's inflated pricing and dosing scheme was effectuated by various unlawful acts that included, but was not limited to, the following: (1) intentionally furnishing the government and Providers with false and misleading information about Procrit, its approved uses, and its pricing; (2) intentionally

publishing a false and artificially inflated AWP that Defendant intended to be relied upon/used in the submission of claims for reimbursement of Procrit; (3) giving providers unlawful monetary inducements ("kickbacks") in the form of free product that was indistinguishable from commercially available product that Defendant intended and knew providers would and did use for reimbursement as if the free product had been purchased; and (4) giving providers unreported unlawful front end and back end payments in the form of "off-invoice" discounts, rebates, account credits, and other cash or cash equivalent payments such as phony "grants", "advisory board honoraria", and "donations" directly tied to the providers' purchase of Procrit.

5. Beginning in 1992 Defendant undertook a scheme to increase market share and profitability by defrauding the Government by failing to reflect in Defendant's official pricing the "kickbacks" that it gave to providers so that the providers could unlawfully pocket the "spread" between the true cost of Procrit and the Federal Government's reimbursement rate. This scheme allowed Providers to profit from using Procrit at the Government's expense. Defendant's conduct included artificially inflating the AWP for Procrit by fraudulently reporting to the Government a false AWP that Defendant knew the government would use to establish the Medicare reimbursement rate, while at the same time decreasing the actual acquisition cost to Providers by off-invoice discounts, unrestricted grants, rebates, donations, free commercially packaged Procrit, and other financial incentives.

6. Beginning in 1997, Defendant also initiated an intentional scheme to unlawfully market and promote the illegal off-label dosage of Procrit for cancer patients in an effort to increase sales, market share, and profitability. Defendant's illegal scheme was designed and intended to increase the number of individuals (patients) receiving Procrit, increase the amount of Procrit being utilized by cancer patients, and increase federal reimbursements for Procrit. Defendant utterly disregarded federal regulation and federal law through the implementation of its illegal scheme. Defendant knew that its actions were illegal.

7. Beginning in 1998, as a direct and proximate result of Defendant's aggressive and illegal marketing strategies, oncologists, cancer clinics, and hospitals began submitting false and fraudulent

claims for reimbursement for Procrit for "off-label" once a week dosing of cancer patients at 40,000 IU.

8. All of Defendant's illegal actions alleged herein were intentional and in knowing violation of the False Claims Act and other applicable state and federal law. As a direct and proximate result of the illegal conduct alleged herein, Defendant caused to be presented false claims to the United States government (hereinafter "government"), resulting in government payments in the millions of dollars.

II. PARTIES

9. Relator Mark Eugene Duxbury ("Relator Duxbury") resides in Gig Harbor, Washington. From 1992 to 1998, Relator Duxbury was employed by Defendant beginning as a Product Specialist and eventually becoming a Regional Key Account Specialist for Defendant's Western Division Oncology sales force. Relator Dean McClellan ("Relator McClellan") resides in Tucson, Arizona. From 1992 to 2004, Relator McClellan was employed by Defendant beginning as a Product Specialist and eventually becoming a Territory Manager for Defendant's Western Division Oncology sales force.

10. Defendant Ortho Biotech Products, L.P., is a New Jersey limited partnership doing business in this District.

III. JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, which specifically confers jurisdiction on this Court of actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

12. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a), which provides that "[a]ny action under § 3730 may be brought in any judicial district in which the Defendant .. can be found, resides, transacts business or in which any act proscribed by § 3729 occurred. Section 3732(a) also authorizes nationwide service of process. Defendant during the relevant period transacted business in this District.

13. As required under the False Claims Act, 31 U.S.C. § 3730(a)(2), Relators have provided the Attorney General of the United States and the United States Attorney for the District of Massachusetts with a statement of all material evidence and information related to the Complaint. This

Disclosure Statement supports the existence of over-charging Medicare for Procrit and reliance by the United States on false and fraudulent invoices for the pharmaceutical product.

14. This Court has jurisdiction over this matter pursuant to 31 U.S.C. § 3730(b) in that the claims for relief in this action are brought in the name of the United States government.

15. Venue is proper pursuant to 28 U.S.C. § 1391(a) in that Defendant does business within this judicial district.

IV. ORIGINAL SOURCE ALLEGATIONS

16. Both Relators have direct and independent knowledge of information on which the allegations are based, and have provided such information to the United States before filing suit, as required by 31 U.S.C. § 3730(e)(4).

17. Relators Duxbury and McClellan were employed by Defendant from 1992 through 1998 and 1992 through 2004 respectively as sales representatives. In their positions, they were responsible for the promotion and sale of the Procrit brand of the drug epoetin alfa for Defendant in the Western United States. Through their respective employment, both Relators obtained direct, independent, first –hand knowledge of the allegations forming the basis of the claims alleged herein.

18. Defendant recognized and rewarded Relators for their success as employees. In 1994, Relator Duxbury received Defendant's Regional Achievement Award. In 1993 and 1994, Defendant awarded Relator Duxbury Defendant's "Biosphere" National Achievement Award, which is its highest national annual sales award given to the top ten percent of its sales force for Procrit sales achievements. In 1994, 1995, 1996, 1997 Defendant awarded Relator McClellan Defendants' "Biosphere" National Achievement Award, and numerous other regional and district awards. In addition, Relator McClellan earned seventy other sales awards and certificates of recognition.

19. During their employment by Defendant, Relators were educated and directed by Defendant to market Procrit by convincing Providers that they could profit from prescribing Procrit by submitting false claims to Medicare for reimbursement based on the inflated AWP. Defendant aggressively "marketed the spread" between the reimbursement rate based on AWP for Procrit and the actual acquisition cost to Providers. Relators principle marketing and sales strategy, as directed and devised by Defendant, was to market the spread and assist Providers in obtaining "profit" by decreasing actual acquisition cost of Procrit, while submitting claims for Medicare reimbursement based on the false and artificially inflated AWP published by Defendant for Procrit.

20. During their employment, Relators aggressively marketed Procrit in accordance with Defendant's instructions, direction, and training. Relators, as former employees, were insiders to Defendant's fraud and obtained unique, first hand, independent, and direct knowledge of the facts related to Defendant's fraud.

21. During their employment by Defendant, both Relators were educated and directed by Defendant to promote, market, advertise, encourgage, and sell Procrit to providers for the off-label/unapproved use in once a week dosing of cancer patients at 40,000 IU. In fact, both Relators' performance evaluations were based, in significant part, on illegal off-label marketing of the 40,000 IU dosage beginning in 1998.

22. Both Relators obtained direct, first hand, and independent knowledge of Defendant's illegal conduct alleged herein, through, but not limited to, the following: written documents setting forth policies and procedures, written performance criteria and reviews, written instructional/educational manuals, written memorandums, attendance at seminars, attendance at meetings, attendance at training sessions, verbal performance reviews, verbal training, verbal reprimands, other training provided by Defendant, e-mails, documents, verbal instruction from Defendant, conversations with and among co-employees of Defendant, interaction with Provider purchasers of Procrit, written communications with Provider

purchasers of Procrit, verbal communications with provider Purchasers of Procrit, and other written and oral communications with Defendants and Provider purchasers of Procrit.

23. Relators make allegations contained herein based upon direct knowledge and belief as to all such allegations for which they posses such knowledge and belief. Relators make all other allegations based upon information and belief.

24. Relators have direct and independent knowledge that Defendant on a regular basis gave free product of Procrit to providers and hospitals to induce them to use Procrit and lower the actual cost of the drug. Relators have direct and independent knowledge that these free commercial packages of Procrit were known and intended by management to be used as a "cash" or "cash equivalent" and that providers made no distinction for Medicare reimbursement purposes as to whether the product had been purchased or provided at no cost.

25. Relators have direct and independent knowledge that Ortho provided other financial inducements to stimulate the sale of Procrit and lower the actual cost of purchasing Procrit.

26. Relators possess documents showing that as sales representatives of Defendant they provided discounts, rebates, and educational grants directly to providers purchasing Procrit for the sole and exclusive purpose of lowering net acquisition cost to Providers and increasing the spread between Medicare Reimbursement and actual acquisition cost to Providers.

27. Relators allege herein and possess first hand, direct, and independent knowledge of : (1) Defendant's development and implementation of the Inflated Dosing Scheme alleged herein; (2) the illegal publication of false and inflated AWP; (3) the provision of off-invoice incentives, grants, rebates, consulting fees, and other equivalents designed to decrease the actual acquisition cost of Procrit to providers; (4) the methods and strategies used by Defendant in "marketing the spread" between actual acquisition costs and the reimbursement based on AWP; and (5) Defendant's illegal actions in giving free Procrit to providers and causing said providers to submit false claims for reimbursement for the free Procrit to Medicare.

28. Relator Duxbury is the original source of the claims and allegations contained in the original Complaint and the Amended Complaint. Through the course of his investigation Relator Duxbury developed Relator McClellan as an additional Relator. Relator McClellan is an additional relator who provides additional supporting facts and information. Relator McClellan does not bring any new legal claims against Defendant, but rather adds additional supporting facts to the legal claims previously made.

V. FIRST-TO-FILE ALLEGATIONS

29. Relator Duxbury is the first person to file a False Claims Act Complaint against Defendant containing these allegations of wrongdoing and these material facts.

30. No earlier-filed False Claims Act suit against Defendant gives rise to the same claims or recovery by the government.

31. Relator Duxbury's status as the first to file a False Claims Act suit against Defendant for this wrongdoing is based on the allegations in his original complaint (the "Complaint") filed November 6, 2003.

VI. FACTUAL BACKGROUND

A. Relevant Legal Provisions

1. Coverage of the Costs of Prescription Drugs Under the Medicare Insurance Program

32. In 1965, Congress enacted Title XVIII of the Social Security Act ("Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care.

33. The United States Department of Health & Human Services ("HHS") is responsible for the funding, administration and supervision of the Medicare Program. The Centers for Medicare and Medicaid Services ("CMMS"), formerly known as the Health Care Financing Administration ("HCFA"), is a division of HHS and is directly responsible for the administration of the Medicare Program.

34. Until very recently, the Medicare Program generally did not cover the cost of prescription drugs that a Medicare beneficiary self administers (*e.g.*, by swallowing the drug in liquid or pill form). However, Medicare Part B has traditionally covered some drugs, including injectables administered directly by a doctor, certain oral anti-cancer drugs, and drugs furnished under a durable medical equipment benefit. Approximately 450 drugs are covered by Medicare Part B ("Covered Drugs").

35. New drugs may not be marketed in the United States until the sponsor has proven to the FDA that the drug is safe and effective for the specific indications at the specified dosages. The indications and dosages approved by the FDA are set forth in the drug's labeling, the content of which also is approved by the FDA.

36. The Medicare program relies for its reimbursement rules on the FDA's findings regarding the uses for approved drugs that are safe and effective.

37. Chemotherapy drugs are covered by Medicare in certain instances.

38. The Medicare Act generally covers "medical and other health services." 42 U.S.C. § 1395k(a)(2). "[M]edical and other health services," in turn, means "services and supplies (including drugs and biologicals which are ***not*** usually self-administered by the patient) furnished as an incident to a physician's professional service, or kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills …." 42 U.S.C. § 1395x(s)(2) (emphasis added). The term "drug" includes "any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication …." 42 U.S.C. § 1395x(t)(2)(A).

39. Reimbursement for anticancer chemotherapeutic drugs is generally limited to the specific use approved by the FDA. 42 U.S.C. § 1395x(t)(2). However, Medicare will reimburse for ***another use*** of anticancer drugs ***if*** (i) the drug is approved ***and*** (ii)(a) the other use is supported by ***specific compendia*** set out in the Medicare Act ***or*** (b) the Medicare carrier determines that such use is "***medically accepted based on supportive clinical evidence*** in peer-

reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary." 42 U.S.C. § 1395x(t)(2)(B).

2. Calculating the Reimbursement Amount for Covered Drugs

40. In determining the amount it will pay, Medicare calculates the "allowed" amount for the drug. During the period 1992 through 1997, Medicare's reimbursement for Covered Drugs was set at the lesser of the estimated acquisition cost or national Average Wholesale Price ("AWP"). This payment methodology was set forth in 42 C.F.R. § 405.517, a regulation first published in the Federal Register on November 25, 1991 and which became effective on or about January 1, 1992.

41. The estimated acquisition cost for a drug could be determined by the Medicare Program "based on surveys of the actual invoice prices paid for the drug" taking into consideration the estimated acquisition cost, including "factors such as inventory, waste and spoilage." However, historically it has been the AWP published in the *Red Book* or other compendia that has been used as a ceiling for Medicare reimbursement.

42. On January 1, 1998, 42 C.F.R. § 405.517 was amended to provide that the allowed amount would be based upon the lower of the billed charge on the Medicare claim form or 95 percent of AWP.

