IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA, ex rel. IVEY WOODARD,	)	
Plaintiffs/Relators,	)	Civil Case No. 1:05CV0227
v.	)	Honorable Marcia A. Crone
FRESENIUS MEDICAL CARE, AG, DAVITA, INC., and JOHN DOES 1-20,	)	
Defendants.	)	

SECOND AMENDED COMPLAINT

Relator, Ivey Woodard, through his attorneys and on behalf of the United States of America, for his Complaint against Defendants, Fresenius Medical Care, AG ("FMC"), DaVita, Inc. ("DaVita"), and John Does 1-20, alleges as follows:

I. NATURE OF THE CASE

1. This action is brought pursuant to the False Claims Act, 31 US.C. §§ 3729-3733, *et seq.*, and the Fraud and Abuse Statute, 42 U.S.C. §§ 1320, *et. seq.* The action arises from the Defendants' fraudulent schemes, in connection with the drugs Epogen, Ferrlecit, and Zemplar. Defendants' receipt of and failure to disclose discounts, rebates, and remuneration, and/or as a result of Defendants' false certifications with respect thereto. The proximate result of Defendants' conduct is the unjust and illegal enrichment of Defendants and the waste of Federal dollars.

2. Relator seeks through this action to recover damages and civil penalties arising from the false and improper charges contained in claims for payment which Defendants and those with

which they were acting in concert caused to be submitted to the government under the federal Medicare program.

3. The False Claims Act provides, inter alia, that any person who knowingly submits a false or fraudulent claim to the Federal government for payment or approval is liable to the Government for a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each claim, plus three times the amount of the false claim. 31 U.S.C. § 3729(a). The Act also permits assessment of the civil penalty even without proof of specific damages. Rex Trailer Co. v. U.S., 350 U.S. 148 (1956).

4. Under the Act, a person ('relator") with knowledge of a false or fraudulent claims against the Government may bring an action against the false claimant on behalf of the Government and himself. Such an action must be filed under seal, without service on the defendant, for sixty days. The seal period is designed to permit the Government to (1) pursue its own investigation of the matter without the Defendant's knowledge of the suit and (2) determine whether to join and take over prosecution of the suit. At the time the suit is filed, the relator must provide a written statement of all material evidence in his possession to the U.S. Attorney General. 31 U.S.C. § 3730.

5. The Fraud and Abuse Statutes, in relevant part, makes it illegal to knowingly and willfully solicit or receive any type of remuneration, including a rebate, in return for purchasing, leasing, ordering, arranging for, or recommending any good, facility, service, or item for which Medicare may pay in whole or in part. 42 U.S.C. §§ 1320-7b(b)(1) & 7a(a)(7). Section 1320a-7b provides for criminal penalties, while § 1320a-7a provides for civil monetary penalties. Most rebates and discounts on Medicare - reimbursed items violate the Fraud and Abuse Statutes. However, if

the rebate or discount is properly reported and passed on to Medicare, it may fall within a "safe harbor" of protected activity. 42 U.S.C. § 1320a-7b(b)(3)(A).

6. Compliance with all applicable laws and regulations is a condition of coverage for reimbursement of dialysis. 42 C.F.R. § 405.2135.

7. Each year, Fresenius Medical Care, AG, DaVita, Inc., and John Does 1-20, submit a cost report known as FCFA-265 to the Health Care Finance Administration. The cost report, FCFA-265, is required from all dialysis facilities that bill to Medicare and this report includes a certification of their adherence to federal laws and regulations. Provision of the cost data, and the certification in FCFA-265, is a condition of coverage. 42 C.F.R. §405.2138.

II. THE PARTIES

8. Relator, Ivey Woodard, is a resident of Signal Mountain, Tennessee. Woodard was employed by Defendant, Amgen, in various capacities between 1990 and September, 2001, and in that capacity, he regularly visited Defendants' facilities and he regularly interacted with their agents and employees. Amgen, is a Delaware corporation with its headquarters and principal place of business in Thousand Oaks, California. Amgen is a biotechnology company that develops, manufactures and markets human therapeutics based on advances in cellular and molecular biology. Epogen, Amgen's "blockbuster" product, has a sales volume in excess of $2 billion per year. From 1990 through June 1996, Woodard was a Professional Sales Representative at Amgen's Houston, Texas facility. From June 1996 through December 1999, Woodard was employed first as a Government Payor Relations Representative, and then as National Accounts Manager, with Amgen. From January 1, 2000 through September 2001, Woodard was a Professional Sales Representative employed at Amgen's Chattanooga, Tennessee facility. As a result of Woodard's employment by

Amgen, Woodard became aware of the fraudulent acts and practices of Defendants as set forth herein and as more particularly described in the Disclosure Statement.

9. Woodard was terminated from his employment with Amgen based, in substantial part, upon his unwillingness to carry out certain of the unlawful acts and schemes alleged herein.

10. Defendant, FMC, is a German stock corporation with its headquarters in Bad Hamburg, Germany, and its American headquarters in Boston, Massachusetts. FMC is engaged primarily in (a) providing kidney dialysis services, clinical laboratory testing and renal diagnosis services, and (b) manufacturing and distributing products and equipment for dialysis treatment. Among, its services, FMC operates a network of over 1,400 dialysis clinics in North America, Europe, Latin America and Asia/Pacific. FMC is one of the world's largest providers of dialysis products.

