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

UNITED STATES OF AMERICA, ex rel. IVEY WOODARD,	)	
Plaintiffs/Relators,	)	
v.	)	**Civil Case No. 1:05-CV-00227**
DAVITA, INC.,	)	
Defendant.	)	

THIRD AMENDED COMPLAINT

Relator, Ivey Woodard, through his attorneys and on behalf of the United States of America, hereby files this Third Amended Complaint against Defendant, DaVita, Inc., and alleges as follows:

I. NATURE OF THE CASE

1. This action, brought pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, *et seq.*, and the Fraud and Abuse Statute, 42 U.S.C. §§ 1320, *et. seq.*, arises from DaVita, Inc.'s ("DaVita") fraudulent schemes in connection with its utilization of and billing practices for the drug Epogen (also referred to as "EPO"). Specifically, Relator, Ivey Woodard ("Relator" or "Woodard"), complains of DaVita's false certifications in its billing records and certifications to the Federal Government pertaining to (1) its overutilization of Epogen without regard to medical necessity or patient need, (2) its re-entry into single-dose vials of Epogen and its misuse of overfill, and (3) its receipt of discounts, rebates, and prohibited remuneration. DaVita's misconduct resulted in its unjust and illegal enrichment at the expense of the United States. Through this action, Relator seeks to

recover damages and civil penalties arising from DaVita's false and improper claims that were submitted to the United States for payment under its health care programs.

II. THE PARTIES

2. Relator, Ivey Woodard, is a resident of Signal Mountain, Tennessee. Woodard was employed by Amgen, Inc. ("Amgen") in various capacities between 1990 and September 2001. In those capacities, he regularly visited DaVita's facilities (some of which were previously known as Total Renal Care), and he regularly interacted with their agents and employees. Amgen is a biotechnology company that develops, manufactures, and markets human therapeutics based on advances in cellular and molecular biology. During the time period at issue, Epogen was Amgen's "blockbuster" product and had 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. In that capacity, Woodard was responsible for sales and marketing in a region that included Livingston, Cleveland, Lufkin, Nacogdoches, Bryan, Kingwood, Humble, and a large portion of Houston. 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 his employment by Amgen, Woodard became aware of the fraudulent acts and practices of DaVita as set forth herein. Woodard was terminated from his employment with Amgen based, in substantial part, upon his unwillingness to carry out the unlawful acts and schemes alleged herein. The information related in this Complaint is derived from the

original, first-hand knowledge and information of Ivey Woodard, which is supplemented by his attorneys' investigation.

3. DaVita, Inc. is a Delaware corporation with its headquarters in Lakewood, Colorado. DaVita is one of the largest providers of dialysis services in the United States. During the time period at issue, DaVita served significantly more than 50,000 patients in 35 states and the District of Columbia. At the time that Relator initiated this litigation, DaVita had over 611 outpatient dialysis centers and also provided acute inpatient dialysis services in over 350 hospitals across the United States. Those numbers have dramatically increased during the pendency of this litigation. By agreement with Relator's counsel, DaVita has agreed to waive service and to appear through its counsel of record.

III. JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. §§ 3729-33.

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

6. This Court has personal jurisdiction over DaVita because it does business within this District.

7. Venue is proper within this District because DaVita conducts business in this District and many of the acts and practices complained of occurred in this District. Acts proscribed by 31 U.S.C. § 3729 were committed by DaVita in this District. Therefore, within the meaning of 28 U.S.C. § 1391(c) and 31 U.S.C. § 3732(a), venue is proper in this

District.

8. As examples of DaVita's misconduct in this District, Relator consulted with DaVita's personnel at its Livingston dialysis center, and he is aware that the conduct at issue occurred in this District. Specifically, Relator consulted with DaVita personnel about Epogen use at its Medicare-certified Livingston Dialysis Center, which provides in-center hemodialysis services with approximately 10 stations at 203 North Houston in Livingston, Texas. In reference to DaVita's over-administration of Epogen, the Livingston Dialysis Center submitted 319 claims in which it administered Epogen to clients who had a three-month average with hematocrit (abbreviated as "Hct") levels of greater than 40.0% for the period of 1995 through 2004. In those 319 claims, DaVita administered approximately 15,111,800 units of Epogen and charged $151,118 for its services. Additionally, in reference to DaVita's over-administration of Epogen, which is one of the claims addressed below, the Cleveland Dialysis Center in this District submitted 272 claims in which it administered Epogen to clients who had a three-month average of a hematocrit of greater than 40.0% for the period of 1995 through 2004. For those 272 claims, DaVita administered approximately 10,138,500 units of Epogen and charged $101,385 for its services.