43. The Medicare Program has publicly announced that it would use the AWP published in pharmaceutical industry magazines as the basis for reimbursement. Specifically, Program Memorandum AB-99-63 (dated September 1999 but re-issuing PM AB-98-76 dated in December 1998), a publicly available Medicare Program bulletin, confirmed that reimbursement for certain Medicare Part B drugs and biologicals "are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in sources such as the *Red Book*, *Blue Book*, or Medi-Span."

44. Pursuant to PM AB-99-63, the AWP for a single-source drug or biological equals the AWP of the single product.

45. Medicare Part B reimburses medical providers 80% of the allowable amount for a drug. The remaining 20% is paid by the Medicare Part B beneficiary, and is called the "co-payment" amount. All medical providers are required by law to bill the 20% co-payment and make attempts beyond merely billing to collect that amount.

46. In setting reimbursement rates, the Medicare Program uses the AWPs generated by the pharmaceutical industry, as do State Medicaid programs. There are no regulations describing how AWPs are to be calculated, nor any regulatory process for approving them. Pharmaceutical companies do not report AWPs directly to the federal government, but instead send their pricing information to independent publishing companies that compile the data and publish the AWPs in trade publications, which are then used by the government, as well as private health plans.

47. The importance of an accurate AWP was recently reconfirmed by the Office of the Inspector General ("OIG") in an April 2003 report: "Compliance Program Guidance for Pharmaceutical Manufacturers." The OIG report found that the "government sets reimbursement with the expectation that the data provided are complete and accurate." The OIG report made it clear that the AWP must be a meaningful figure that is not artificially inflated:

> Where appropriate, manufacturers' reported ***prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers***. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements. [Emphasis added.]

48. The OIG rejected the notion that purposeful AWP manipulation was a lawful practice:

The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. ***The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute***. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product. [Emphasis added.]

3. The Anti-Kickback Law Limits Medicare and Medicaid Reimbursement of Chemotherapy Drugs

49. The Medicare and Medicaid anti-kickback law, 42 U.S.C. § 1320a-7b(b), regulates drug marketing in order to prevent over utilization of prescription drugs. Under the anti-kickback law, drug companies may not offer or pay any remuneration, in cash or kind, to induce physicians or others to order or recommend drugs that may be paid for by a federal healthcare program. This statute prohibits not only outright bribes and rebates, but any payment by a drug company to a physician that has as one of its purposes to induce the physician to write additional prescriptions for the company's drugs.

50. In 1994, the Inspector General of the U.S. Department of Health and Human Services issued a Special Fraud Alert concerning prescription drug marketing practices that violated anti-kickback laws. Among the improper practices cited by the Inspector General were drug companies' payment of "research grants" to substantial prescribers of their medications; payments to physicians for "studies" of the companies' products when the studies were "of questionable scientific value and require little or not actual scientific pursuit"; and payments to physicians where the physician had offered no particular services of benefit to the drug companies but the payment appeared to have been based on the volume of business the doctor generated in the past, or could generate in the future, for the company.

4. Drug Companies May Promote Their Products Only for the Specific Uses Approved by the FDA

51. It is not unlawful for physicians to prescribe approved drugs for indications or at dosages different than those set forth in a drug's labeling. Nevertheless, the Food, Drug and Cosmetic Act prohibits drug companies from marketing or promoting approved drugs for uses, dosages, and administration other than those set forth in the drugs' approved labeling. This regulatory scheme protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government agency.

52. The FDA requires that both Epogen and Procrit carry indications ***for all approved uses*** in their Package Inserts because the two brands are identical in every way, except the label. For example, Defendant is prohibited from marketing Procrit for dialysis use, but its Package Insert carries the indication for dialysis. In addition, Medicare acknowledges no difference between the two products and ***will reimburse for both brands*** when they are used to treat dialysis patients in the End Stage Renal Disease ("E.S.R.D.") program under Medicare Part B.

5. Prohibitions on the Sale or Distribution of Drug Samples

53. At all times material to this Complaint, the Prescription Drug Marketing Act provided in part as follows:

a. Section 331(t) of Title 21 of the United States Code prohibited the sale, purchase and trade, and the offer to sell, purchase and trade, drug samples in violation of § 353(c) of that Act. Section 331(t) also prohibited causing such conduct.

b. Section 353(c) provided that no person may sell, purchase or trade or offer to sell, purchase or trade any drug sample. Section 353(c)(1) applied to samples of a drug which was intended for human use but, because of its toxicity, potential for harmful effect and method of use, and the collateral measure necessary for use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug and with written prescription of such practitioner. Section 353(c)(1) further provided that a sample of such a drug was a unit of drug not intended to be sold but intended to promote the sale of the drug. Procrit is a drug subject to the requirements of § 353(c)(1).

c. Section 353(c)(3) permitted a manufacturer of a drug to distribute samples of the drug through its sales representatives but only if a practitioner licensed to prescribe the drug made a written request for such samples, which request contained at least the following: the name, address and professional designation of the practitioner, the identity and quantity of the drug requested, the name of the manufacturer of the drug, the date of the request, and the practitioner's signature.

B. Defendant's Drug Procrit

54. Defendant manufactures and markets Procrit. According to Defendant's website, it is one of Defendant's "most important products."

55. Procrit is Defendant's brand name for epoetin alfa, and it is used in treating anemia induced by disease or the sequelae of treatments such as chemotherapy and it is indicated for peri-surgical use as a prophylactic for otherwise healthy patients facing high blood-loss surgery.

56. Procrit is an expensive drug.

57. The two brands of the drug epoetin alfa were the products accounting for the two highest pharmaceutical reimbursements by Medicare in 2002, totaling 12% of Medicare's drug expenditures.

58. The brand accounting for the highest pharmaceutical reimbursements by Medicare, Amgen's Epogen, is used in dialysis treatment. It accounted for $1.4 billion in Medicare payments in 2002. The number two brand, Procrit, accounted for $928 million in Medicare costs in 2002.

59. Procrit meets the requirements for reimbursement by Medicare when it is prescribed for the specific uses approved by the FDA.

60. The FDA originally approved Procrit for use to treat anemia in chronic renal failure patients, cancer patients receiving chemotherapy, HIV patients treated with AZT, and patients anticipating high blood-loss surgery such as hip replacement surgery.

61. In 1993, the FDA approved dosing of Procrit in cancer patients at 150iu/Kg three times per week, which translates to three 10,000-unit doses for a 70kg/154lb. adult.

62. In the mid-1990s, Defendant obtained FDA approval for Procrit to be used in surgeries at a higher less frequent dose than its historical chemotherapy dosing. This surgical indication has an approved dosage of 40,000 units in a once-a-week injection.

63. Surgical patients unlike chemotherapy patients do not have compromised bone marrow. In a surgical patient Procrit is used for a short duration as a prophylactic to stimulate red blood cell production in anticipation of blood loss from surgery. In contrast Cancer chemotherapy patients have anemia related to their suppressed bone marrow and therefore the dosing need for Procrit is a much longer duration than the peri-surgical need. There is therefore no physiologic similarity between the surgical and the chemotherapy patient regarding the administration of Procrit.

C. Defendant's Illegal Conduct.

C(1). Defendant's Scheme to Increase the Spread Between AWP and the Effective Cost of Procrit

a. Defendant Intentionally and Artifically Inflated the AWP for Procrit

64. During all relevant times herein, Defendant provided AWPs for Procrit to *Red Book*, the *Blue Book*, Medi-Span and other pharmaceutical compendia .

65. During all relevant times herein, Medicare reimbursement was based on the published Average Wholesale Price, or "AWP" in the pharmaceutical compendia.

66. During both Relators' employment by Defendant, Relators were directly educated and directly informed by Defendant that the AWP was false, artificially high, and that they should convince Providers that Providers would "make money" by submitting claims for reimbursement to Medicare for Procrit, because actual acquisition cost was always less than the Medicare reimbursement rate based on the false and artificially inflated AWP.

67. Relators have first hand direct and independent knowledge of the fact that the spread between Provider's actual acquisition cost and Medicare reimbursement rates based on AWP was the motivating factor determining which drug Providers that administered epoetin alfa would use. Relators obtained this knowledge through their employment with Defendant and interaction with Procrit Provider purchasers.

68. Relators have first hand, direct, and independent knowledge that Defendant refrained from stating post-discount actual prices on its invoices to Providers in order to hide the spread between the actual acquisition cost and Medicare reimbursement rate. For example, in an April 5, 1995 e-mail, Relator Duxbury, reported to his management (Donald Cope) that St. Peter's Hospital in Olympia, Washington switched to Procrit because of the "lower net acquisition cost" in relation to the hospital's AWP based Medicare re-imbursement rate for its dialysis patients.

69. Relator Duxbury testified under oath in 1995, in a deposition in the AMGEN ligitation, that providers would choose whichever brand of epoetin alfa would maximize their financial benefit, considering "reimbursement rates." The subject of this deposition was regarding Ortho Biotech's efforts to market Procrit in Dialysis accounts. Dialysis providers, both freestanding dialysis centers and hospitals which provide dialysis services obtained their reimbursement for epoetin alfa almost exclusively from Medicare and Medicaid.

70. Defendant's documents dating as early as the mid-1990s, as well as Relator Duxbury's 1995 testimony, demonstrate Defendant's unlawful actions in "marketing the AWP spread" by reducing actual acquisition cost to Providers through various off-invoice incentives (rebates, discounts, grants, free product, etc.), while contemporaneously publishing a false and fraudulently inflated AWP to be used in the submission of claims for reimbursement of Procrit to Medicare. Some of the many Defendant documents that show this illegal conduct include, but are not limited to, the following:

- e-mail from Relator to Robert C. Nelson dated December 10, 1992 re: Grant Request for St. Joe's;
- e-mail from Relator to Robert C. Nelson dated December 11, 1992 re: St. Joe's Add'l Info.;
- Ortho Biotech check to St. Joseph's Hospital dated January 20, 1993 for $10,000;
- Rebate checks dated February 21, 1994 (for $2,280), March 8, 1993 (for $760 and $1,520), and March 29, 1993 (for $760) from Marketchek, Inc. for Ortho Biotech Inc. to Mid Columbia Kidney Center;

- Memorandum dated October 26, 1993 from Robert C. Nelson to William Ball re: Grant for St. Joseph's Hospital, Tacoma, WA;
- E-mail from Relator to Robert C. Nelson dated December 4, 1993 re: Fall Promotion Update;
- Letter dated December 6, 1993 from Albert J. Linggi, St. Joseph Hospital and Health Care Center, to Relator re: conversion to Procrit due to pricing;
- Memorandum dated January 5, 1994 from William Ball to Beth Michael re: Procrit Grant Program – Check Requisition;
- Ortho Biotech Requisition dated January 20, 1994 for $20,000 check for St. Joseph's Hospital from Beth Michael to Lori Lonczak;
- Ortho Biotech check to St. Joseph's Hospital dated February 1, 1994 for $20,000;
- Letter dated February 16, 1994 from Robert C. Nelson to Albert J. Linggi re: check from Ortho for $20,000;
- Letter dated February 17, 1994 from Albert J. Linggi to Relator re: Educational Grant;
- Letter dated February 17, 1994 from Albert J. Linggi to Robert C. Nelson re: Educational Grant;
- Letter dated February 17, 1994 from Albert J. Linggi to William D. Ball re: Educational Grant;
- Letter dated March 3, 1994 from James A. Plourde, Franciscan Foundation for Health Care, to Robert C. Nelson re: Educational Grant;
- Letter dated March 3, 1994 from James A. Plourde, Franciscan Foundation for Health Care, to Williams D. Ball re: Educational Grant;
- E-mail from Relator to Michael Barton dated June 13, 1994 re: Limited time rebate offer;
- Letter dated February 21, 1995 from Michael C. Barton to Relator re: rebates and grants to St. Peter's Hospital and St. Joseph's Hospital.

71. Defendant deliberately and intentionally published false and inflated AWPs for Procrit.

72. Defendant published false and inflated AWPs for Procrit that did not reflect the actual pricing structure of the drugs, but was created solely to cause overpayment for Procrit by Medicare and Medicaid. Defendant created and perpetuated this scheme so that Providers who

purchased these drugs at a low cost would bill Medicare and Medicaid at the inflated AWPs and earn a substantial profit from the "spread" between the real cost and the AWP-related reimbursement rates.

73. Defendant knew and understood that Medicare and Medicaid used the *Red Book, Medispan* and other such pharmaceutical compendia to determine the AWPs of the drugs. Because Defendant controlled the AWPs published in the *Red Book* and other pharmaceutical compendia, Defendant knew and understood that it could manipulate the Providers' profits by inflating the AWP while decreasing the actual acquisition cost of the drug to Providers.

74. Defendant's purpose and effect in artificially inflating the AWP was to create a profit-spread between the Provider's actual cost and the amount of Medicare/Medicaid reimbursement. In effect, the spread resulted in an illegal kickback to the Providers funded by Medicare and Medicaid.

75. Defendant intended to create a profit-spread between Medicare reimbursement rate for Procrit and the actual cost of Procrit to Providers.