11. Defendant, DaVita, is a Delaware corporation with its headquarters in Torrance, California. DaVita is one of the largest providers of dialysis services in the United States. DaVita serves nearly 52,000 patients in 35 states and the District of Columbia from over 611 outpatient dialysis centers. DaVita also provides acute inpatient dialysis services in over 350 hospitals across the United States.

12. John Does 1-20 are defendants, the true names and capacities of which (whether individual, corporate, associates, or otherwise) are unknown to Relator at this time. Relator is informed and believes and thereon alleges that each of the defendants fictitiously named herein as Doe is legally responsible in some actionable manner for the events and happenings described herein. Relator will seek leave of Court to amend this Complaint to state the true name(s) and capacities of such factitiously named defendants when the same have been ascertained.

13. The Defendants' fraudulent scheme included the following elements:

a. Overutilization of Epogen without regard to medical necessity or patient need and false certifications related thereto.

b. False claims related to using Epogen in an off-label administration, and not consistent with good medical practice, and false certifications related thereto.

c. Receipt of prohibited remuneration, and false certifications related thereto.

d. False claims related to switching patients to the more expensive drug, Zemplar without regard to medical necessity and failure to disclose rebates, and false certifications related thereto.

e. False claims related to switching patients to the more expensive drug, Ferrlecit with regard to patient necessity and failure to disclose rebates, and false certifications related thereto.

III. SOURCE OF RELATOR'S ALLEGATIONS/DISCLOSURE STATEMENT PROVIDED TO GOVERNMENT

14. The information related in this Complaint is derived from the original and first-hand knowledge and information of Ivey Woodard, supplemented by his counsels' additional factual investigation. Pursuant to the requirements of 31 U.S.C. § 3730(a)(2), Relator will provide a written statement of all material evidence in his possession to the U.S. Attorney General and the U.S. Attorney for the Eastern District of Texas.

IV. JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question) and 31 U.S.C. §§ 3729-33 (False Claims Act).

16. In addition, this Court has jurisdiction under the doctrine of supplemental jurisdiction over the state created claims pleaded or which may be pleaded to the extent that these claims arise out of a common nucleus of operative facts.

17. The acts alleged herein occurred in numerous locations throughout the United States, including in Houston and Beaumont, Texas.

18. This Court has personal jurisdiction over the parties because all defendants do business within this District.

19. Venue is proper within this District because many of the acts and practices complained of occurred in this District.

COUNT I

A. EPOGEN

20. Epogen is a drug used in the treatment of severe anemia associated with kidney disease. Epogen is Amgen's brand name for Epoetin alfa, a glycoprotein manufactured though recombinant DNA technology which stimulates red blood cell production. Epogen is formulated as a sterile, colorless liquid in a solution for IV or SC administration.

21. Epoetin Alfa ("EPO" or "Epogen") is a synthetic hormone used to treat anemia, which is a complication in nearly all patients with ESRD. FMC and DaVita, administer EPO to patients at all of its dialysis facilities. EPO is manufactured by Amgen, Inc., which has an exclusive patent on EPO until 2005.

22. The principal users of Epogen are chronic renal failure patients, most of whom require regular dialysis treatment. As a result, dialysis clinics, including those run by Defendants, are by far the largest volume purchasers of Epogen.

23. Because of the condition treated by Epogen, the population of potential Epogen users in the United States is essentially fixed. Unlike the situation with many other drugs, Epogen sales cannot be increased by marketing to a wider audience. Instead, the principal way Amgen sales people can increase their sales is to increase the dosage for existing patients, most of whom are treated on an outpatient basis at dialysis clinics, is to maximize the dosage without triggering an investigation. Likewise, to avoid a reduction in sales, the Amgen dales force must avoid any efficiencies or new technologies that reduce the necessary dosage. One of the best ways to accomplish these ends is to gain access to Defendants' confidential patient information in order ascertain the dosages administered to the patients and the level of the hematocrit and hemoglobin, and preventing any large scale changes in the way Epogen is administered that would negatively affect per-patient dosages.

24. The Epogen Product Information Sheet provides the parameters for Epogen dosage. The Product Information Sheet provides for a starting dose of 50 to 100 units per kilogram for adult patients, administered three times per week (for a 175 pound adult male, this would amount to a starting dosage of between 4,000 and 8,000 units, three times per week). Specifically, it provides that Epogen should be utilized for most adult chronic renal failure (CRF) patients to bring the patient's hematocrit (Hct.) to within a target range of between 30% and 36% (the target range is also sometimes measured by hemoglobin (Hb) level, corresponding to a Hb level of 10 to 12). See, Epogen Product Information Sheet, "Dosage and Administration," pages 18-19. These patients must be monitored regularly, and the dosage reduced when the Hct. approaches 36% or increases by more than 4 points in any 2 week period. Id. The Product Information Sheet also notes that "if the suggested target range is exceeded, Epogen therapy may be withheld until the Hct. returns to the

suggested target range; Epogen therapy may then be resumed using a lower dose." Id. "Overdosage" at pp. 17-18.