IV. FACTUAL BACKGROUND

A. Governmental Entities With Financial Interest in this Litigation

9. The federal Medicare program is a health insurance program administered by the United States and funded by taxpayer revenue. The Medicare program is overseen by the United States Health and Human Services Department. Medicare assists state

governments with the payment for medical services to persons over the age of 65 and others who qualify under the Medicare program.

10. The federal Medicaid program is a health insurance program administered by the United States and funded by taxpayer revenue. Similar to Medicare, the Medicaid program is overseen by the United States Health and Human Services Department. Medicaid assists state governments with the payment for medical services to persons who have financial need and qualify for Medicaid coverage.

11. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") is funded by the United States and provides medical benefits to retired members of the military services as well as spouses and children of active duty, retired, and deceased members, as well as reservists who were ordered to active duty for thirty days or longer. CHAMPUS is administered by the United States Department of Defense.

12. The Civilian Health and Medical Program of the Veterans Administration ("CHAMPVA") is funded by the United States and provides medical benefits to spouses and children of veterans who are entitled to permanent and total disability benefits from the Veterans Administration and to widows and children of veterans who died of service-related disabilities. CHAMPVA is administered by the United States Department of Defense.

13. Medicare, Medicaid, CHAMPUS, and CHAMPVA are collectively referred to herein as the Federal Government.

B. Statutory Requirements that Provide Basis for Relator's Claims

14. Compliance with all "applicable Federal, state, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements" is a condition of the Federal Government's payment for medical care provided by dialysis facilities. 42 C.F.R. § 405.2135; 42 C.F.R. § 494.20.

15. Each year, DaVita submits a cost report known as HCFA-265 to the Health Care Finance Administration. The HCFA-265 report is required from all dialysis facilities that bill to the Federal Government, and the report includes a certification of DaVita's adherence to federal laws and regulations. The tender of the cost data and the certification in HCFA-265 are conditions of coverage. 42 C.F.R. § 405.2138; 42 C.F.R. § 413.20(b); 42 C.F.R. § 494.180(h)(3).

16. The Fraud and Abuse Statute makes it illegal to knowingly and willfully solicit or receive any type of remuneration, including a rebate, in return for purchasing, arranging for, or recommending any good or service for which the Federal Government may pay in whole or in part. 42 U.S.C. § 1320A-7b(b)(1) & 7a(a)(7). Section 1320a-7b provides for criminal penalties, while § 1320a-7a provides for civil monetary penalties. Because of these provisions, most rebates and discounts on government-reimbursed items violate the Fraud and Abuse Statutes. If, however, the rebate or discount is properly reported and passed on to the Federal Government, it may fall within a "safe harbor" of protected activity. 42 U.S.C. § 1320a-7b(b)(3)(A).

17. 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 and not more than $11,000 for each claim, plus three times the actual damages that the government sustained. 31 U.S.C. § 3729(a). The Act also permits assessment of the civil penalty even without proof of specific damages.

18. For the reasons stated below, DaVita has, in reckless disregard or in deliberate ignorance of the truth or the falsity of the information involved, made or used false or fraudulent records and statements in order to get false or fraudulent claims paid or approved. Such conduct is violative of the False Claims Act. 31 U.S.C. § 3729(a)(1) and (a)(2).

C. Epogen - Generally

19. Epogen is Amgen's brand name for epoetin alfa, a glycoprotein manufactured through recombinant DNA technology, which stimulates red blood cell production. The same epoetin alfa product, manufactured by Amgen, is also marketed and distributed by Ortho Biotech, L.P., a subsidiary of Johnson & Johnson, under the proprietary name Procrit.