76. Defendant knew and intended that the AWP reported to the pharmaceutical compendia was inflated , inaccurate, and false.

77. Defendant educated Relators and its sales representatives that the AWP was higher than any price paid by providers for the drug, and was a false and inflated number.

78. In January, 1993, Seattle District Sales Manager Robert Nelson verbally told Relator Duxbury that the AWP was intentionally inflated by Defendant to an amount higher than the cost any Provider actually paid, and that Relator Duxbury could assure Providers that they would "make money" on prescribing Procrit because Defendant made sure that its AWP was high enough for Providers to profit.

79. During that same conversation, Relator's manager Nelson explained how Procrit's AWP was determined by finding a number high enough to ensure that Providers could profit by prescribing Procrit.

80. Relator McClellan was told by Multiple San Diego District Sales managers from 1993 through 2004, that AWP was reported at a falsely inflated AWP to guarantee a profit for Providers.

81. Throughout 1993 to 1998, Relator Duxbury personally attended sales training meetings where he was taught and educated by Defendant on how to "market the spread" to Providers by decreasing net acquisition cost for Procrit and instructing Providers to submit claims for reimbursement to Medicare based on the false and inflated AWP. Relator Duxbury, and other sales representatives, were directed by Defendant to show Providers how money can be made (profit to Providers) by submitting claims for Medicare reimbursement to the U.S. government based on an inflated AWP, but actually purchasing Procrit for a net acquisition cost that is significantly less. For example, Seattle District Manager Robert Nelson instructed Relator Duxbury to analyze profits gained by the spread at St. Peter's and St. Joseph's hospitals and present them in writing as a "financial analysis" of the benefits of purchasing Procrit.

82. Defendant instructed its sales representatives to intentionally market and educate Providers on how to submit false claims based on the spread between the inflated AWP and the net acquisition cost of Procrit.

83. Defendant created and utilized a computer software program known as the MVP program, that demonstrated to Providers how they could generate additional revenue by prescribing Procrit by taking advantage of lowered net acquisition cost through rebates and discounts and then submitting claims to the U.S. government based on the inflated AWP.

84. Both Relators personally attended sales meetings and training sessions where Defendant told them how to market to Providers the spread between AWP and net acquisition cost.

85. Both Relators, pursuant to Defendant's direction, instruction and training, "marketed the profit-spread" between Medicare reimbursement based on false AWP and the net

acquisition cost to Providers. Both Relators taught Providers how to submit false claims to the U.S. government based on the inflated AWP.

86. On or about 2003, Relator McClellan sold more than $725,000.00 Procrit to Dr. Katakkar's Tucson office, and told office manager Ryan Armstrong and billing manager Tammy Oughton how to bill Medicare based on AWP. Relator McClellan personally saw the HCFA 1500 that was submitted by Tammy Oughton for the Procrit, seeking reimbursement based on an inflated AWP. Relator McClellan followed up with Tammy Oughton and obtained first-hand knowledge that Dr. Katakkar had received reimbursement based on the inflated AWP and that due to the spread between the false AWP and the actual acquisition cost, Provider Dr. Katakkar had actually "profited" by submitting the false claim to Medicare.

87. By reporting an inflated AWP, Defendant knowingly caused false claims to be submitted to the U.S. government.

88. By causing Providers to submit claims for reimbursement to Medicare based on the false and fraudulent AWP, Defendant knowingly caused false claims to be submitted to the U.S.government.

89. By marketing the spread between AWP and actual acquisition cost to Providers, Defendant knowingly caused false claims to be submitted to the U.S.government.

90. Defendant's illegal scheme, as alleged herein was common and uniform throughout the United States. Defendant caused thousands of Providers to submit millions of false claims to the U.S. government during the relevant time period including, but not limited to, the false claims submitted by Relators' accounts (Providers that Relators sold to), as alleged herein.

b. Defendant's Kickbacks to Increase the Spread Between AWP and the Effective Cost of Procrit

(1) Free Drug

91. Defendant, through Relators and other sales personnel and marketing representatives, also provided free commercially packaged and labeled drugs to Providers as a means of lowering actual acquisition cost of Procrit to Providers. The free drugs were used to offset the total cost associated with the purchases of the drugs, thereby increasing the "spread" between actual acquisition cost and Medicare reimbursement rates based on AWP.

92. Defendant specifically told Providers to bill patients for the free Procrit, which Defendant knew was unlawful.

93. Both Relators have personal knowledge that Defendant commonly directed its sales representatives to provide free Procrit to Providers and instruct the Providers to submit claims for Medicare reimbursement for said Procrit.

94. Free product is not used by Defendant in calculating or reporting the AWP despite the fact that the substantial quantities of free drug given to Providers effectively lowered net acquisition cost. The failure to include free drugs in calculating the AWP, contributed to the inflated AWP.

95. Although Defendant provided free product and marketed free Procrit as a way to lower the Providers' actual cost of Procrit. Defendant did not include the value of the free product in calculating the AWP for Procrit. Thus, Defendant effectively and improperly passed on the cost of the free product directly to Medicare.

96. The free Procrit provided to Providers by Defendant's sales representatives, including but not limited to Relators, were drug samples within the meaning of 21 U.S.C. § 353(c)(1). Defendant provided the free Procrit with the illegal intent that Provider's submit claims for reimbursement to Medicare for said free drug.

97. Defendant offered substantial quantities of free Procrit through "Patient Trial Cards." These are sequentially numbered documents that identify the Provider who received the drug and the representative who provided the drug. There were thousands of "Patient Trial Cards" provided to sales representatives, each of which was worth well over one thousand dollars ($1,000) in free Procrit. For example, Relator McClellan had over 400 Patient Trial Cards in his possession at one time. Medicare was billed for free Procrit and the free Procrit was not accounted or in calculating AWPs. Relator McClellan has copies of hundreds of "Patient Trial Cards" that he gave directly to Providers with the intent that the Providers would submit claims for reimbursement to Medicare for the free Procrit.

98. Relators have direct and independent knowledge that Defendant gave free samples of Procrit to Providers to induce them to use Procrit and lower the actual cost of the drug.

99. Both Relators, at the direction of and as agents of Defendant, personally and directly gave free Procrit to Providers and told providers to submit claims for reimbursement to Medicare for the free Procrit.

100. Defendant routinely referred to free Procrit as "cash." Defendant employees Thomas Amick, William Pearson, Robert Ashe, George Mooney, William Ball, John Woodhouse, Keith Wood, Michael Barton and Robert Nelson instructed Relator Duxbury to treat free Procrit as a "cash" equivalent incentive to Providers.

101. Defendant employees which include numerous managers during this time period, including but not limited to Dwayne Marlowe, James Scelfo, Robert Ashe instructed Relator McClellan to treat free Procrit as a "cash" equivalent incentive to Providers.

102. For example, in or about February 2001, one of Defendant's product specialists reported to Defendant's regional manager, Dwayne Marlowe, in a Status Report that an oncology clinic within his territory had failed to obtain reimbursement for approximately $8,500 worth of Procrit. Marlowe instructed the product specialist to provide free Procrit to the account equal in

value to the clinic's reimbursement losses. Marlowe instructed the product specialist to submit to Defendant Patient Trial Cards on the clinic's behalf, to get it free Procrit. The product specialist would have a doctor sign numerous cards at a time so as not to draw attention, and then every two weeks he would submit just a few of them to Defendant for fulfillment. These allegations are supported by contemporaneously generated documents in the possession of Relator McClellan.

103. Both Relators have direct and independent knowledge of Defendant's unlawful practices, promotional and marketing policies, and illegal schemes related to the provision of free Procrit to Providers with the direction to Providers to submit claims for reimbursement to Medicare.

(2) Discounts and Rebates

104. Defendant offers Providers discounts and rebates for Procrit purchases to induce them to buy Procrit.

105. Both Relators have direct and independent knowledge that Ortho provided discounts, rebates, and other financial inducements to stimulate the sale of Procrit and lower the actual cost of purchasing Procrit.

106. Both Relators possess documents showing that as a sales representative of Defendant they provided discounts, rebates, and educational grants directly to Providers purchasing Procrit.

107. Both Relators, at the direction of and in agency for Defendant, gave Providers "off-invoice" hidden discounts, grants, rebates and other incentives to lower the actual acquisition cost of Procrit.

108. Relator Duxbury also possesses documentation of rebates given in 1993 by Defendant to the Mid-Columbia Kidney Center, for purchases of Procrit. Again, Relator Duxbury has independent and direct knowledge of the provision of the rebate to Mid-Columbia Kidney Center, because Defendant directed Relator Duxbury to provide the off-invoice rebate.

Defendant represented to Relator Duxbury that the rebate was provided "off-invoice" for the exclusive purpose of inducing more Procrit purchases by lowering the actual acquisition cost and increasing the kidney center's profit to be made by the AWP spread at the expense of Medicare.

109. Both Relators possesses first hand direct and independent knowledge that Defendant's purpose of giving cash payments to physicians to serve on Advisory Boards was to influence them to prescribe and advocate the prescription of Procrit. Both Relators were told by Defendant that the purpose was to influence the providers to prescribe Procrit. Both Relators were also given a February 26, 1997 memorandum, to Hematopoietic Product Specialists, from Defendant's manager William Pearson re: Advisory Board Member Interaction, that set forth in writing the unlawful intent to provide cash payments as an inducement to physicians to prescribe Procrit.

110. As of August 13, 2003, Defendant guaranteed physicians a discount of 6% (and potentially up to 10%) off the list price if they purchased Procrit.

111. In an April 13, 2004 internal training presentation, Defendant's Executive Director of Contracting and Government Contracts Tom Hiriak described Defendant's discount and rebate program for physicians. He explained that physicians can purchase Procrit off several discount programs" that "provide a 5% off-invoice (upfront) discount." However, this discount is not provided directly by Defendant. Rather, through a "chargeback" process, the drug distributor provides the discount and "'charges back' to collect the 5% discount."

112. Rebates of 5% were normal until approximately 2002, when Amgen released Aranesp. Until then, Procrit was 17% cheaper than Amgen's competing product, Epogen.

113. Since the introduction of Aranesp, Defendant has marketed an aggressive rebate program.

114. A copy of a 2003 promotion piece for physicians refers to rebates "paid in product."

115. The Hiriak internal training presentation states that Ortho Biotech rolled out two physician rebate programs in January 2004. As of that date, physicians could qualify for rebates of between 15.5% and 20% off the discounted price, depending on their purchase volume.

116. Several additional rebate percentage points were authorized in March 2004.

117. Hospitals receive reimbursement under an "APC" code. As of early 2004, they received 73.4 percent of AWP. Because the reimbursement is based in part on AWP, Defendant did "market the spread" between the actual sales price to hospitals and AWP.

118. In 2003, Defendant had a rebate program offering hospitals an 8% rebate.

119. Defendant's executives trained sales representatives on calculating the Medicare reimbursement for Procrit at annual sales meetings. Combined with the promotional materials described above, sales representatives were equipped to calculate the spread between a customer's net cost and the Medicare reimbursement.

(3) Unrestricted Educational Grants

120. Defendant maintained large pools of money to be disbursed as unrestricted educational grants in what was called "business development grants" later renamed the S.A.F.E. program. Each unrestricted educational grant required a written request from the sales representative to his/her manager and included a description of what benefit to Defendant is expected in return for the grant. Defendant used these grants as "kickbacks" to buy influence with physicians and hospitals. These "kickbacks" were directly tied to the Providers' purchase of Procrit.

121. One example of this type of "kickback" given to Providers to purchase Procrit is Relator Duxbury possesses documentation of a ten thousand dollar ($10,000) and twenty thousand dollar ($20,000) unrestricted grants that Defendant gave St. Joseph's Hospital in Tacoma, Washington in 1992 and 1993 conditioned upon the purchase of Procrit. The grants were given in connection with and in consideration for continued purchase of Procrit, and was used as a way to lower the actual acquisition cost of Procrit to the Provider.

122. In order to convert a hospital with a large dialysis center to Procrit, Defendant provided unrestricted educational grants totaling $30,000 during an 18-month period beginning in the spring of 1993. The account was St. Joseph's Hospital in Tacoma, Washington. The grants substantially reduced the effective net acquisition price (which was already 15% below AWP) for Procrit and were not used by Defendant in reporting its AWP.

123. In 2002, a site of U.S. Oncology, a nationwide oncology practice, within the district of Defendant's manager James Scelfo, was given an annual grant of $50,000 to support a "Life Beyond Cancer" educational program. In 2003, however, after Defendant lost U.S. Oncology's contract to provide it with Procrit, Defendant reduced its funding to $10,000.

(4) Membership on Advisory Boards

124. Pharmaceutical companies established Advisory Boards to allow the drug manufacturer to bring medical experts to a central location where they can hear presentations on the manufacturer's products, new research areas and information regarding off-label use. The Advisory Board members are expected to provide feedback to the manufacturer on the quality of the information they heard, evaluate the relative importance of clinical data they were presented, and reinforce existing research directions or suggest new ones.