25. The Product Information Sheet also notes that treatment will vary from patient to patient. "The dosage of Epogen must be individualized to maintain the hematocrit within the suggested target range. At the physician's discretion, the suggested target hematocrit range may be expanded to achieve maximal patient benefit." Product Information Sheet, "Dosage and Administration," p. 18. The Product Information Sheet also notes that patients' maintenance doses must be individually titrated. Id. See also, Product Information Sheet, "Warnings" and "Precautions," pp. 7-9 (discussing potential risks, including increased risk of thrombosis when Hct. exceeds the target range, and the consequent need for individualized monitoring of patients on Epogen therapy).

B. Overutilization of Epogen Without Regard to Medical Necessity or Patient Need, and False Certifications Related Thereto

26. Since in or about 1996, in return for using Epogen, Amgen has provided "anemia management training" and support to Defendants' staff either by conducting "chart reviews" or by attending quality assurance meetings. Sometimes the training would be provided at the Defendants' clinics and sometimes Amgen provide training at Amgen's expense at a hotel. This training is provided at no cost to the Defendants and results in Defendants saving substantial amounts of money because they did not have to provide such necessary training for their employees, and in effect, the training represents and in-kind kickback to Defendants. Amgen would provide the training at its expense and would provide rewards to the employees of Defendants as part of the training process. Also, however, this was also one of the principal methods by which Amgen carried out its systematic

upward manipulation of Epogen usage levels at Defendants' clinics, and Defendants' employees willingly went along with this practice.

27. Amgen Regional Sales Managers regularly instructed sales personnel that a major method of increasing sales was to obtain individual, confidential patient charts or patient specific data without patient consent or knowledge in violation of 42 C.F.R. § 405.2139, and various state laws. To carry this out, the sales person would approach the person at one of Defendants' dialysis facilities with access and authority over patient charts. Most often, the person with control of patient charts is the Director of Nursing ("DON").

28. In many instances, clinic DON's allow Amgen sales people to review patient charts "as is." That is, the DON simply turns over the charts or printouts to the Amgen sales person, and allows unfettered review of the chart. In other instances, DON's take a marker and cross out, often crudely, patient names before turning over patient charts. Sometimes, instead of review by the Amgen sales person, the sales person arranges for an Amgen clinical support person to conduct the chart review.

29. At certain of Defendants' clinics, the DON's resist allowing Amgen sales staff to review patient charts. When this happens, the first step is to attempt to enlist the aid of the clinic administrator, who typically is more financially oriented than the DON. Often, the administrator will instruct the DON to allow chart review by Amgen. When these direct efforts to obtain confidential medical records fails, the next recourse is for the sales person to advise his or her superior, typically the Amgen regional sales manager. The sales manager then is often able to contact higher-up authorities than the "business side" of the clinic, and arrange for the DON to be instructed to allow Amgen access to the clinic's patient charts.

30. Once the Amgen sales person or the Amgen clinical support person obtains access to patient charts or patient specific data, the goal is simple and straightforward: increase the Epogen dosage for as many patients, and for the maximum amount, as possible, and to get the Hct. above 36% without regard to medical need and without regard to good medical practice. This obviously increases Amgen's sales revenue, and at the same time increases profits at the Defendants' clinics, which uses more Epogen and earns the "spread" between the purchase price and the reimbursement rate. Further, as discussed below, the clinic can obtain volume discounts by increasing sales, further increasing it's spread and it's profits. Thus, with respect to increasing Epogen usage, the financial interests of seller Amgen and Defendants' clinics are aligned.

31. Thus, even though the Product Information Sheet sets out the target Hct. level of between 30% and 36%, Amgen sales people were instructed to strive to get Hct. levels up to the top end of that range, and beyond the target range. Neither scientific research nor the Product Information Sheet support these higher levels, but increasing Hct. requires higher Epogen dosages. The sole "basis" for striving for these higher Hct. levels is that most Medicare fiscal intermediaries will allow for Epogen reimbursement at Hct. levels of 36% to 37.5% and above without running a substantial risk of additional review. As the Amgen sales staff and Defendants' clinics now know, only around when Hct. is 40% or above is there a "red flag", but even then, Medicare would pay if the usage was "justified" for a given treatment regimen, regardless of an individual patient's diagnosis or medical necessity, i.e., by coding "angina." Amgen personnel were encouraged to distribute a list of reasons that could be used by Defendants' clinics to justify an HCT of 40 percent or above.

32. In conducting the anemia management reviews or chart reviews, the goal of the Amgen sales person is to increase Epogen usage at Defendants' facilities without regard to medical necessity, and Defendants went along with the practice. In making their determination, the sales staff looks primarily at Hct. or Hb. levels, together with a small number of additional factors with the goal of achieving the highest Hct. level possible without regard to medical necessity and well beyond the target Hct. levels between 30% and 36%. This results in Defendants regularly administering Epogen in an off-label manner.

33. In adjusting the patient's Epogen levels, the Amgen sales person thus does not take into account the individualized circumstances of the patient. Furthermore, the Amgen sales person does not take into account whether for the particular patient there would be medical benefits resulting from an increase in dosage to levels at the top of, or beyond the target range. Instead, the sole consideration is to increase the dosage, and Defendants' clinics go along with this practice.