20. Epogen/Procrit was licensed in June 1989, with the following indication: "treatment of anemia associated with chronic renal failure, including patients on dialysis (end stage renal disease) and patients not on dialysis." Under a contractual agreement with Amgen, Ortho Biotech, L.P. has rights to development and marketing of Procrit for any indication other than for the treatment of anemia associated with chronic renal failure. Epogen and Procrit have identical labeling information for all approved indications based on development programs conducted by Amgen or Ortho Biotech. Labeling was expanded

in April 1993 to include a supplemental indication for the treatment of anemia associated with cancer chemotherapy. Amgen had a patent on Epogen until 2005.

21. Epogen is used in the treatment of severe anemia commonly associated with end stage renal disorder ("ESRD") or kidney disease. The metrics used to determine whether a patient is anemic are hemaglobin (abbreviated as "Hgb") and hematocrit levels through a blood test. Because nearly all ESRD patients experience anemia as a complication of their illness, DaVita's dialysis facilities administer Epogen to its patients, most of whom require regular dialysis treatment. As a result, dialysis clinics such as those run by DaVita are the largest volume purchasers of Epogen.

22. Amgen produces and sells Epogen in preservative-free, single-use vials and also in preserved vials intended for multiple uses/patients.

23. For the time period at issue, dialysis sessions for the treatment of ESRD were capped by Medicare at a bundled or composite rate. However, the Federal Government paid separately for certain dialysis-related drugs based on the dose and frequency of administration. Epogen and the supplies used to administer it were reimbursed by the Federal Government in addition to the composite rate paid for each dialysis session.

24. Because the Federal Government reimbursed dialysis clinics for ERSD injectable drugs outside of the composite rate, DaVita's administration of drugs such as Epogen was a source of additional revenue to its dialysis centers. In other words, so long as DaVita was profiting from the administration of Epogen, it was in DaVita's financial interest to maximize the treatments and the dosages of Epogen. In fact, Epogen payments

by Medicare empirically have been the second-largest source of for-profit dialysis facilities' income, estimated to be approximately 25% or more of their income.

25. Epogen therapy has been the largest single Medicare drug expenditure. In 2004 alone, Medicare paid more than $1.8 billion on Epogen therapy, which was a 17% increase from the 2003 expenditures. During that same period, Epogen treatments comprised 11% of all ERSD costs to Medicare.

D. DaVita's Receipt of Discounts Based on the Volume of Purchases

26. Amgen incentivized DaVita's clinics to overutilize Epogen because the drug got progressively less expensive—thereby increasing DaVita's profit margin on the drug—with an increased volume of Epogen purchases. The combination of volume and performance discounts (and the "free" product through overfills, as addressed below) made Epogen one of the most profitable, if not the most profitable, revenue sources in DaVita's facilities.

27. DaVita's clinics received substantial discounts off the Average Wholesale Price ("AWP"). A price history "cheat sheet" from 1995 indicates that the Wholesale Acquisition Price ("WAP") was calculated based on a 20% reduction from the AWP. DaVita paid Amgen for its Epogen at or below the discounted WAP, but DaVita based its charges to the Federal Government on the AWP.

28. Additional discounts for DaVita included: (1) a fixed 7% discount off the WAP; (2) an optional Hematocrit/Hemoglobin Incentive of up to 1% based on the percentage of patients maintaining a hematocrit level of greater than 33% (paid after the fact as a refund rather than as a pricing discount); (3) a 1% Electronic Data Discount for

electronic payment; and (4) "Volume Performance Discounts" up to 5.5% on sliding scale for purchases over $184,800/year. The discounts increased in small increments (around $1,500 for each category), and thus, DaVita's clinics were able to see tangible increases in their discounts with their increased administration of Epogen.

29. The total possible discounts totaled 14.5% off the listed WAP, which itself was heavily discounted off the AWP. These discounts were the basis for enticing clinics into over-utilizing Epogen. The discounts set up a substantial spread between the clinics' purchase price and reimbursement rate. This spread, which was increased by higher usage, then motivated the clinics to develop, allow, and encourage the manipulative practices described herein.

30. Having worked with many of DaVita's clinics and having taken their orders as an Amgen sales representative, Relator is aware of these levels of discount. Also, based on his conversations with DaVita's clinic administrators, Relator is aware that DaVita regarded these discounts as a source of additional profit and did not pass the discounts along to the Federal Government as required by applicable regulations. DaVita also did not pass on the discounts or reduced billing to its patients.