125. Defendant used Advisory Boards not to gather new research ideas, but to give cash and benefits to oncologists to promote sales of its drug.

126. In a memorandum to Defendant's Procrit sales force dated February 26, 1997, National Field Sales Manager Bill Pearson explained the purpose of Ortho Biotech's Advisory Boards: "One of the operating strategies for our Integrated Business Plan is to ***develop thought leader endorsement to establish PROCRIT as standard of care.*** Our Clinical Affairs Department has been very active in developing tumor specific, HIV, and fatigue advisory boards to develop thought leader endorsement and establish PROCRIT as the standard of care in treating anemic cancer patients."

127. Defendant used Advisory Boards to make cash payments to influential physicians and take them to meetings at resorts in order to gain influence among leaders in the oncology community. At these meetings, minimal time was spent discussing information of medical value.

(5) Phony Drug Studies

128. Another method of inflating reimbursement for use of Procrit was through phony drug studies. Phase IV clinical trials are defined by the FDA as a method of evaluating a drug in a "real world" clinical setting. Defendant extensively used a Phase IV marketing trial as a way to accomplish a number of marketing goals:

a) To provide cash payments to a physician, clinic or hospital which lowered the effective net acquisition cost of the drug. This allowed the manufacturer to provide a lower "best price" to physicians than what it reported to Federal or State Governments, resulting in inflated Medicare and Medicaid payments for the drug;

b) To provide cash payments to a physician, clinic or hospital to influence the physician to use more of the drug in practice.

c) To provide cash payments in order to encourage the physician, clinic or hospital to use the drug in a way which was higher than the FDA-approved dosage. In 1997, Defendant launched a massive Phase IV marketing trial to increase the dosage – and Government reimbursement – by 33% for each Medicare Beneficiary receiving Procrit for Other Hidden and Improper Inducements and Price Reductions

(6) Other Hidden and Improper Inducements and Price Reductions

129. Defendant has provided and/or arranged for many other non-public financial inducements to stimulate sales of Procrit at the expense of Medicare and Medicaid. Such inducements included volume discounts, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and educational and promotional grants. All of these incentives were designed to lower the providers' net cost of purchasing Procrit. And again, the value of

these services was kept "off the book," so as to not be reflected in the AWP, which in turn inflated the AWP.

130. During the time of both Relators' employment, Defendant offered substantial discounts, rebates, unrestricted educational grants, and free commercially packaged Procrit to Providers in order to create a lower effective net purchase price and a greater profit spread from the inflated AWP reported to Medispan, *Red Book*, and other publishers. Defendant used surrogate companies like Charise Charles, Lt. and MarketCheck, Inc., to facilitate these schemes. The surrogate companies would use the U.S. mail to send rebates to Providers throughout the country. These rebates were hidden from Medicare and were not accounted for in calculating Defendant's reported AWP for Procrit.

C(2). Defendant's Inflated Dosing Scheme

131. In or about 1997, Defendant initiated a scheme to use illegal promotion and kickbacks to induce reimbursement claims for the off-label use of Procrit (the "Inflated Dosing Scheme"). Defendant's purpose was to increase sales of Procrit and reimbursement by Medicare.

132. The key elements of the Inflated Dosing Scheme were:

(i) affirmatively promoting the off-label dosing of Procrit, in violation of the Food, Drug and Cosmetic Act;

(ii) promoting Ortho Biotech's FDA-approved surgery indication for Procrit, which is for a higher dose than the FDA-approved cancer indication, to oncologists to induce them to prescribe the higher dose for cancer patients, who comprise the majority of Medicare patients receiving the drug;

(iii) paying kickbacks to physicians and hospitals in the form of cash and free drugs to induce use of Procrit;

(iv) using sham drug "trials" to falsify eligibility under a special provision in the Medicare Act addressing reimbursement for off-label uses of cancer drugs; and

(iv) changing the vial size in which free Procrit was distributed to inhibit administration at the approved dose.

133. Both Relators were employed by Defendant at the inception of the "Inflated Dosing Scheme" (described more fully below) in 1997.

134. Both Relators have direct and independent knowledge that Defendant developed a scheme to use illegal promotion and kickbacks to cause submission of reimbursement claims for the use of Procrit at a dosage and purpose that was not approved by the FDA.

135. Both Relators possess documents obtained during their employment showing that in late 1997 and early 1998 Defendant distributed to its oncology sales staff materials to promote the 40,000-unit, once-per-week dosing regimen for non-surgical/unapproved use, despite the fact that the 40,000-unit dosing regiment was only approved for surgery indications.

136. On December 10, 1997, Relator Duxbury received a performance review called a "Field Conference Report" that stated that Defendant's corporate policy was to promote the dosing of Procrit for chemotherapy patients at 40,000 units once per week, a dosage not approved by the FDA. This "Field Conference Report" directed Relator Duxbury to advance this policy by aggressively marketing the 40,000 unit dose for off-label/unapproved use. The Field Conference Report stated: "Areas for Development to carry through 1998: (1) 1x weekly dosing – move accounts toward this dosing schedule."

137. In January 1998, both Relators attended an annual national sales meeting in Seattle, WA, which was summarized in a February 2, 1998 memorandum from Defendant's San Diego district manager, Dwayne Marlowe. At the January 1998 meeting, Vice President of Sales W. Thomas Amick announced the corporate strategy for the off-label/unapproved increasing of the dosing of Procrit for cancer patients to 40,000 units per week. Amick announced that a "Phase IV trial" would be used to promote adoption of the higher off-label dosing for cancer patients under the guise of a legitimate study. The February 2, 1998 memorandum recounted that "once-a-week-dosing" of Procrit to chemotherapy patients at 40,000 units was one of Amick's "top five" strategies at the start of 1998. Further, the February 2, 1998 memorandum

recounted Defendant's plan to use a Phase IV trial and "mini-trials," both of which involved giving providers free Procrit.

138. On February 13, 1998, Relator Duxbury was given a second Field Conference Report by his manager that further confirms Defendant's policy of aggressively promoting the 40,000 IU off-label/unapproved use for cancer patients. This Field Conference Report stated that the "Strategic Driver" for Relator was to get "qw Dosing [*i.e.*, 40,000 units once per week] established." It also provided: "Business priorities to focus on: (1) Q.W. Dosing."

139. On March 11, 1998, Relator Duxbury was given a third "Field Conference Report" by his manager. Like the second Field Conference Report, this Report stated that the "Strategic Driver" for Relator was to get "Once Weekly Dosing" established, and that Relator's first "[b]usiness priorit[y] to focus on … [was] Q.W. Dosing."

a. The Trigger Event for the Inflated Dosing Scheme: FDA Approval of the 40,000-Unit Surgery Indication

140. In the mid-1990s Defendant obtained FDA approval of a surgery indication for Procrit at 40,000 units once weekly.

141. In 1997, Defendant developed a strategy to leverage the approved surgery indication to procure widespread acceptance, without FDA approval, of this increased dosing once a week for chemotherapy patients.

142. Because of the different physiological needs of surgery and chemotherapy patients, there is no medically necessitated need for chemotherapy patients to receive the surgery dosage. The main reason that Defendant developed this strategy was to increase sales of Procrit by a margin of a third (from 30,000 to 40,000 units weekly) for oncology patients – much of which was paid by Medicare.

143. In fall 1997, Defendant managers instructed the ***oncology*** sales force to show oncologists that the package insert now included once weekly dosing at 40,000 units, and to inform providers that if this dosing regimen worked safely for surgical patients it would for

cancer patients as well. Both relators directly received this instruction from Defendant managers.

144. On October 31, 1997, Defendant added a promotional piece on weekly dosing of Procrit for the surgery indication to its ***cancer*** promotional materials. Defendant's sales supply department (Margaret Woods) sent an e-mail to the sales staff re: Sales Supply Update announcing new promotional materials, including "Cancer Materials Added: PCT-C-574, Folder for Surgery Weekly Dosing." Both Relators received a copy of this e-mail and promotional materials.

145. Defendant distributed no other medical justifications for the increased dosing to its sales staff, and it had none. Neither Relator ever received any other medical justification for the increased dosing.

146. On January 7, 1999, in an e-mail to all managers, including oncology sales managers, Defendant's President, Gary Reedy, announced that the FDA had approved a new 40,000-unit vial of Procrit, even though Procrit was not approved by the FDA for oncology patients in 40,000-unit doses. Relator McClellan directly received this instruction and the e-mail from Gary Reedy.

147. In Defendant's Oncology Product Specialists' Training materials used at its Managers' Meeting in January 2001, Defendant trained its sales staff on how to promote once-weekly 40,000-unit dosing for oncology patients. Defendant directed its sales representatives to state that "Ortho Biotech [is] well versed in facilitating reimbursement for use in oncology regardless of dose …" and that "Medicare reimburses for 60K Procrit/week." Both Relators directly received said training.

b. The Initial Phase of the Inflated Dosing Scheme: the Sham "Phase IV Trial"

148. Defendant's strategy for achieving widespread acceptance, without FDA approval, of the 40,000-unit dosing for chemotherapy patients included developing and

promoting a bogus Phase IV clinical trial. This step in the Inflated Dosing Scheme involved creating an unscientific "study" of the treatment of anemic oncology patients at the 40,000-unit dose, paying doctors to enroll patients in the "study," and promoting this unapproved use to oncologists in violation of the Food, Drug and Cosmetic Act.

149. During the week of January 26, 1998, Defendant held a National Sales Meeting in Seattle that was referred to as POA (for Plan of Action) I. Both Relators attended this meeting, and possesses a February 1998 sales roster with a list of sales representatives at the time of meeting.

150. At this meeting, Vice President of Sales W. Thomas Amick announced the corporate strategy for increasing the dosing of Procrit for cancer patients to 40,000 units per week. Both Relators directly heard the announcement and direction from W. Thomas Amick.

151. Amick announced that a "Phase IV trial" would be used to promote adoption of the higher off-label dosing for cancer patients under the guise of a legitimate study. Both Relators directly heard this announcement from W. Thomas Amick.

152. Amick's presentation was memorialized by San Diego District Sales Manager Dwayne Marlowe in a memorandum dated February 2, 1998. In the memo, Marlowe identified Amick's priorities and recaps them for his sales district. Further, he sets an ambitious goal for his sales staff for "converting" oncologists to the unnecessarily inflated dosing regimen*:* ***30% of the physicians in just 4 months time.*** Relator McClellan has a copy of the Memorandum written by Dwayne Marlowe.

153. In this memo, Marlowe instructs members of his sales district to: "Follow through with Phase IV study physicians. Follow and document the outcomes of these patients. Provide mini-trials on once a week dosing on all offices who are currently using three times a week dosing. Use Clinical Affairs and Wacholtz ASH abstract as resources. Our goal is to have ***30% of our physicians converted to once-a week dosing regimen by June 1998***." Marlowe instructed and directed sales representatives to achieve the goal to convert cancer patients to

once-a-week dosing, despite the fact that it was an unapproved use and dosage of Procrit. Relator McClellan directly received this instruction and memorandum from Marlowe. Relator Duxbury received a similar follow up directive from the Seattle District Manager John Woodhouse.

154. In early 1998, Defendant selected 500 oncologists whom it deemed "thought leaders" in their communities to whom it planned to offer cash and free drug to place anemic chemotherapy patients on a once weekly, 40,000-unit dosing regimen for 16 weeks, in an effort to illegally achieve "acceptance" as a standard of care despite its lack of FDA approval. Shortly thereafter, both Relators were told by their respective Managers of the plan to gain acceptance without FDA approval.

155. Defendant trained its sales staff, including both Relators, to offer these doctors $500 for each patient they enrolled in the study, up to 5 patients. The doctors could keep the payment even if the patient did not complete the study. Defendant told its sales representatives, including both Relators, that the purpose of the five hundred dollar ($500.00) payment was to induce providers to prescribe the off-label/unapproved 40,000 IU dosage to cancer patients. Both Relators were directly instructed by Defendant to tell providers that each provider would receive five hundred dollars ($500.00) per patient.

156. As an additional incentive, Defendant gave the doctors free drug to perform the study. Both Relators were directly instructed by Defendant to give Providers free drugs as an incentive to perform the study.

157. In a memorandum from Doreen McCullough, an employee of Defendant, to providers, Defendant notified providers that they would receive $500 per patient who enrolled in Phase IV trial, reduced if the patient did not complete the study. McCullough stated that providers would be sent an initial supply of Procrit for the study and could call Defendant's agent, Kern McNeill International, if they wanted additional free Procrit. Both Relators were directly given a copy of the memorandum by Defendant to supply to providers.

158. Over the course of Defendant's Phase IV trial, oncologists enrolled roughly 3000 patients, and approximately 1500 patients completed the trials.

159. Defendant paid oncologists between $750,000 and $1.5 million to enroll patients in the Phase IV trial. In addition, it gave oncologists many millions of dollars in drug as part of the study.

160. If all patients enrolled had completed the study, the market value of the free Procrit distributed by Ortho Biotech would have been approximately $17 million.