34. Moreover, even if the Amgen sales person did consider the patient's individual circumstances or the medical utility of dosage change, such decisions are not within the proper authority or expertise of the sales staff or clinical support staff, but rather should only be made by a medical doctor, assisted by medical staff of the Defendants' clinics. In Relator's experience and the experience of others, although doctors at Defendants' clinics ultimately were required to "sign off" on all dosage changes, they typically signed stacks of orders presented to them by the medical staff, either without knowledge of, or without regard for, the fact the chart review and change orders had been prepared or dictated by Amgen sales personnel.

35. Relator, Woodard, is aware of these practices generally. He specifically conducted anemia management reviews or chart reviews at some of the Defendants' dialysis clinics. Even

though Woodard opposed the practice, he estimates that he conducted anemia management reviews or chart reviews at approximately 25% of the clinics for which he was responsible as a result of the pressure applied on him by his supervisor. At numerous meetings with his supervisors, he was castigated because this percentage was so low, and contrary to Amgen's practice. More typically, in Relator's region and other regions with which he is familiar, on the order of 50% to 70% of clinics permitted Amgen sales staff to conduct chart review.

36. In the event the fiscal intermediary conducted a review of a particular patient's Epogen dosage, Amgen sales people would advise ("train") Defendants' employees of the proper ICD-9 code to use and even provided the clinic with draft letters including language which Medicare considered appropriate justification for exceeding recommended dosages (for instance, "angina," a relatively subjective diagnosis, was one such Medicare-accepted justification).

37. Another related method by which Amgen attempted to upwardly manipulate Epogen usage at Defendants' dialysis clinics was to persuade clinics to allow Amgen to write the clinics' internal protocols for Epogen usage. Whenever possible, Amgen takes the opportunity to create these protocols for its clinic customers. The opportunity to write protocols was so great, and the reward so substantial that Amgen even developed a computer program which its sales people could utilize in preparing internal protocols for clinics.

38. Although the Product Information Sheet specified 30% to 36% Hct. (Hb 10 to 12) as the target range, the Amgen program set up a protocol that would encourage substantially higher Epogen use than the clinics would have dictated in independently created protocols. The higher Epogen use set forth in the protocols was driven by the desire to achieve higher revenue - not patient need and without regard to patient benefit. Some of the protocols might even state that Medicare

allows a rolling average of 37.5% which would be outside the parameters of the Product Information Sheet.

C. Overutilization Relating to IV Administration Versus SC Administration

39. Epogen is approved to be administered by an IV or SC route.

40. When Epogen was first administered during the initial clinical trials in the United States, studies had not yet shown whether IV or SC administration was more effective in treating dialysis patients. As a result, during the clinical trials, only IV administration was utilized.

41. After the clinical trials, and after Epogen had been available on the marketplace for several years, a number of studies noted that SC administration provided elevated blood levels of Epoetin longer than the same dosage provided via the IV route. Through the early and mid-1990's, these studies cumulatively showed that, on average, dosages were reduced by between 15% and 505 with SC administration as against IV administration.

42. In 1997, the National Kidney Foundation's Dialysis Outcomes Quality Initiative ("DOQI"), the first comprehensive, evidence-based guidelines for clinical dialysis treatment, summarized the growing body of research about anemia of chronic kidney disease and issued a series of guidelines based on the consensus of the research. In Section IV, "Administration of Epoetin," Guidelines 11 through 19 set out a framework for providing Epogen to patients. In DOQI Guideline 11, the National Kidney Foundation stated that "Epoetin should be administered subcutaneously in chronic kidney disease and peritoneal dialysis patients," and that "the most effective route of Epoetin administration is SC in hemodialysis patients." The DOQI Guidelines then went on to state the evidentiary support for this finding/recommendation, noting that the thirty-six studies published to

that time showed the dosage was dramatically lower when Epoetin was administered SC rather than IV.

43. The National Kidney Foundation went on, at DOQI Guideline 13, to state that patients who were switched from IV to SC administration should be given, after achieving the target Hgb/Hct level, an initial dosage approximately two-thirds the weekly IV dosage. Guideline 13 went on to note that if, after conversion to SC dosage, the weekly SC dosage was greater than the IV dosage required, the IV rate of administration should be resumed.

44. The DOQI Guidelines also recognized that despite the superiority of SC administration, some dialysis patients might not be able to tolerate SC Epogen administration. In this circumstance, DOQI Guideline 17 recognized that IV administration should be used, and a 50% higher dosage given than the SC dosage.

45. Switching from IV to SC dosage was obviously against the financial interests of both the Defendants and Amgen, and Amgen's sales staff told Defendants' agents and employees to focus on the revenue implications of switching from IV to SC dosage. Because Epogen was profitable to the Defendants' clinics, particularly with Amgen's volume discount program (described below), a medical decision that resulted in less Epogen use would reduce the clinics' revenue and profitability. This information was presented regularly to Defendants' clinic employees orally and on occasion in memoranda, and Defendants pushed the IV method with their patients without regard to medical necessity because that resulted in more Epogen being used and therefore more profit.