31. DaVita acknowledged the significance and impact of these discounts in its 2005 annual report: "our agreement with Amgen for the purchase of EPO [epoetin] includes volume discount and other thresholds which could negatively impact our earnings if we are unable to meet these thresholds." This statement indicates that the savings associated with the bulk purchase and over-utilization of Epogen resulted in earnings to the company, not savings to the Federal Government as required under 42 U.S.C. §

1320a-7b.

E. DaVita's Over-Utilization of Epogen

(1) Epogen - FDA Labels

32. The 1993 FDA Label, which is perhaps more commonly known as the package insert, provided the parameters for Epogen dosage during much of the time period at issue. The label provided 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). The 1993 FDA Label provided that Epogen should be utilized for adult chronic renal failure (CRF) patients to bring the patient's hematocrit to within a target range of between 30% and 33% (corresponding to a hemoglobin level of 10 to 11). Under the 1993 FDA Label, patients must be monitored regularly, and the dosage must be reduced as the hematocrit level approaches 33% or increases by more than four points in any two week period. When the patient's hematocrit reaches 30 to 33%, the dosage should be decreased by approximately 25 units/kg "to avoid exceeding the target range." The 1993 FDA Label dictated that, as the hematocrit level approaches or exceeds 36%, Epogen treatment should be suspended until the patient's hematocrit decreases to the target range of 30 to 33%, and upon re-initiation, the dosage should be reduced by approximately 25 units/kg.

33. The 1999 FDA Label modified the suggested target range of hematocrit to 30 to 36%. The FDA Label called for a reduction in Epogen dosage as patients' hematocrit levels approach 36% or when hematocrit increases by more than four points in a two-week interval. The 1999 FDA Label specifies:

> If the hematocrit is increasing and approaching 36%, the dose should be reduced to maintain the suggested target hematocrit range. If the reduced dose does not stop the rise in hematocrit, and it exceeds 36%, **doses should be temporarily withheld** until the hematocrit begins to decrease, at which point therapy should be reinitiated at a lower dose.

(emphasis added). As with the 1993 FDA Label, the 1999 label required that Epogen dosage must be individualized to maintain patients' hematocrit within the suggested target range.

(2) Epogen - CMS/DHHS Guidelines

34. On February 1, 1997, the Department of Health and Human Services (DHHS) issued a Program Memorandum with the following observations and procedure:

> ESRD patients with symptomatic anemia considered for EPO therapy should be treated until the hematocrit reaches a target range of 30 - 36%. As the hematocrit approaches 36%, administration of EPO should be reduced temporarily. The dosage of EPO required to maintain target hematocrit levels is subject to individual patient variation and should be titrated according to patient response, with a goal of not exceeding a hematocrit level of 36%.
>
> Effective immediately, but no later than July 1, 1997, begin calculating EPO payments based on a 90-day rolling average hematocrit measurement for ESRD patients whose hematocrit levels are greater than 36%. . . .
>
> If the average of the 90 days of readings is 36.5% or less, pay for EPO. If the hematocrit level exceeds 36.5%, **deny** payment for EPO.

(emphasis in original).

35. In March 1998, having received more complaints and appeals than it could process efficiently, the DHHS modified the procedure on paying for Epogen administration:

> Effective for claims for monthly billing periods beginning on or after March 10, 1998, pay claims when the three month rolling average exceeds 36.5 percent. Payment is based on the lower of the actual dosage billed for the current month or 80% of the prior month's allowable EPO dosage.

36. In July 1998, the DHHS issued a new Program Memorandum to its intermediaries and carriers:

> When indicated, conduct post-payment review of EPO by looking at a 90-day rolling average of hematocrit levels. Because of the natural variability in hematocrit levels and because we are encouraging practitioners to maintain a hematocrit level within the range of 33 to 36 percent as recommended by the Dialysis Outcomes Quality Initiative, use a threshold hematocrit value of 37.5 percent in targeting aberrant cases. Identify practitioners with an atypical number of patients with hematocrit levels above a 90-day rolling average of 37.5 percent for routine medical review activities, such as educational efforts or pre-payment reviews.

The DHHS continued this directive in subsequent memoranda dated August 16, 2000, July 24, 2002, and September 5, 2003.