161. The ultimate purpose of the study was to establish 40,000-unit once weekly dosing as the community standard, and thereby to obtain Medicare reimbursement, despite the lack of evidence of medical need or safety of this dosage. Both Relators were both directly informed of the purpose of the study by Defendant.

162. Because Defendant's stated purpose of the Phase IV trial was to induce physicians to prescribe a drug paid for by Medicare, the cash and free drug given the participating physicians violated the anti-kickback law.

163. Rather than being approached to conduct the study, Defendant affirmatively drafted influential, high profile, high prescribing oncologists to participate in the Phase IV trial. By promoting an unapproved use of Procrit, Defendant's Phase IV trial also violated the Food, Drug and Cosmetic Act.

c. A Parallel Phase of the Inflated Dosing Scheme: the Sham "Mini-Trials"

164. Concurrently with the Phase IV trial, Defendant promoted "mini-trials" of the 40,000-unit once weekly dosing.

165. Defendant's sales representatives, including both Relators, portrayed these as legitimate "studies" of the inflated dosing regimen, but again they involved illegal promotion and kickbacks to establish a purported "community standard" for, and Medicare reimbursement of,

unnecessary 40,000-unit dosing for cancer patients. Both Relators were directed by Defendant to conduct sham "mini-trials."

166. Both Relators did in fact, at the direction of Defendant, conduct sham "min-trials" for the sole purpose of providing an illegal promotion/kickback (free product that the provider submitted as a false claim to Medicare for reimbursement). The use of mini-trials by Defendant was extensive.

167. Defendant did not develop a protocol for these trials, did not submit any protocol to any Investigational Review Board. They did not involve a control group, data was not systematically or purposely collected, and the results were not published in peer-reviewed medical literature. Both Relators possess direct and independent knowledge that none of the sham mini-trials that they conducted as agents of Defendant were submitted for approval by the IRB, involved a control group, or had results published in peer-reviewed medical literature.

168. At the national sales meeting in January 1998, Defendant's management directed sales representatives to target oncologists who "are currently using three times a week dosing" and who were not participating in the Phase IV trial to perform their own "mini-trial" purportedly to evaluate the efficacy of the higher once-a-week dose. Relators Duxbury and McClellan were both in attendance at this meeting and received this direction.

169. Like the Phase IV trial, this study involved promoting an off-label use and giving oncologists free drug to induce them to switch to the higher dosing regimen, in violation of the Food, Drug and Cosmetic Act and the anti-kickback law.

170. Defendant created thousands of additional "Patient Trial Cards" for its sales representatives to distribute to oncologists as part of the "mini-trials." These are 3x5 cards with "Ortho Biotech Inc." at the top, and they are entitled "Procrit (Epoetin Alfa) – Non-Dialysis Patient Trial Program – Physician Request Form." Both Relators were directly provided with numerous "Patient Trial Cards" to use to conduct the sham "mini-trials."

171. Each Patient Trial Card gave the physician free Procrit for one patient's 3-week regimen at the 40,000-unit once weekly dose.

172. As an example of the pervasiveness of the mini-trial scheme, Relator McClellan even indicated on the " delivery instructions" line of the card that the free Procrit was for illegal once-weekly dosing mini-trials. Defendant never questioned Relator McClellan's use of clearly marked Patient Trial Cards for the illegal mini-trials. In fact, Defendant provided Relator McClellan with literally as much free Procrit as he could use to perform illegal mini-trials as long as he could show that he was successful in convincing his oncologists to administer Procrit at the off-label, inflated weekly dose.

173. This free Procrit was not packaged as a sample or marked "not for resale." None of the free Procrit that either Relator gave to providers was ever marked "not for resale" or otherwise marked to indicate that it was a sample, free, or not for resale.

174. Both Relators were never provided any product that was marked as a "sample" "not for re-sale". Neither Relator has ever seen a box of Procrit that was marked "free" "not for resale" or "sample."

175. Defendant sales representatives identified the oncologists in their territory who agreed to participate in this program and requested the Patient Trial Cards from their District Managers. Both Relators identified oncologists in their territory who agreed to participate in the program and received Patient Trial Cards from Defendant to give to the oncologists. Relator McClellan, identified more than 25 oncologists who agreed to conduct "mini-trials" and Relator McClellan ultimately received approximately 800 Patient Trial Cards – worth approximately $1 million – to distribute to them.

176. As part of the scheme to promote the off-label use, sales representatives hosted dinners for oncologists and their staffs at which they reported the purported clinical benefits of the increased dosing. Both Relators hosted, or attempted to host, these dinners on behalf of Defendant.

177. As part of the Inflated Dosing Scheme, Defendant changed its previous Patient Trial Cards to encourage physicians to use the higher dose.

178. Defendant's previous cards permitted doctors to receive Procrit vials in 2,000, 3,000, 4,000, or 10,000 units, any of which in the right combination could be used to administer 10,000-unit doses. After the initiation of the Inflated Dosing Scheme, Defendant's new cards only permitted physicians to obtain 20,000-unit vials. The purpose of the change was to encourage administration of Procrit to cancer patients at the "off-label" dosing regime of 40,000 IU 1X/week.

d. Other Examples of Ortho Biotech's Illegal Promotion of Off-Label Dosing

179. Defendant used Oncology Nurse Educators ("ONEs") to promote the off-label use of Procrit.

180. ONEs were paid by the Oncology Nursing Society to assist defendant in its promotion of Procrit. However, the salaries for ONEs were paid from grants to the Oncology Nursing Society from defendant.

181. ONEs attended Ortho Biotech sales meetings, reported to Ortho Biotech district sales managers, and were trained to meet with oncology nurses and promote the off-label, 40,000-unit dosing of Procrit.

182. In addition, ONEs assisted in the collection of data for patients involved in the Phase IV trial and mini-trials.

183. In a Business Planning Process form prepared by one of defendant's oncology sales representatives for the Caring Cancer Center, the representative noted that ONEs would be used in the mini-trials to review study participants' charts.

184. Form business plans provided by defendant to its oncology sales staff in 1998 admonished the sales representatives to promote 40,000-unit dosing.

185. Later internal training materials also encouraged sales representatives to promote inflated, off-label dosing.

186. In January 2001, defendant held a managers' meeting attended by defendant's oncology management. Its Sales and Marketing Department developed internal materials to educate managers on how to train oncology sales representatives to address Amgen's new competing product, Aranesp. These materials were designed to address concerns that may be raised by customers.

187. In response to the concern that, in contrast to Aranesp, Procrit is not indicated for once weekly dosing, the materials urged sales specialists to promote once weekly dosing of Procrit. They should respond that "Ortho Biotech [is] well versed in facilitating reimbursement for use in oncology regardless of dose [and] dosing schedule," and that "Medicare reimburses for [60,000 units]" (not mentioning that this is for the surgery indication).

188. The internal training materials also advocated that sales personnel inform physicians that "we have data available on [once weekly] dosing with Procrit for cancer patients … available from our Clinical Affairs department," and to offer to fill out a request form for the physician to sign.

189. Other documents originated by defendant also encourage sales representatives to promote once weekly 40,000-unit dosing.

190. A sales representative from the San Diego District prepared a status report to his management in February 2001 in which he reported as "results" that he had worked with a doctor to identify several patients to put on once weekly dosing.

191. On October 22, 2001, Jim Scelfo, one of defendant's manages, wrote a memorandum to the San Diego District sales staff re: POA 3 Recap, in which he summarized the 2001 annual national sales meeting ("POA 3"). In this memo, Scelfo directed sales representatives to compare the cost of Procrit to Aranesp at Procrit's once weekly, 40,000-unit dosing level.

192. Defendant prepared internal training materials that directed oncology sales representatives to compare the cost of Aranesp to Procrit using once weekly, 40,000-unit dosing. It prepared worksheets separately for Part B reimbursement providers ("clinics") and Part A reimbursement providers ("hospitals"). It also prepared a worksheet entitled "List Price Comparison Workshop." In this document, defendant instructed sales specialists to respond to Amgen's claim that Aranesp has a "compendia listing," unlike Procrit, by stating that Medicare reimburses Procrit even without a compendia listing. It directed specialists to state: "Procrit has well established reimbursement programs that are proven beneficial to your office, billing staff, and patients."

e. Defendant's Executives Knew the Inflated Dosing Scheme Was Illegal

193. Defendant's executives knew the Inflated Dosing Scheme was against the law. On August 28, 2001, Defendant's President Gary Reedy sent a memorandum to the Ortho Biotech Sales Force stating that "it is important for you to communicate the appropriate dosing information" to physicians treating anemic chemotherapy patients, including "[t]hat Procrit is indicated for [three times per week] dosing" and "[t]hat Procrit is not indicated for [once weekly] dosing" for these patients. Yet contrary to this legal requirement, Defendant's documents demonstrate that at the core of the Inflated Dosing Scheme was a pervasive plan to train sales representatives to promote once weekly, 40,000-unit dosing. Relator McClellan was provided a copy of this Memorandum from Defendant.

194. Defendant trained its sales staff to prepare false documentation stating that physicians had requested information concerning 40,000-unit once weekly dosing and created a paper trail to conceal its promotion of the off-label dosing. Both Relators were trained by Defendant to prepare this false documentation.

195. In Defendants' Oncology Product Specialists' Training Materials created for the Managers' Meeting in January 2001, Defendant instructed its sales staff how to respond to providers' concerns that "Procrit [is] not indicated for [once weekly] dosing." Defendant

directed its sales staff to state to providers: "We have data available on [once weekly] dosing with Procrit for cancer patients, as well as pharmacokinetic data comparing [once weekly] dosing very favorably with [three-times-weekly] dosing. This information is available from our Clinical Affairs department. Let me fill out a request form for you to sign". Relator McClellan was directly provided with these training materials by Defendant.

196. Defendant's Clinical Affairs Office maintained information regarding the safety and efficacy of once weekly dosing of Procrit.

197. Defendant prepared "medical information request forms," which are printed forms provided by Defendant's sales personnel to physicians to enable them to request medical information regarding Procrit from the Clinical Affairs Office.

198. Defendant instructed sales representatives to falsify these forms by stating that physicians had requested information about once-a-week dosing, when in fact the sales representative had affirmatively approached the physician to adopt this use. Both Relators were instructed by Defendant to falsity these forms.

f. The Inflated Dosing Scheme Fails to Produce Supportive Clinical Evidence for 40,000-Unit Dosing for Chemotherapy Patients

199. The Inflated Dosing Scheme was intended to gain widespread acceptance of 40,000-unit dosing for chemotherapy patients and produce clinical evidence that at least would appear to satisfy the Medicare Act's narrow authorization for reimbursement of off-label uses.

200. Defendant's efforts to gin up this evidence – including the Phase IV trial, the mini-trials, and the accompanying kickbacks to physicians – were a failure.

201. Defendant paid doctors to publish the results of the Phase IV trial.

202. In June 2001, the results of the Phase IV trial were published in the Journal of Clinical Oncology.

203. The authors were four doctors paid by Ortho Biotech, an Ortho Biotech employee, and another doctor.

204. The authors concluded that the clinical benefits of *once weekly* dosing were similar to those of three times weekly dosing.

205. While the article concluded that once-weekly administration had the same clinical effect as three-times-a-week administration, the authors did not analyze in isolation the effect of the increased dose.

206. The authors did not study or comment on the benefit of *increasing the dose of Procrit by a third*. Thus, they did ***not*** conclude that the increased dosing (and corresponding increased cost to Medicare) was supported by any clinical evidence.

207. A letter to the editor of the Journal of Clinical Oncology 7 months later pointed out that the study design and analysis contained in the June 2001 article were flawed.

208. The Ortho Biotech-funded study did not properly compare the populations receiving different doses, 42% of the patients studied were not reported on, the measure of clinical benefit used the wrong sample size, and in fact a third of the patients had experienced unchanged or deteriorated clinical results.

209. The authors of the letter to the editor concluded that "although the [Journal of Clinical Oncology article's] authors' conclusion may be true, it was not supported by the study's data."

210. A subsequent article pointed out the absence of clinical evidence supporting the 40,000-unit dose for chemotherapy patients. An October 2002 article in the journal Blood states: "Good evidence from clinical trials supports the use of [Procrit] … thrice weekly (150 U/kg) …. Less strong evidence supports an alternative weekly (40,000 U/wk) dosing regimen, *based on common clinical practice.*"

D. Defendant's Illegal Conduct Caused False Claims to be Submitted to Medicare

D(1). RELATOR DUXBURY'S ACCOUNTS:

211. From 1992 through 1998, Relator Duxbury sold over 13 million dollars worth of Procrit on behalf of the defendant. Relator Duxbury has specific knowledge that approximately 80 percent of the Procrit sales that he generated were submitted by his accounts as false or fraudulent claims for Medicare reimbursement. This knowledge is based on his personal knowledge, observation and direct communications with the accounts he developed and maintained during his employment and is supported by the documents contemporaneously generated by Relator Duxbury and defendant during the term of his employment.