46. As will be more particularly described in Count II, Defendants preferred using the single-use vials of Epogen, not because of medical benefit, but to increase revenue since they would make multiple entries into single-use vials to extract and use the overfill (which was larger in single-

use vials). Defendants also preferred to use the single-use vials because it would discourage doctors and patients from using the SC method. Epogen, when administered SC from a single-use vial, produced a sting (due to the ascorbic acid in the single-use vial, but which due to the preservative, was not present in the multiple use vials). This sting would be less or nonexistent when Epogen was administered IV, so patients would naturally prefer the IV route. However, if Epogen from the multiple entry vials were used for the SC method of administration, the patients would have had no preference, but using the SC method would drastically lower Defendants' revenue since less Epogen would be used. Defendants preferred using more Epogen through the IV method of administration even though the same patient results could be obtained through the use of substantially less Epogen.

47. In Relator's experience, Defendants' clinics acknowledged that a principal reason not to switch from IV to SC dosage was the negative effect on revenue, and not due to patient benefit or medical necessity.

48. Several years after DOQI Guidelines were published, the National Kidney Foundation published revised guidelines after a review of the literature published between 1996 and 2000 and not part of the analysis the initial DOQI Guidelines. Because the literature continued to show SC administration as the most efficacious method, the new guidelines released in 2001 (the "Kidney Disease Outcomes Quality Initiative," or "K/DOQI"), retained Guidelines 11, 12 and 14, noting that "[i]n aggregate, the bulk of the published data still suggest that SC administration results in a more efficient use of Epoetin."

49. On information and belief, Defendants, FMC and DaVita, are willing participants in the overutilization scheme described above. Some clinics actually shifted for a time from IV to SC administration, but most eventually returned to IV, and Amgen personnel would actively attempt to

discourage the SC method because it lowered Epogen sales. Many clinics candidly acknowledged that the reason they switched back to IV administration was "revenue."

50. FMC and DaVita have violated 31 U.S.C. § 3729 in that they knowingly submitted claims for Epogen administered as described above when it is not medically necessary and even though by doing so they are not in compliance with Federal, State and local laws and regulations, nor are they using Epogen consistent with its label or good medical practice, both of which are conditions for reimbursement. Moreover, Defendants have falsely certified that they are in compliance with Federal, State and local laws and regulations, and because such certifications are a condition of coverage by Medicare, and Defendants violated 31 U.S.C. § 3729 in that they knowingly submitted false claims for Epogen to Medicare.

COUNT II

A. Multiple Entries into Single-Dose Vials of Epogen

51. The allegations of Paragraphs 1 through 50 are hereby restated in full.

52. Epogen is produced in single and multi-use vials. Until recently (when the percentages were essentially equalized), multi-use vials were "overfilled" by approximately twelve percent, while the single-use vials were "overfilled" by twenty-five percent. The purpose of the overfill is to insure that no matter what type of syringe or needle is used in administration, the vial will produce the labeled quantity of Epogen. The single dose vials do not contain preservatives and to avoid potential infection rises to the patient, the potentially contaminated overfill in single-use vials should be disposed of after the single dose has been withdrawn. Many states prohibit multiple entries into single-use vials in their pharmaceutical laws and regulations. Because Epogen single

dose vials are labeled single-use only, multiple entries into Epogen vials are considered "off-label" use and violations of good medical practice.

53. Because until recently the percentage overfill was far greater in the single-use vial, Defendants' clinics naturally tended to choose the more profitable single-use vial over the multi-use vial. As previously stated, this was equally advantageous to Defendants, because the Epogen in the single-use vial discouraged the more economical SC method of administration because it produced a stinging sensation when used subcutaneously and patients would object to this, which meant that the single use vial was highly unlikely to be used for subcutaneous administration due to "patient comfort" concerns. Multiple use vials would not produce a sting (or would produce less sting) when administered SC.

54. Defendants' dialysis clinics soon learned that they could collect the overfill in the single-use vials and use it as a source of substantial amounts of "free" Epogen, which they could nevertheless bill to Medicare as though it came from new vials. However, the single-use vials are labeled as single-use and many states prohibit multiple entries into single use vials. Multiple entries into EPO single-use vials are considered "off-label" and violations of good medical practice.

55. Amgen's sales force became adept at marketing the "overfill" of Epogen single-use vials in a way that encouraged IV administration and overutilization of Epogen.

56. Since on or about 1992, Defendants instructed their employees to make multiple entries into single-use vials of Epogen to capture the overfill and these instructions may have been reduced to writing. Defendants combined the overfill from multiple vials to form additional doses of Epogen, and the additional doses were billed to Medicare as if it came from new vials.

57. Such multiple entries into single-use vials are a violation of standard medical practice, state law, and Medicare conditions of coverage for such, which require use of medications according to their labels or consistent with good medical practice. Multiple entries also pose a significant risk of infection to patients.

58. Thus, the effect of the high overfill in the single-use vials was to encourage the Defendants' clinics to use single entry vials and achieve unnaturally high profitability on Epogen. At the same time, the sting produced by the single-use vial Epogen served Amgen's and Defendants' goals by assuring that Defendants' clinics would be likely to continue to administer the Epogen by IV administration, thereby continuing the overutilization that is key to Amgen's Epogen success.