37. Effective April 1, 2006, the Centers for Medicare and Medicaid (CMS) implemented a new policy for the monitoring of Epogen usage:

> In order to allow for unanticipated increases in hematocrit, Medicare contractors will not be required to initiate monitoring until the hematocrit level reaches 39.0 (or hemoglobin of 13.0). For claims with hematocrit readings above the threshold of 39.0 (or hemoglobin of 13.0), the dose should be reduced by 25 percent over the preceding month in accordance with the FDA labeling.

(3) Amgen's Involvement in DaVita's Over-Administration of Epogen

38. The principal way that Amgen sales representatives increased their sales of Epogen was to increase the dosage of Epogen for existing patients, most of whom were treated on an outpatient basis at dialysis clinics, such as those owned by DaVita. Likewise, the Amgen sales force worked with DaVita to avoid reductions in the application and per-patient dosage of Epogen. Because the scope of treatments with Epogen did not change in the time period at issue, the population of potential Epogen users in the United

States did not increase greatly. Unlike the use of many other drugs, Epogen sales could not be increased by marketing to a wider audience. Therefore, under the circumstances, Amgen sales personnel, such as the Relator, called upon DaVita and assisted its facilities with increasing the frequency and dosage of Epogen administrations.

39. By no later than 1994, Amgen was working with its sales representatives to increase the utilization of Epogen. That year, Medicare reduced its reimbursement rate for Epogen. In a memorandum to its sales representatives and district managers, Amgen addressed the impact of the reduction in profits caused by Medicare's lowering of the reimbursement rate:

> Due to your efforts many of our customers are prepared and understand the economic impact of Anemia management. The reduced margins reflected in their payments will reinforce the need now more than ever to dose appropriately to achieve the target Hct. This increase in utilization will in turn provide additional revenues to their centers.
>
> On the other hand, there are providers who will view this reduction in their margins as a signal to reduce Epogen usage.
>
> Our sales professionals can 'make the difference' on the way their providers react to this change.
>
> As we visit our customers over the next month be on the look our [sic] for:
>
> - Dose reducing protocols
> - Dose withholds
> - Patients not achieving target Hct.
>
> These actions may be an indication that our customers are unaware of the 'connection' between higher Hcts, better outcomes, and increased revenues that can only be achieved through appropriate utilization of Epogen therapy. This would be a perfect opportunity to demonstrate the financial impact of achieving the target Hct.

40. Through training, review of patient records, and the drafting of treatment protocols, Amgen taught DaVita's facilities about the "increased revenues" and "financial impact" arising from the increased utilization of Epogen.

a. Amgen's Training of DaVita Personnel

41. Beginning in roughly 1996, Amgen provided "anemia management training" and support to DaVita's staff in return for using Epogen. Amgen provided this training either at DaVita's clinics or at a hotel at Amgen's expense. In addition to paying for the training, Amgen provided rewards to the DaVita employees as part of the training process. In the process, DaVita saved substantial amounts of money that it otherwise would have spent on the training of its employees. In effect, the training represented an in-kind kickback to DaVita. More importantly, this "training" was one of the principal methods by which DaVita educated its employees on a systematic upward manipulation of Epogen usage levels, including how to manipulate the system and maximize the use of Epogen.

b. Amgen's Review of DaVita's Patient Charts

42. Another significant means of auditing and increasing Epogen usage was through Amgen's access to DaVita's confidential patient information. As Relator witnessed, Amgen sales managers regularly instructed sales personnel to increase Epogen sales through review of confidential patient charts or patient-specific data without the patients' knowledge or consent, in violation of the patients' privacy rights granted by 42 C.F.R. § 405.2139, 42 C.F.R. §§ 494.70(a)(3), (4) and 494.170(a) and state laws. The purpose of the chart reviews was to determine the dosages administered to the patients in particular ranges of hematocrit and, by learning the clinics' practices, assist them in

increasing Epogen dosages.

43. To carry this out, Amgen sales representatives approached DaVita's personnel with access to and authority over patient charts. Most often, the person with control of patient charts was the Director of Nursing ("DON"). Frequently, clinic DONs allowed Amgen sales representatives to review patient charts "as is." That is, the DON simply turned over the charts or printouts to the Amgen representative for an unfettered review of the chart. In other instances, DONs crossed out patient names before turning over patient charts. Sometimes, instead of reviewing charts in person, the Amgen sales representatives arranged for an Amgen clinical support person to conduct the chart review.