The following accounts submitted false and fraudulent claims for Medicare reimbursement:

a. St. Joseph's Hospital in Tacoma, Washington purchased approximately 1.7 million to 2 million dollars a year of Procrit from Defendant during the period between approximately 1993 through 1997, which was submitted to and reimbursed by Medicare. The Procrit was administered for the treatment of patients with dialysis related anemia. During this period St. Joseph's submitted approximately 4,800 claims a month for Medicare reimbursement. St. Joseph's was provided so-called "unrestricted educational grants" by the Defendant totaling more than $30,000, which Defendant intended to be and was in fact not a "grant" but a "kickback" for St. Joseph's purchase of Procrit. These "kickbacks" were paid out of Defendant's "Regional Business Development" pool which was a "slush fund" to induce the purchase of Procrit by accounts. Defendant intentionally failed to report these payments to the US Government in order to keep secret the profit spread between the rate upon which Medicare

reimbursed medical providers like St. Joseph's for Procrit. St. Joseph's contract with Defendant provided St. Joseph's with an "off-invoice" rebate of 14% for the purchase of Procrit. Defendant intentionally failed to report these "off-invoice" rebates to the US Government in order to keep the Medicare reimbursement rate to Providers like St. Joseph's at artificially inflated levels so that the Providers could benefit from the profit-spread between the Provider's actual acquisiton cost and the Medicare reimbursement rate. Defendant actively marketed Procrit to St. Joseph's by representing to St. Joseph's that it could profit on the administering of Procrit by exploiting the profit spread so that St. Joseph's could "turn the dialysis unit into a profit center". As a result of Defendant's actions, Defendant knowingly caused the presentation by St. Joseph's of these false and fraudulent claims to the United States Government.

b. In 1998 Rainier Oncology of Puyallup, Washington was provided more than $20,000 of free commercially packaged Procrit from Defendant under the direction of John Woodhouse (Seattle District Manager) under the guise of running an unlawful mini-trial so that Rainier Oncology could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to Rainer Oncology in order to induce the provider to administer Procrit at the "off-label" dosage of 40,000 IU 1X/week. As a result, Defendant knowingly caused the presentation by Rainier Oncology of these false claims to the United States Government.

c. In 1993 Memorial Clinic in Olympia, Washington was provided approximately $15,000 of free commercially packaged Procrit from Defendant under the direction of Robert Nelson (Seattle District Manager) so that Memorial Clinic could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid

for the product. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to Memorial Clinic in order to induce the provider to purchase Procrit. Memorial Clinic was reimbursed by Medicare for the free commercially packaged Procrit. In 1993-98 Defendant induced Memorial Clinic to use the fraudulently obtained Medicare reimbursement to purchase additional Procrit by giving Memorial Clinic "off-invoice" rebates of 5-8% so that Memorial Clinic would receive Medicare reimbursement which was significantly more than what they actually paid for the product. As a result, Defendant knowingly caused the presentation by Memorial Clinic of these false claims to The United States Government.

d. In 1997-98 Western Washington Cancer Treatment Center in Olympia, Washington received more than $5,000 of free commercially packaged Procrit from Defendant under the direction of Robert Ashe so that Western Washington could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to Western Washington in order to induce the provider to purchase Procrit and to administer Procrit at the "off-label" once a week dosing regimen. Western Washington was reimbursed by Medicare for the free commercially packaged Procrit. As a result, Defendant knowingly caused the presentation by Western Washington of these false claims to The United States Government.

e. In 1993, the Mid Columbia Kidney Center in Kennewick, Washington under the direction of Dr. John Boykin, submitted claims to Medicare and was subsequently reimbursed by Medicare approximately $75,000 for the administering of Procrit to Mid Columbia Kidney Center's patients. Mid Columbia Kidney Center's agreement with Defendant provided Mid Columbia Kidney Center with an "off-invoice" rebate of 5-8% for the purchase of Procrit.

Defendant intentionally failed to report these "off-invoice" rebates in order to keep secret the "profit spread" between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread. Defendant actively marketed Procrit to Mid Columbia Kidney Center by representing that Mid Columbia Kidney Center could profit on the administering of Procrit by exploiting the "profit-spread" between the actual acquisition cost and the Medicare reimbursement rate. As a result of Defendant's actions, Defendant knowingly caused the presentation by Mid Columbia Kidney Center of these false and fraudulent claims to The United States Government.

f. In 1994-1996, St. Peter's Hospital in Olympia, WA, submitted claims to Medicare and was subsequently reimbursed by Medicare for approximately two million dollars of Procrit. St. Peter's contract with Defendant provided St. Peter's with an "off-invoice" rebate of 14% for the purchase of Procrit. Defendant intentionally failed to report to the US Government these "off-invoice" rebates in order to keep secret the "profit spread" between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread. Defendant actively marketed Procrit to St. Peter's by representing to St. Peter's that it could profit on the administering of Procrit by exploiting the "profit-spread". As a result of Defendant's actions, Defendant knowingly caused the presentation by St. Peter of these false and fraudulent claims to The United States Government.

g. In 1994-1997 Memorial Clinic Oncology Group in Washington purchased about approximately $750,000 of Procrit. Memorial Clinic Oncology Group's agreement with Defendant provided Memorial Clinic Oncology Group with an "off-invoice" rebate of 5% for the purchase of Procrit. Defendant intentionally failed to report to the US Government the "off-invoice" rebates in order to keep the "profit spread" between the actual acquisition cost to the

Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread. Defendant actively marketed Procrit to Memorial Clinic Oncology Group by representing to Memorial Clinic Oncology Group that it could profit on the administering of Procrit by exploiting the "profit-spread". In 1998 Memorial Clinic's Oncology Department participated in a sham "Phase IV" trial through which they received more than $32,000 of free drug that was intended to be submitted for Medicare reimbursement as if the Provider had paid for the drug. Approximately sixty percent of Procrit administered by Memorial Clinic Oncology Group was submitted and reimbursed by Medicare. As a result of Defendant's actions, Defendant knowingly caused the presentation of Memorial Clinic Oncology Group's false and fraudulent claims to the United States Government. Memorial Clinic Oncology Group also received approximately $50,000 in free commercially packaged Procrit from the Defendant, so that Memorial Clinic Oncology Group could submit the free Procrit to and be reimbursed by Medicare. Memorial Clinic Oncology Group was reimbursed by Medicare for the free commercially packaged Procrit. As a result, Defendant knowingly caused the presentation by Memorial Clinic Oncology Group of these false and fraudulent claims to The United States Government.

h. In 1996 Swedish Hospital in Seattle, Washington under the direction of Defendant's Regional Business Director, George Mooney and Manager Hilton Dempsey was given cash in the form of a so-called "unrestricted educational grant" in the amount of approximately $15,000. In actuality the payment was a monetary inducement or "kickback" to induce the provider to purchase Procrit. Provider subsequently purchased over $100,000 of Procrit of which approximately 50% was submitted for Medicare reimbursement. Defendant intentionally failed to report to the US Government the cash payment made to Swedish Hospital

in order secret the "profit-spread" between the actual acquisition cost to the Provider and the Medicare reimbursement rate. As a result, Defendant knowingly caused the presentation by Swedish Hospital of these false and fraudulent claims to The United States Government.

D(2). RELATOR McCLELLAN'S ACCOUNTS:

212. From 1992 through 2004, Relator McClellan sold over sixty-five million dollars worth of Procrit on behalf of the defendant. Relator McClellan has specific knowledge that approximately fifty percent of the Procrit sales that he generated were submitted by his accounts as false or fraudulent claims for Medicare reimbursement. This knowledge is based on his personal knowledge, observation and direct communications with the accounts he developed and maintained during his employment and is supported by the documents contemporaneously generated by Relator McClellan and defendant during the term of his employment.

The following accounts submitted false and fraudulent claims for Medicare reimbursement:

a. From 1997-2004, Defendant under the direction of Regional Manager Dwayne Marlowe provided the Northwestern Cancer Clinic AKA Arizona Hematology and Oncology located in Tucson, Arizona with more than $100,000 worth of free commercially packaged Procrit so that the provider could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. During this period Defendant used sham mini-trials and sham "Phase IV" trials as the guise through which it funneled the free drug to the Provider. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to provider in order to induce the provider to purchase Procrit and to administer Procrit at the "off-label" once a week dosing regimen. The provider was reimbursed by Medicare for the free commercially packaged Procrit. In 2001-02,

Providers' principal Dr. Katakkar was also given cash "kickbacks" in the form of so-called "speaker's fees", "preceptorships", and "unrestricted grants" totaling more than $5,000 in order to induce Provider to purchase more Procrit and administer Procrit at the "off-label" dosage regimen of 40,000 IU 1X/ week to cancer patients instead of the approved dosage of 10,000 IU 3X/week. In addition, Defendant from 1997-2004 provided Provider discounts and "off-invoice" rebates ranging from 5% to 30% for the purchase of Procrit. Defendant intentionally failed to report to the US Government the "off-invoice" rebates and the "kickbacks" in order to keep the AWP rate upon which Medicare reimbursed medical providers for Procrit at artificially inflated levels. Defendant actively marketed Procrit to provider by representing to provider that it could profit on the administering of Procrit by exploiting the artificially inflated AWP in conjunction with the rebate and "kickbacks" which Defendant gave provider so that provider would pay a price significantly less than that which Medicare would reimburse them at. Approximately 40% of the Procrit administered by Provider during this period, more than $3 million, was submitted and reimbursed by Medicare. As a result of these actions, Defendant knowingly caused the presentation by Provider of these false and fraudulent claims to The United States Government.

b. From 1996-2004, Defendant under the direction of District Manager Dwayne Marlowe provided the Arizona Cancer Center located in Tucson, Arizona with more than $80,000 worth of free commercially packaged Procrit so that the provider could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to provider in order to induce the provider to purchase Procrit. The Provider was reimbursed by Medicare for the free commercially packaged Procrit. In 2001

in order to assist Provider who was having trouble getting Medicare reimbursement, Defendant induced the Provider's Director Dr. Von Hoff to write a letter on Provider's stationary that represented that once a week dosing at the 40,000 IU dosage for cancer patients was the "community standard" and that Provider should be reimbursed. As a result of Von Hoff's letter provider was reimbursed more than $1 million for 1998-2003 for administering Procrit at the "off-label" once a week dosing regimen. In 2004, Defendant gave Provider cash "kickbacks" in the form of so-called "unrestricted grants" totaling more than $50,000 in order to induce provider to purchase more Procrit and administer Procrit at the "off-label" dosage regimen of 40,000 IU 1X/ week to cancer patients instead of the approved dosage of 10,000 IU 3X/week. Approximately 50% of the Procrit administered by provider during the period 1998-2004, more than $1 million, was submitted and reimbursed by Medicare. As a result of these actions, Defendant knowingly caused the presentation by Provider of these false and fraudulent claims to The United States Government.

c. In 1996-04, Defendant under the direction of District Manager Dwayne Marlowe provided the Nevada Cancer Center located in Las Vegas, Nevada with more than $350,000 worth of free commercially packaged Procrit so that the provider could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to provider in order to induce the provider to purchase Procrit. The Provider was reimbursed by Medicare for the free commercially packaged Procrit. In 1998-99, Defendant gave Provider cash "kickbacks" of more than $175,000 in the form of so-called "unrestricted grants", "stipends", "scholarships", "preceptorships", and "free" "advertising" in order to induce Provider to purchase more Procrit and administer Procrit at the "off-label"

dosage regimen of 40,000 IU 1X/ week to cancer patients instead of the approved dosage of 10,000 IU 3X/week. In 1998-99 Defendant used sham mini-trials and "Phase IV" trials to funnel the free product to the Provider. In addition, Defendant from 1994-2004 provided provider discounts and "off-invoice" rebates ranging from 5% to 30% for the purchase of Procrit. Defendant intentionally failed to report to the US Government the "off-invoice" rebates and the "kickbacks" in order to keep the AWP rate upon which Medicare reimbursed medical providers for Procrit at artificially inflated levels. Defendant actively marketed Procrit to provider by representing to provider that it could profit on the administering of Procrit by exploiting the artificially inflated AWP in conjunction with the rebate and "kickbacks" which Defendant gave provider so that provider would pay a price significantly less than that which Medicare would reimburse them at. Approximately 50% of the Procrit administered by provider during the period 1998-2004, more than $5 million, was submitted and reimbursed by Medicare. As a result of these actions, Defendant knowingly caused the presentation by Provider of these false and fraudulent claims to The United States Government.