59. On top of all this, by the volume discounting structure described below, Amgen further incentivized the Defendants' clinics to overutilize Epogen, because the drug got progressively less expensive as the volume purchased increased. The combination of volume and performance discounts and the "free" product through overfills made Epogen one of the Defendants' clinics' most profitable revenue items.

60. Amgen employees would teach Defendants' employees to extract the overfill of the single-use vials and how to make multiple entries, and the clinics were encouraged to bill what they used. Defendants' management has consistently encouraged dialysis facilities to increase the volume of Epogen that is billed per vial by rewarding employees for increasing the volume of what is billed per vial. As a result, some of Defendants' clinics have submitted false claims by administering Epogen in an off-label manner.

61. Defendants have violated 31 U.S.C. § 3729 in that they have knowingly submitted claims for Epogen administered as described above, even though by doing so they are not in

compliance with federal, state and local laws and regulations, nor are they using the drug consistent with its label or good medical practice, both of which are conditions for reimbursement.

62. FMC and DaVita, have knowingly submitted false claims for Epogen by administering the medication in an off-label manner by making multiple entries into single-use vials, by billing overfill medication as if it came from a new vial, and by billing Medicare for more medication than was actually administered.

63. FMC and DaVita, have violated 31 U.S.C. § 3729 in that they knowingly submitted claims for EPO administered as described above, even though by doing so they are not in compliance with Federal, State and local laws and regulations, nor are they using the drug consistent with its label or good medical practice, both of which are conditions for reimbursement.

64. As a result of the above practices, FMC and DaVita have submitted and have continued to submit false claims for EPO to Medicare in substantial amounts per year.

COUNT III

A. Violations of Fraud and Abuse Statutes Related to Epogen

65. The allegations of Paragraphs 1 through 64 are hereby restated in full.

66. FMC and DaVita have knowingly submitted false claims to Medicare for reimbursement of Epogen in that it has received prohibited remuneration (in the form of rebates and in-kind kickbacks) in return for purchasing Epogen, while falsely certifying to Medicare that it was in compliance with all applicable laws and regulations.

67. As noted above, compliance with all applicable laws and regulations is a condition of coverage for reimbursement of dialysis. 42 C.F.R. § 405.2135.

68. Moreover, each year, FMC and DaVita, submit a cost report known as FCFA-265 to the Health Care Finance Administration. HCFA-265 is required from all dialysis facilities that bill to Medicare and includes a certification of FMC and DaVita's adherence to federal laws and regulations. Provision of the cost data and the certification in FCFA-265 is a condition of coverage. 42 C.F.R. § 405.2138.

69. Clinics receive very substantial discounts off both the Average Wholesale Price (AWP) and the Wholesale Acquisition Price (WAP). Available discounts include: (1) substantial reduction from reported AWP to WAP; (2) a further fixed 7% discount off WAP; (3) Optional Hematocrit/Hemoglobin Incentive of up to 1% depending on percentage of patients maintaining a Hct. level of greater than 33% (paid after the fact as a refund rather than as a pricing discount); (4) a 1% Electronic Data Discount for electronic payment; (5) "Volume Performance Discounts" up to 5.5% on sliding scale for purchases over $184,800/year (the levels at which the discount increases are very small (around $1500 each category) and thus there is always the possibility for the clinic of increasing the percentage). The total possible discounts, amount to 14.5% off the listed WAP, which itself is heavily discounted off the AWP. These discounts were and are the basis for enticing clinics into over-utilizing Epogen and to utilize the IV route of administration. The discounts set up a substantial spread between the clinic's purchase price and reimbursement rate. This spread, which can be increased by higher usage, then motivates the clinics to allow the manipulative practices described herein.

70. FMC and DaVita have violated 42 U.S.C. §§ 1320a-7a & 7b in that:

a. FMC and DaVita purchase Epogen from Amgen at a reduced rebated price;

b. On information and belief, FMC and DaVita have failed to disclose or pass on its Amgen rebate to Medicare, either in its bills for EPO or in HCFA-265;

c. The undisclosed rebate received by FMC and DaVita constitutes prohibited remuneration under 42 U.S.C. §§ 1320a-7a & 7b because it is paid by Amgen in exchange for FMC and DaVita's purchase of Epogen, for which Medicare reimburses FMC and DaVita.

71. Since in or about 1994, FMC and DaVita have also violated 42 U.S.C. §§ 1320a-7a & 7b in that:

a. Amgen has provided anemia management training and support to FMC and DaVita staff. This service is provided by Amgen without charge to FMC and DaVita and saves them some substantial expenditures each year;

b. In return for FMC and DaVita's purchases of Epogen and access to patient records, Amgen also provides FMC and DaVita with clinical and sales staff at no charge and expends significant funds entertaining clinic staff and physicians;

72. Since in or about 1994, the anemia management training, clinical and sales staff, and entertainment funds provided to FMC and DaVita by Amgen constitute prohibited in-kind remuneration under 42 U.S.C. §§ 1320a-7a & 7b because it is provided in exchange for FMC and DaVita's purchase of Epogen, for which FMC and DaVita are reimbursed by Medicare.