44. At certain of DaVita's clinics, the DONs resisted allowing Amgen sales staff to review patient charts. When that happened, the Amgen representatives were trained to enlist the aid of the clinic administrator, who usually understood that the Amgen chart reviews were intended to instruct DaVita personnel on how to maximize Epogen usage and to increase the sales of the DaVita clinic. Often, the administrators instructed the DON to allow chart review by Amgen. When these direct efforts to obtain confidential medical records failed, the next recourse was for the salesperson to advise his or her superior, typically the Amgen regional sales manager. The sales manager then contacted higher-up authorities on the "business side" of the clinic and arranged for the Amgen representative to have access to the clinic's patient charts.

45. Once the Amgen salesperson or the Amgen clinical support person obtained access to patient charts or patient-specific data, the goals were simple and straightforward: (1) maximize the frequency and dosage of Epogen treatments for as many patients as

possible, and (2) continue Epogen treatments even after patients' hematocrit levels were above 36%, without regard to medical need and/or good medical practice. This practice increased Amgen's sales revenue while, at the same time, increasing profits at DaVita's clinics. DaVita profited from each Epogen administration, because of the "spread" between DaVita's purchase price and the Federal Government's reimbursement rate. Further, as discussed below, DaVita obtained volume discounts by increasing sales, further increasing its spread and, subsequently, its profits. Thus, with respect to increasing Epogen usage, the financial interests of seller Amgen and DaVita's clinics were aligned.

46. Thus, even though the FDA label set out the target hematocrit level of between 30% and 36%, DaVita personnel, with the assistance and training by Amgen sales representatives, were instructed to push hematocrit levels above the target range. As part of his required tactics to increase sales, Relator taught—at Amgen's behest—DaVita employees to increase the clinics' Epogen usage by driving patients' hematocrit levels above 36%. In his dealings with DaVita employees and his review of patients' records, Relator saw that DaVita followed through with Amgen's recommendations of increasing Epogen dosage.

47. DaVita's systematic increasing of hematocrit levels were brought about through higher Epogen dosages and uninterrupted treatments, neither of which was supported by scientific research nor permissible under the FDA Label for Epogen. Higher Epogen doses, of course, enabled DaVita to bill more Epogen doses to the Federal Government and qualified it for a greater volume discount from Amgen. Both the increase

in sales and the increase of discounts and rebates increased DaVita's profit from Epogen.

48. The sole "basis" for striving for these higher hematocrit levels was that most fiscal intermediaries for the Federal Government allowed for Epogen reimbursement at hematocrit levels of 36% to 37.5% and above without running a substantial risk of additional review. As the Amgen sales staff and DaVita's clinics knew, only around when hematocrit levels reached 40% or above was there a "red flag" with these intermediaries. But, even then, the Federal Government would pay once the usage was "justified" for a given treatment regimen, regardless of an individual patient's diagnosis or medical necessity. Amgen personnel provided a list of reasons that could be used by DaVita's clinics to justify a hematocrit level of 40% or above (*i.e.*, the coding of "angina," a relatively subjective diagnosis, was a Medicare-accepted justification). Relator used such a list as part of his normal sales practices, including use at DaVita clinics within his territories. Therefore, in the event that a fiscal intermediary reviewed the Epogen treatments of a patient with a hematocrit above the target range, DaVita's employees had been trained on the proper ICD-9 code to use. Also, DaVita's facilities often had been provided draft letters with language that the Federal Government considered appropriate justification for exceeding recommended dosages.

49. In Relator's experience, although doctors at DaVita's 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 with the approval of DaVita's staff.

50. Relator Woodard is aware of the cooperative efforts between Amgen and DaVita to maximize the administration of Epogen. He specifically conducted anemia management training or chart reviews at many of DaVita's dialysis clinics. Even though Woodard opposed the practice, he estimates that he conducted anemia management training or chart reviews at approximately 25% of the clinics for which he was responsible because 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, approximately 50% to 70% of DaVita's clinics permitted Amgen sales staff to conduct chart reviews.

c. Amgen's Assistance in Writing DaVita Protocols for Epogen Administration

51. Another related method by which DaVita manipulated Epogen usage at its dialysis clinics was to allow Amgen to write the clinics' internal protocols for Epogen usage. Whenever possible, Amgen took 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 that its salespeople could utilize in preparing internal protocols for clinics. Relator used this type of program during sales calls on renal clinics, including those owned by DaVita, and he participated in the design of protocols for Epogen usage in DaVita's clinics.