d. In 1998-2004, Defendant under the direction of District Manager Dwayne Marlowe provided the Oncology Hematology Clinic located in Yuma, Arizona with more than $45,000 worth of free commercially packaged Procrit so that the provider could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. During this period Defendant used sham mini-trials and sham "Phase IV" trials to funnel the free drug to the Provider. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to provider in order to induce the provider to purchase Procrit. The Provider was reimbursed by Medicare for the free commercially packaged Procrit. In addition, Defendant from 1998-2004 provided Provider

discounts and "off-invoice" rebates ranging from 5% to 30% for the purchase of Procrit. Defendant intentionally failed to report to the US Government the "off-invoice" rebates and the "kickbacks" in order to keep the AWP rate upon which Medicare reimbursed medical providers for Procrit at artificially inflated levels. Defendant actively marketed Procrit to provider by representing to provider that it could profit on the administering of Procrit by exploiting the artificially inflated AWP in conjunction with the rebate and "kickbacks" which Defendant gave provider so that provider would pay a price significantly less than that which Medicare would reimburse them at. Approximately 80% of the Procrit administered by Provider during the period 1998-2004, more than $2.5 million, was submitted and reimbursed by Medicare. As a result of these actions, Defendant knowingly caused the presentation by Provider of these false and fraudulent claims to The United States Government.

e. In 1998-2004, Defendant under the direction of District Manager Dwayne Marlowe provided US Oncology's (subsequently changed to American Oncology Resources (AOR)) five affiliated offices located in Tucson and Green Valley, Arizona with more than $300,000 worth of free commercially packaged Procrit so that the provider could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. During this period, Defendant used sham mini-trials and sham "Phase IV" trials to funnel the free drug to the Provider. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to provider in order to induce the provider to purchase Procrit. The Provider was reimbursed by Medicare for the free commercially packaged Procrit. In 2002-03, Defendant gave provider cash "kickbacks" of approximately $75,000 in the form of so-called "unrestricted grants" in order to induce Provider to purchase more Procrit and administer Procrit at the "off-label" dosage regimen of 40,000 IU

1X/ week to cancer patients instead of the approved dosage of 10,000 IU 3X/week. In addition, Defendant from 1998-2004 provided Provider discounts and "off-invoice" rebates ranging from 5% to 30% for the purchase of Procrit. Defendant intentionally failed to report to the US Government the "off-invoice" rebates and the "kickbacks" in order to keep the AWP rate upon which Medicare reimbursed medical providers for Procrit at artificially inflated levels. Defendant actively marketed Procrit to provider by representing to provider that it could profit on the administering of Procrit by exploiting the artificially inflated AWP in conjunction with the rebate and "kickbacks" which Defendant gave provider so that provider would pay a price significantly less than that which Medicare would reimburse them at. Approximately 50% of the Procrit administered by Provider during the period 1998-2004, more than $8 million, was submitted and reimbursed by Medicare. As a result of these actions, Defendant knowingly caused the presentation by Provider of these false and fraudulent claims to The United States Government.

f. During the term of Relator McClellan's employment with Defendant, Relator McClellan developed more than 200 Providers as accounts purchasing Procrit. Relator McClellan has personal knowledge that each and every one of the accounts he developed submitted false and fraudulent claims for Medicare reimbursement for Procrit. The following is a partial listing of the accounts developed and/or maintained by Relator McClellan during the term of his employment. Each and every one of the following accounts purchased Procrit and submitted false and fraudulent claims for Medicare reimbursement. Every one of these accounts, as documented by contemporaneously generated records in the possession of Relator McClellan, submitted claims for Medicare reimbursement for Procrit that was provided to them as free product:

1. Southeast Arizona Medicare Center at Oak Avenue and Hospital Road, Douglas, Arizona;

2. Talbert Madera Vista Health Center at 275 W. Continental in Green Valley, Arizona;

3. Thomas Davis Medical Center at 1141 South Lancanda in Green Valley, Arizona;

4. Carondelet Holy Cross Hospital at 1171 West Target Range in Nogales, Arizona;

5. Southern Arizona Hospital at 1921 West Hospital Drive in Tucson, Arizona;

6. Talbert Health Services at 850 North Kolb in Tucson, Arizona;

7. Coram Alternate Service at 4565 South Palo Verde Suite in Tucson, Arizona;

8. Doctor Arthur Goldberg M.D. at 4550 East Grant Road in Tucson, Arizona;

9. Tucson Medical Center at 5301 East Grant Road in Tucson, Arizona;

10. American Transitional Hospital at 3838 North Campbell in Tucson, Arizona;

11. Tucson General Hospital at 3838 North Campbell Avenue in Tucson, Arizona;

12. South Arizona Home Therapeutic at 3509 N. Campbell Avenue in Tucson, Arizona;

13. University of Arizona Medical Center Hospital at 1501 North Campbell in Tucson, Arizona;

14. Rainbow Medical at 5 Cactus Garden Drive Boulevard in Henderson, Nevada

15. THC Las Vegas at 5100 West Sahara Avenue Las Vegas, Nevada;

16. Nephrology Associates at 500 South Rancho Drive Street in Las Vegas, Nevada;

17. Valley Hospital Medical Center at 620 Shadow Lane in Las Vegas, Nevada;

18. Doctor Joseph Quagliana at 3380 South Eastern Avenue in Las Vegas, Nevada;

19. Sunrise Hospital at 3186 Maryland Parkway Box in Las Vegas, Nevada;

20. HEM/ONC Physicians at 2625 North Craycroft Road Street in Tucson, Arizona;

21. Doctor Morris H. Fine at 5225 East Knight in Tucson, Arizona;

22. Doctor Gerald Hagin at 3984 North Campbell in Tucson, Arizona;

23. Associates in HEMA-Oncology at 1773 West Saint Mary's Road in Tucson, Arizona;

24. Cancer Care Consultants at 2020 West Palomino Lane Number 1 in Las Vegas, Nevada;

25. Las Vegas Cancer Center at 600 Shadow Lane Number B in Las Vegas, Nevada;

26. Cancer & HEMA Center of Nevada at 3380 South Eastern Avenue in Las Vegas, Nevada;

27. The Nevada Cancer Center at 1950 East Desert Inn Road in South Las Vegas, Nevada;

28. Southwest Cancer Clinic at 3920 South Eastern Avenue Suite in Las Vegas, Nevada;

29. Yuma Regional Medical Center at 2400 Avenue A in Yuma, Arizona;

30. Havasu Samaritan Hospital at 101 Civic Center in Lake Havasu, Arizona;

31. Oncology Clinic at 1210 West 24th Street Number 1 in Yuma, Arizona;

32. Giangreco Medical Hospital at 1320 West 24th Street in Yuma Arizona;

33. Doctor Suresh Katakkar at 75 West Calle De Los in Green Valley, Arizona;

34. Doctor Gerald of Oncology Clinic at 3984 North Campbell in Tucson, Arizona;

35. Oncology Clinic at 1773 West Saint Marys in Tucson, Arizona;

36. Nevada Cancer Clinic at 1225 East Hancock Road in Rivera, Arizona;

37. Las Vegas Cancer Oncology Clinic at 600 Shadow Lane Number B in Las Vegas, Nevada;

38. Cancer and Blood Oncology Clinic at 801 South Rancho in Las Vegas, Nevada;

39. Las Vegas Cancer Oncology Clinic at 2010 Goldring Avenue in Las Vegas, Nevada;

40. Nevada Cancer Oncology Clinic at 3380 South Eastern Avenue in Las Vegas, Nevada;

41. Southwest Cancer Oncology Clinic at 3920 South Eastern Avenue in Las Vegas, Nevada;

42. Dr. Heather Allen at 3920 South Eastern in Las Vegas, Nevada;

43. Dr. Richard Rosenberg at 1860 East Florence Boulevard in Casa Grande, Arizona;

44. Dr. Arnold Wax at 3920 South Eastern Avenue in Las Vegas, Nevada;

45. Dr. Ann Wierman at 4794 Monterrey Avenue in Las Vegas, Nevada;

46. Dr. Paul Michael at 3920 South Eastern Suite 20 in Las Vegas, Nevada;

47. Dr. Luis Fayad at 6901 East Lake Mead Boulevard in Las Vegas, Nevada;

48. Dr. Nikolaos Touroutogl at 220 East Flamingo Road Apartment 306 in Las Vegas, Nevada;

49. Dr. Russell Gollard at 1950 East Desert Road in Las Vegas, Nevada;

50. Dr. Edgardo Faylona at 1950 East Desert Road in Las Vegas, Nevada;

51. Dr. Guillermo Gonzalez at 2625 North Craycroft Road in Tucson, Arizona;

52. Dr. John Sullivan at 2095 West 24th Street C in Yuma, Arizona.

213. All of the above providers, knowingly submitted false claims to the U.S. government, by intentionally submitting claims for reimbursement to Medicare, on HCFA 1500s or their electronic equivalent, for Procrit based on an inflated AWP and submitted claims for reimbursement of Procrit, on HCFA 1500s or their eletronic equivalent that it had received at no charge from Defendant.

214. All of the above Providers, actually submitted false and fraudulent HCFA 1500s,

and actually received reimbursement from the U.S. government for the false and fraudulent claims, during the relevant timeframe alleged herein.

215. At all relevant times herein, Defendant was aware of , participated in, and caused the above individuals and entities to submit false claims for reimbursement to Medicare.

216. During all relevant times herein, in furtherance of its scheme to defraud the U.S. government, Defendant intentionally falsified and inflated the AWP, provided free product to the above-named individuals and entities, and engaged in other illegal activities designed to ensure that the above individuals and entities would "profit" from the submission of false claims to the U.S. government.

217. All of the above Providers were taught by Defendant, through Relator McClellan as directed by Defendant's management, how to make money and increase profits by submitting false claims to Medicare for reimbursement of Procrit.

VII. COMMON AND WIDESPREAD SCHEME

218. Defendant's actions, as alleged herein that caused the submission of false and fraudulent claims to the U.S. government for reimbursement of Procrit were widespread, common, consistent, and pervasive throughout the United States.

219. At all relevant times, Defendant submitted a false and inflated AWP to pharmaceutical compendia for reimbursement nationwide.

220. At all relevant times, Defendant intentionally and knowingly created a spread between the published AWP and the actual acquisition cost for Procrit.

221. At all relevant times herein, the published AWP was never the same as the Average Sales Price ("ASP") to providers.

222. At all relevant times herein, Defendant directed, instigated, and caused Providers nationwide to submit false and fraudulent claims to Medicare for reimbursement of Procrit that Defendant had given to Providers at no charge.

223. At all relevant times herein, Defendant directed, instigated, and caused Providers nationwide to submit false and fraudulent claims to Medicare for reimbursement of Procrit based on a false and inflated AWP.

224. At all relevant times herein, Defendant used standard, common, and/or substantially similar training materials, for sales representatives nationwide, that taught Defendant's sales representatives how to, among other things: market the spread between AWP and actual acquisition cost; cause Providers to submit claims for reimbursement based on the false and inflated AWP; cause Providers to prescribe and submit claims to Medicare the 40,000 unit dose of Procrit for an unapproved "off-label" use; and cause Providers to submit claims for reimbursement to Medicare for Procrit that Defendant had given to Providers at no charge.

225. Both Relators have first hand knowledge that the scheme to defraud the U.S. government by causing the submission of false and fraudulent claims was implemented by Defendants throughout all regions of the United States in a systemic and common fashion. Relators derived their first hand, direct and independent knowledge of the nationwide scheme through the course of their employment with Defendant, including but not limited to the following: training sessions, performance reviews, standard documentation, e-mails, conversations with Defendant Management employees, common written materials, conversations with fellow sales representatives from other regions, attendance at training seminars, and other written and oral communications from Defendant.

VIII. COUNTS

COUNT I

KICKBACKS IN VIOLATION OF THE FALSE CLAIMS ACT (31 U.S.C. §§ 3729(a)(1), (a)(2), and 3732(b))

226. Relators reallege and incorporate by reference the preceding allegations.

227. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-32, as amended.

228. Defendant gave kickbacks to providers and hospitals to induce them to prescribe Procrit. These kickbacks included free Procrit, off-invoice discounts and cash in the form of rebates, consulting fees, educational grants, payments to participate in studies or trials, and advisory board honoraria.

229. Defendant's kickbacks caused providers and hospitals to submit false claims for payment to Medicare for Procrit. In addition, by giving off-invoice discounts to Providers and hospitals that resulted in actual invoices to be false, Defendant used a false record or statement to get a false claim paid by the Government.

230. Defendant caused Providers to submit/use the HCFA Form 1500, and other such forms as a false statement/record to get a false claim paid.

231. Defendant published a false AWP in the pharmaceutical compendia, thus using a false record/statement to get a false claim paid by the government.

232. Relator cannot identify at this time all of the false claims caused by Defendant. The false claims were submitted by Providers with most of whom Relator has had no dealings, and the records of the false claims are not within Relator's control. Specification of the vast number of false claims would be burdensome to the Court and the parties. The time period of the false claims was from December 1992 to the present. Such claims were made across the United States.

233. In submitting these claims for payment, providers and hospitals expressly or impliedly certified that they complied with the anti-kickback statute.

234. This certification included the Certification Statement in the Medicare Health Care Provider/Supplier Application, OMB Approval No. 0938-0685. This Certification Statement reads in part: "I understand that payment of a claim by Medicare or other federal health care programs is conditioned on the claim and the underlying transaction complying with such laws, regulations and program instructions (including the anti-kickback statute and the Stark law) …."