73. Because FMC and DaVita have falsely certified that they are in compliance with Federal, State and local laws and regulations when in fact they were violating 42 U.S.C. §§ 1320a-7a & 7b, and because such certification is a condition of coverage by Medicare, FMC and DaVita, violated 31 U.S.C. § 3729 in that they have knowingly submitted false claims for Epogen to Medicare.

74. As a result of their violations of 31 U.S.C. § 3729 in regard to Epogen, FMC and DaVita have submitted and continue to submit false claims to Medicare in substantial amounts. Moreover, the unnecessary increase in each Epogen dose, as discussed herein has resulted in false claims in substantial amounts.

COUNT IV

A. Violations Related to Selection of Vitamin D Analogs

75. The allegations of Paragraphs 1 through 74 are hereby reinstated in full.

76. On information and belief, FMC and DaVita have knowingly submitted false claims to Medicare in that they have billed for unnecessary medication and in that they have received prohibited remuneration (in the form of rebates) in return for purchasing the drug Zemplar, while falsely certifying to Medicare that they were in compliance with applicable law and regulations.

77. Vitamin D analogs are drugs prescribed for dialysis patients for a variety of disorders, including hypocalcemia and secondary hyperparathyroidism. Some 50-60% of dialysis patients receive a Vitamin D analog as part of their treatment. Medicare reimburses for two Vitamin D analogs, Calcijex and Zemplar. The two are clinically identical for most patients, although Zemplar is more expensive.

78. In 1999, Abbott Laboratories, Inc., the manufacturer of both Calcijex and Zemplar, began a program to encourage providers to use the more profitable Zemplar instead of Calcijex. As part of that program, Abbott offered a rebate to FMC and DaVita if it would increase the amount of Zemplar administered to patients.

79. As a result of the rebate, use of Calcijex became even less profitable for FMC and DaVita than use of Zemplar, which is 1.9 times more expensive.

80. After the rebate was announced, during 1999 and 2000, on information and belief, FMC and DaVita management waged an aggressive campaign to encourage its employees to use Zemplar instead of Calcijex and to have employees switch patients using Calcijex to Zemplar without regard to medical necessity, and to otherwise encourage physicians to prescribe Zemplar instead of Calcijex for their patients. Relator observed this aggressive campaign while visiting certain of Defendants' clinics.

81. As part of the campaign that Relator observed, FMC and DaVita encourages referring physicians to change their patients' medication from Calcijex to Zemplar through a variety of means, including but not limited to, representing that Zemplar was the "preferred drug" for patients requiring Vitamin D. Analogs.

82. On information and belief, to facilitate changing current patients' medication from Calcijex to Zemplar, FMC and DaVita instructed dialysis facility staff to write physician orders documenting the change for each patient's chart. The physician was then requested to sign the order the next time he reviewed the chart. On information and belief, none of these orders contained documentation of medical necessity for the change, because all of the changed patients were doing well on the less profitable Calcijex.

83. By making false representations to the physicians, FMC and DaVita caused said physicians to unnecessarily change patients' medication from Calcijex to Zemplar.

84. Although they received the rebate from Abbott, on information and belief, FMC and DaVita did not properly disclose, nor did their costs and charges appropriately reflect, the rebate for Zemplar.

85. FMC and DaVita have violated 31 U.S.C. § 3729 in that they have submitted claims for unnecessary doses of Zemplar.

86. In addition, because FMC and DaVita falsely certified that they were in compliance with all laws and regulations when they were in fact violating 42 U.S.C. §§ 1320a-7a & 7b by receiving an illegal rebate, and because such certification is a condition of Medicare reimbursement, FMC and DaVita violated 31 U.S.C. § 3729 in that they knowingly submitted claims for Zemplar to Medicare.

87. As a result of their violations of 31 U.S.C. § 3729, FMC and DaVita submitted false claims for Zemplar to Medicare in substantial amounts. On information and belief, the rebate, which FMC and DaVita received from Abbott in late 2000, was substantial.

COUNT V

A. Violations Related to Selection of Iron Supplements

88. The allegations of Paragraphs 1 through 87 are hereby restated in full.

89. On information and belief, FMC and DaVita have knowingly submitted false claims to Medicare in that they have has billed for unnecessary medication and in that they have received prohibited remuneration (in the form of rebates) in return for purchasing Ferrlecit, while falsely certifying to Medicare that they were in compliance with applicable law and regulations.

90. Anemia is a complication in virtually all cases of ESRD. In addition to Epogen, about 60% of dialysis patients receive an intravenous iron supplement for anemia. Two iron supplements for which Medicare reimburses are Infed and Ferrlecit. Although Infed may cause more side effects when initially administered to a patient, for patients established on Infed, Infed is clinically identical to Ferrlecit in terms of side effects and efficacy.

91. In 1999, Schein Pharmaceuticals, Inc., the manufacturer of both Infed and Ferrlecit, began a program to encourage providers to use the more profitable Ferrlecit instead of Infed. As part of that program, on information and belief, Schein offered a rebate to FMC and DaVita if they would increase the amount of Ferrlecit administered to patients.