52. Although Epogen's FDA Label in 1999 specified 30 to 36% hematocrit as the target range,[1] DaVita's protocols under the Amgen program encouraged 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 by patient need, and without regard to patient benefit. As confirmed in research studies, the more aggressive dosing of Epogen recommended by DaVita was the likely explanation for the "over-utilization" of Epogen in the DaVita chains as compared to other for-profit dialysis facilities.

53. With input from Amgen as previously noted, DaVita designed protocols to increase its usage of Epogen. Examples of DaVita's protocols included the following provisions:

- Once a patient's hematocrit level is greater than 36%, this constitutes the beginning of the maintenance phase, and the current dosage should be decreased ten percent. Actual dose after adjustment may be rounded to the nearest 100 units (i.e., 3850u rounded to 3900u).

- Subsequent decreases of ten percent or increases of 25% can be made every four weeks to move and maintain hematocrit within the acceptable range of 33 to 36%.

- With proper adjustment, Epogen should be held only if hematocrit is greater than 39.9% and there is no medical justification to maintain a higher level. Weekly

[1] As previously noted, the 1993 FDA Label for Epogen specified a target range for hematocrit at 30 to 33%.

monitoring of hematocrit is appropriate at this time.

54. DaVita protocols were not consistent with CMS guidelines and FDA label indications for Epogen usage. For CMS and the FDA, the label indications were to target hematocrit at 30 to 36% and to reduce the Epogen dosage as hematocrit approaches 36%. In DaVita's protocol, Epogen usage should not be decreased until after the patient's hematocrit exceeds 36%, and at that point, dosage should only be decreased by ten percent. The FDA Label, on the other hand, indicates that dosage should be decreased by 25% before the patient's hematocrit level reaches 36%. If the patient's hematocrit drops below 36%, DaVita's protocol calls for increased dosages by 25%; this strongly indicates that DaVita's intention is to keep hematocrit levels above 36%. In contrast to DaVita's protocol of quickly increasing dosage, its protocol does not call for a 25% decrease in dosage until hematocrit levels reach 40% and no medical justification can be noted for a continuation of treatment; again, this is contrary to the package insert and FDA instructions for Epogen usage. Having trained DaVita's staff and having reviewed DaVita patients' medical files, Relator knows that the requirement of "medical justification" was contrived by DaVita as a nominal impediment to Epogen administration. DaVita's staff was instructed on how to code files for continued Epogen usage, was encouraged to continue the administration of the drug, and routinely caused their patients to have hematocrit levels in excess of 40%.

55. While these protocols may have been created under the guise of "patient safety" or "medical necessity," they in fact eschew these goals in favor of increasing Epogen usage for DaVita's financial gain. Without question, permitting Amgen employees

to create the protocols governing the very drug that Amgen sold seriously undermines any argument that the protocols had patient safety or medical necessity as their bases.

56. Whether developed in-house or by Amgen's salespeople, DaVita designed protocols to maximize Epogen use without regard to medical necessity, were contrary to the FDA label and CMS guidelines, and were potentially harmful to its patients. Some of the protocols may have even noted that the CMS allowed a rolling hematocrit average of 37.5%, which was outside the parameters of the FDA Label.

57. Through anemia management training, chart reviews, and the drafting of protocols, DaVita and Amgen met their financial goals of maximizing Epogen usage without regard to medical necessity. Based on Relator's experience while working at Amgen and in adjusting patients' Epogen levels, DaVita personnel and Amgen sales representatives did not take into account the individualized circumstances of the patient. Furthermore, they did not take into account whether, for a particular patient, there would be medical benefits resulting from an increase in dosage to levels beyond the target range. Instead, the sole consideration was how to increase the dosage. Thus, with encouragement from Amgen, DaVita's personnel regularly administered Epogen well beyond the recommended target range of hematocrit levels between 30% and 36%.