235. In addition, hospital cost reports (Form HCFA-2552) provide:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified by this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines, and/or imprisonment may result.

236. The form also requires the following certification by an officer or administrator of the health care provider:

> I hereby certify that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by . . . (Provider Name(s) and Number(s)) for the cost reporting period beginning … and ending … and that to the best of my knowledge and belief it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.

237. In addition, on hospitals' cost reports, they certify that the reports are "true, correct, and complete" and "prepared … in accordance with applicable instructions, except as noted."

238. Because Defendant had provided the providers and hospitals kickbacks to induce them to use Procrit, all these certifications were false.

239. Defendant's kickbacks were a substantial factor causing the submission of the false claims for payment for Procrit. Defendant used kickbacks to induce providers and hospitals to use Procrit to treat dialysis patients and to submit reimbursement claims for such prescriptions. In the absence of these kickbacks, the providers and hospitals would not have purchased Procrit. In addition, Defendant used kickbacks to convince providers and hospitals to prescribe 40,000 units of Procrit 1X/per week to oncology patients and to submit corresponding reimbursement claims, and in the absence of the kickbacks providers and hospitals would have prescribed 30,000 units in 10,000 IU 3X/week of Procrit or the Providers would have used another alternative product or therapy.

240. Providers' and hospitals' submission of false claims for payment to Medicare, were a foreseeable result of Defendant's kickbacks. Further, not only were they foreseeable but they were the intended consequence of the kickbacks.

241. Defendant's kickbacks would have been material to the Government's decision to pay the reimbursement claims for Procrit. Compliance with the anti-kickback statute is central to the reimbursement plan of Medicare. If the Government had known that the reimbursement claims were induced by Defendant's kickbacks, it would not have paid them.

242. Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the United States government false and fraudulent claims, records, and statements in order to obtain reimbursement for health care services provided under Medicare.

243. Providers' false and fraudulent claims were submitted for reimbursement based on AWP to Medicare on a HCFA 1500.

244. These claims for payment were false because (i) they were not for a use eligible for reimbursement under the Medicare Act, (ii) they did not disclose the illegal scheme that

induced the claims for reimbursement at inflated doses, (iii) were seeking reimbursement based on a false and inflated AWP; (iv) were for reimbursement of Procrit that Defendant gave to at no cost, and/or (iv) they were induced by illegal kickbacks and other monetary incentives.

245. Through the acts described above and otherwise, Defendant and its agents and employees knowingly made, used, and/or caused to be made or used false records and statements in order to get such false and fraudulent claims paid and approved by the United States government.

246. The United States and its fiscal intermediaries/carriers, unaware of the falsity of the records, statements, and claims made or submitted by Defendant and its agents and employees paid and continue to pay Defendant for claims that would not be paid if the truth were known.

247. By reason of the Defendant's false records, statements, claims, and omissions, the United States has been damaged in the amount of many millions of dollars in Medicare reimbursement costs.

COUNT II

SCHEME TO INCREASE THE AWP SPREAD IN VIOLATION OF THE FALSE CLAIMS ACT (31 U.S.C. §§ 3729(a)(1), (a)(2), and 3732(b))

248. Relator realleges and incorporates by reference the preceding allegations.

249. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-32, as amended.

250. By publishing inflated AWPs for Procrit that did not (a) represent a real average of wholesale prices and (b) failed to account for free drug, off-invoice discounts, educational grants, and rebates, Defendant knowingly caused providers and hospitals to submit false claims for payment to Medicare for Procrit. In addition, by falsely inflating the AWP and giving off-invoice discounts to Providers and hospitals that resulted in actual invoices to be false, Defendant used a false record or statement to get a false claim paid by the Government.

251. Relator cannot identify at this time all of the false claims caused by Defendant. The false claims were submitted by Providers and hospitals with most of whom Relator has had no dealings, and the records of the false claims are not within Relator's control. Specification of the vast number of false claims would be burdensome to the Court and the parties. The time period of the false claims, however, was from December 1992 to the present. Such claims were made across the United States.

252. In submitting these claims for payment, Providers and hospitals expressly certified that they were entitled to reimbursement at the rate tied to the published AWP. Because Defendant had falsely inflated the published AWP through the means identified above, this certification was false.

253. In submitting these claims for payment, Providers and hospitals also expressly or impliedly certified that they complied with the anti-kickback statute.

254. This certification included the Certification Statement in the Medicare Health Care Provider/Supplier Application, OMB Approval No. 0938-0685. This Certification Statement reads in part: "I understand that payment of a claim by Medicare or other federal health care programs is conditioned on the claim and the underlying transaction complying with such laws, regulations and program instructions (including the anti-kickback statute and the Stark law) …."

255. In addition, hospital cost reports (Form HCFA-2552) provide:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified by this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines, and/or imprisonment may result.

256. The form also requires the following certification by an officer or administrator of the health care provider:

> I hereby certify that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by . . . (Provider Name(s) and Number(s)) for the cost reporting period beginning … and ending … and that to the best of my knowledge and belief it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.

257. In addition, on hospitals' cost reports, they certify that the reports are "true, correct, and complete" and "prepared … in accordance with applicable instructions, except as noted."

258. Because Defendant had provided the providers and hospitals kickbacks that increased the spread between the effective cost and the AWP for Procrit to induce them to use the drug, all these certifications were false.

259. Defendant's falsely inflated AWP caused the claims for payment for Procrit to be false, because the claims certified entitlement to a reimbursement amount that was incorrect in direct correlation to the amount of the falsely inflated AWP for Procrit. Defendant's falsely inflated AWP would have been material to the Government's decision to pay the claims. If the Government had known that the reimbursement claims were inflated by the amount of Defendant's falsely inflated AWP, it would not have paid the inflated amount of the claims.

260. In addition, Defendant's kickbacks to increase the spread between the effective cost and the AWP for Procrit were a substantial factor causing the submission of the false claims for payment for Procrit. Defendant used the increased spread as a marketing tool to promote the lower cost of Procrit over Epogen and Aranesp, and in the absence of the kickbacks providers and hospitals would not have prescribed Procrit.

261. Providers' and hospitals' submission of false claims for payment to Medicare were a foreseeable result of Defendant's falsely inflated AWP for Procrit and its kickbacks.

Further, not only were they foreseeable but they were the intended consequence of the false AWPs and kickbacks.

262. Defendant's kickbacks would have been material to the Government's decision to pay the reimbursement claims for Procrit. Compliance with the anti-kickback statute is central to the reimbursement plan of Medicare. If the Government had known that the reimbursement claims were induced by Defendant's kickbacks, it would not have paid them.

263. Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the United States government false and fraudulent claims, records, and statements in order to obtain reimbursement for health care services provided under Medicare.

264. Through the acts described above and otherwise, Defendant and its agents and employees knowingly made, used, and/or caused to be made or used false records and statements in order to get such false and fraudulent claims paid and approved by the United States government.

265. Providers false and fraudulent claims were uniformly submitted for reimbursement based on AWP to Medicare on a HCFA 1500.

266. These claims for payment were false because: (i) they were not for a use eligible for reimbursement under the Medicare Act; (ii) they did not disclose the illegal scheme that induced the claims for reimbursement at inflated doses; (iii) were seeking reimbursement based on a false and inflated AWP; (iv) were for reimbursement of Procrit that Defendant gave to at no cost; and/or (iv) they were induced by illegal kickbacks and other monetary incentives.

267. The United States, its fiscal intermediaries/carriers were unaware of the falsity of the records, statements, and claims made or submitted by Defendant and its agents and employees and paid Defendant for claims that would not be paid if the truth were known.

268. By reason of the Defendant's false records, statements, claims, and omissions, the United States has been damaged in the amount of many millions of dollars in Medicare reimbursement.

COUNT III

INFLATED DOSING SCHEME IN VIOLATION OF THE FALSE CLAIMS ACT (31 U.S.C. §§ 3729(a)(1) and 3732(b))

269. Relators reallege and incorporate by reference the preceding allegations.

270. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-32, as amended.

271. By (i) affirmatively promoting the off-label dosing of Procrit, in violation of the Food, Drug and Cosmetic Act; (ii) promoting Defendant's FDA-approved surgery indication for Procrit that was for a higher dose than the FDA-approved cancer indication to oncologists to induce them to prescribe the higher dose for cancer patients; (iii) paying kickbacks to physicians and hospitals in the form of cash and free drugs to induce use of Procrit; (iv) using sham drug "trials" to falsify eligibility under a special provision in the Medicare Act addressing reimbursement for off-label uses of cancer drugs; and (iv) changing the vial size in which free Procrit was distributed to inhibit administration at the approved dose, Defendant knowingly caused providers and hospitals to submit false claims for payment to Medicare for Procrit.

272. The administration of Procrit at 40,000 units 1X per week to oncology patients was not eligible for reimbursement by Medicare. Until June 2004, this dosage was not approved by the FDA, and the June 2004 FDA approval was procured by the fraudulent scheme outlined above. Further, this dosage was not supported by any of the specified compendia set out in the Medicare Act, and it was not warranted by supportive clinical evidence. No clinical evidence supported that administering Procrit to chemotherapy patients at 40,000 IU 1X/week rather than 10,000 units 3X/week provided any clinical benefit.

273. Relator cannot identify at this time all of the false claims caused by Defendant. The false claims were submitted by providers with most of whom Relator has had no dealings, and the records of the false claims are not within Relator's control. Specification of the vast number of false claims would be burdensome to the Court and the parties. The time period of the false claims was from in or about January 1998 to the present. Such claims were made across the United States.

274. Providers' false and fraudulent claims were uniformly submitted for reimbursement based on AWP to Medicare on a HCFA 1500.

275. These claims for payment were false because: (i) they were not for a use eligible for reimbursement under the Medicare Act; (ii) they did not disclose the illegal scheme that induced the claims for reimbursement at inflated doses; (iii) were seeking reimbursement based on a false and inflated AWP; (iv) were for reimbursement of Procrit that Defendant gave to at no cost; and/or (iv) they were induced by illegal kickbacks and other monetary incentives.

276. In submitting these claims for payment Providers and hospitals also expressly or impliedly certified that they complied with the anti-kickback statute.

277. This certification included the Certification Statement in the Medicare Health Care Provider/Supplier Application, OMB Approval No. 0938-0685. This Certification Statement reads in part: "I understand that payment of a claim by Medicare or other federal health care programs is conditioned on the claim and the underlying transaction complying with such laws, regulations and program instructions (including the anti-kickback statute and the Stark law) …."

278. In addition, hospital cost reports (Form HCFA-2552) provide:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified by this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines, and/or imprisonment may result.

279. The form also requires the following certification by an officer or administrator of the health care provider:

> I hereby certify that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by . . . (Provider Name(s) and Number(s)) for the cost reporting period beginning … and ending … and that to the best of my knowledge and belief it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.

280. In addition, on hospitals' cost reports, they certify that the reports are "true, correct, and complete" and "prepared … in accordance with applicable instructions, except as noted."

281. Because Defendant gave providers and hospitals kickbacks to induce them to use Procrit for chemotherapy patients at a non-reimbursable dose, all these certifications were false.

282. Defendant's inflated dosing scheme was a substantial factor causing the submission of the false claims for payment for Procrit. Defendant's scheme caused providers and hospitals to administer Procrit to chemotherapy patients at 40,000 units 1X/weekl, and in the absence of Defendant's scheme they would have administered Procrit at 10,000 IU 3X/week.

283. Providers' and hospitals' submission of false claims for payment to Medicare was a foreseeable result of Defendant's scheme. Further, not only were they foreseeable but they were the intended consequence of the scheme.

284. Defendant's Inflated Dosing Scheme would have been material to the Government's decision to pay the reimbursement claims for Procrit. If the Government had known that reimbursement claims at 40,000 units 1X/week was induced by Defendant's scheme, it would not have paid the inflated dosage.

285. Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the United States government false and fraudulent claims, records, and statements in order to obtain reimbursement for health care services provided under Medicare.

286. The United States, its fiscal intermediaries/carriers were unaware of the falsity of the records, statements, and claims made or submitted by Defendant and its agents and employees paid Defendant for claims that would not be paid if the truth were known.

287. By reason of the Defendant's false records, statements, claims, and omissions, the United States has been damaged in the amount of many millions of dollars in Medicare reimbursement funds.

IX. PRAYER FOR RELIEF

WHEREFORE, Relators pray for judgment against Defendant as follows:

A. That Defendant ceases and desists from violating 31 U.S.C. § 3729 *et seq*.;

B. That the Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained as a result of Defendant's actions, as well as a civil penalty against Defendant of $11,000 for each violation of 31 U.S.C. § 3729;

C. That Relators be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;

D. That Relators be awarded all costs and expenses of this action, including attorneys' fees; and

E. That the United States and Relators receive all such other relief as the Court deems just and proper.

X. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relators hereby demand a trial by jury.

Dated: October 14, 2006

Respectfully submitted by his attorneys,

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