92. As a result of the rebate, use of Infed became even less profitable for FMC and DaVita than use of Ferrlecit, which on information and belief is 1.5 times more expensive.

93. As a part of the campaign that Relator observed, Defendants' management waged an aggressive campaign to encourage its employees to use Ferrlecit instead of Infed and to have employees switch patients to Ferrlecit without regard to medical necessity and to encourage physicians to change their patients' medication from Infed to Ferrlecit. This was accomplished through a variety of means, including but not limited to, representing that Ferrlecit was the "preferred drug" for patients requiring iron.

94. FMC and DaVita's representation that Ferrlecit was the "preferred drug" for patients requiring an iron supplement was false in that Infed and Ferrlecit are clinically identical for patients already established on Infed, both in terms of efficacy and side effects.

95. On information and belief, to facilitate changing current patients' medication from Infed to Ferrlecit, FMC and DaVita instructed dialysis facility staff to write physician orders documenting the change for each patient's chart. The physician was then requested to sign the order the next time he reviewed the chart. On information and belief, none of these order contained documentation of medical necessity for the change, because all of the changed patients were doing well on the less profitable Infed.

96. By making false representations to the physicians, FMC and DaVita caused said physicians to unnecessarily change patients' medication from Infed to Ferrlecit.

97. Although they received the rebate from Schein, on information and belief, FMC and DaVita did not properly disclose, nor did their costs and charges appropriately reflect, the rebate for Ferrlecit.

98. FMC and DaVita have violated 31 U.S.C. § 3729 in that they have submitted claims for unnecessary doses of Ferrlecit.

99. In addition, because FMC and DaVita falsely certified that they were in compliance with all laws and regulations when they were in fact violating 42 U.S.C. §§ 1320a-7a & 7b by receiving an illegal rebate, and because such certification is a condition of Medicare reimbursement, FMC and DaVita violated 31 U.S.C. § 3729 in that they knowingly submitted claims for Ferrlecit to Medicare.

100. As a result of their violations of 31 U.S.C. § 3729, FMC and DaVita submitted false claims for Ferrlecit to Medicare. On information and belief, the rebate, which FMC and DaVita received from Schein in late 2000, was substantial.

WHEREFORE Relator, Ivey Woodard, prays that this Court:

1. Assess a civil penalty of not less than $5,500.00 and not more than $11,000.00 against Defendant, Dialysis Clinic, Inc., National Nephrology Associates, Inc., Renal Care Group, Inc., and John Does 1-20 for each and every false claim set forth herein, as provided by 31 U.S.C. § 3729(a);

2. Award damages in the sum of three times the amount fraudulently billed to Medicare as set forth herein, as provided by 31 U.S.C. § 3729(a), plus interest;

3. Award him reasonable expenses, attorney's fees and costs, as provided by 31 U.S.C. § 3730(d);

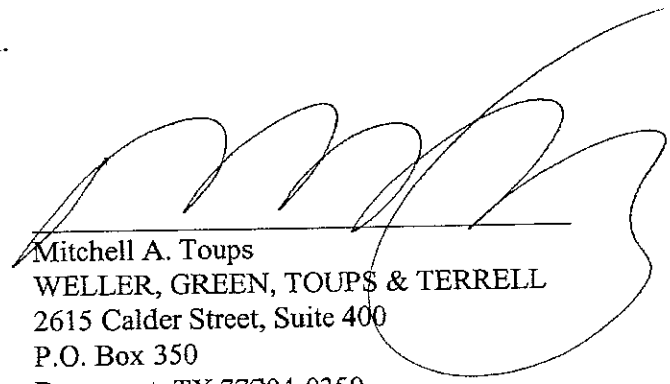
4. Exclude FMC and DaVita from participation in Federal health care programs; and

5. For such other and further relief as this Court deems just and proper.

JURY TRIAL DEMANDED

Relator hereby demands a jury trial.

Dated: March 3, 2005.

By: 

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ATTORNEYS FOR RELATOR

CERTIFICATE OF SERVICE

I certify that, pursuant to the terms and requirements of the United States False Claims Act, 31 U.S.C. § 3730(b)(2) and Fed.R.Civ.P. 4(d)(4), true and correct copies of the foregoing were served on March 30th, 2005 by certified mail, return receipt requested, addressed to the following:

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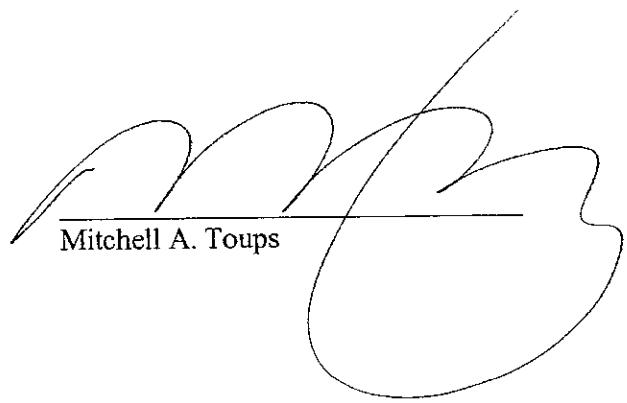

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