(4) Studies Do Not Support the Use of Epogen to Increase Hematocrit Levels Above 36%

58. Scientific studies have repeatedly found that ESRD patients show an increase in adverse effects and/or no medical benefit from the normalization of hemoglobin/hematocrit levels. In the trials that supported the original approval of Epogen

and Procrit, evidence was presented of an increased risk of thrombotic events, such as severe or catastrophic cardiovascular adverse events. Several years later, researchers found that the targeting of higher hematocrit levels than required for avoidance of transfusion caused an increased risk of fatal cardiovascular events and impaired survival. By the time of FDA-approval of the 1999 label, it referenced medical research findings that Epogen usage for patients with a maintained hematocrit level at 42 ± 3% resulted in a statistically-significant increase in the risk of mortality.

59. Researchers have repeatedly found that there is no additional benefit in the quality of life for increasing hematocrit levels above 36%. Moreover, having found that target hematocrit levels of approximately 40% are associated with poorer outcomes and increased risks among patients with anemia caused by chronic kidney disease, researchers concluded that target hematocrit levels should not be higher than 36% and that Epogen should be discontinued, not merely reduced, when patient hematocrit levels reach 39%.

(5) For-Profit Dialysis Facilities Administer the Highest Epogen Dosages and Target Higher Hematocrit Levels than Not-For-Profit Facilities

60. In a study published in the Journal of the American Medical Association in April 2007, researchers and medical doctors found that patients in for-profit dialysis facilities, such as those owned by DaVita, "were consistently administered the highest doses of epoetin regardless of anemia status."[2] Based on empirical data on 159,522 Medicare-eligible ERSD patients collected from the U.S. Renal Data System, the study

[2] Dialysis Facility Ownership and Epoetin Dosing in Patients Receiving Hemodialysis, M. Thamer, PhD, et al., JAMA, April 18, 2007, 297: 1667.

found that "[d]ifferent epoetin dosing patterns suggest that large for-profit chain facilities used larger dose adjustments and targeted higher hematocrit levels."[3]

61. Studies have found that for-profit facilities, such as DaVita, continued to increase Epogen dosages in patients who had reached the hematocrit target of 33%. The studies further noted that for-profit facilities commonly increased Epogen dosage until their patients' hematocrit had reached the target of 36%. Based on empirical data, this "overshooting" of the recommended hematocrit target was significantly more prevalent in for-profit chain facilities than in not-for-profit chain facilities.

62. Despite the large differences in Epogen dosages and treatment regimens between for-profit and not-for-profit facilities, the study found that most not-for-profit facilities meet CMS performance goals (*i.e.*, 70% of patients having a hematocrit level in excess of 33%).

(6) DaVita's Records Demonstrate the Over-Utilization of Epogen, Particularly at Hematocrit Levels Above 36%

63. DaVita's unnecessary administration of Epogen on patients with hematocrit levels above the target range grew exponentially from 1995 through 2004. During that period, for patients receiving Epogen despite a three-month rolling average hematocrit ("a rolling average hematocrit") at or above 37.5%, DaVita's billings for Epogen to the Federal Government's Medicare program grew from annual sales of $858,082 to $87,669,999 (an increase of 10,216%). Similarly, for patients with a rolling average hematocrit above 40%, DaVita's billings for Epogen to Medicare increased from $204,372 to $30,290,083 (an increase of 14,821%) during that same ten year period.

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[3] *Id.* at 1667.

64. DaVita also saw exponential growth during certain years. From 1998 to 1999, Davita's claims and billings for Epogen where the patient's rolling average hematocrit was in excess of 37.5% increased from $7,915,932 to $30,202,666 (an increase of 282%). Similarly, from 2003 to 2004, DaVita's Epogen billings to Medicare increased from $61,489,247 to $87,669,999 (an increase of 43%).

65. Likewise, Davita's claims and billings for Epogen in which the patients' rolling average hematocrit levels were in excess of 40% increased from $2,159,613 to $9,456,830 from 1998 to 1999 (an increase of 388%), and from $20,215,884 to $30,290,083 from 2003 to 2004 (an increase of 50%).

66. In 1998, approximately 10% of all dialysis patients had hematocrit levels that exceeded 36%, but by 2000, 40% of all dialysis patients receiving Epogen had hematocrit levels above the target amount. During that same time, there was also a significant increase in the average Epogen dose administered to dialysis patients. These increases occurred despite the fact that, in 1998, the Normal Hematocrit Study showed that there was a higher risk of death or myocardial infarction in aiming for a hematocrit level of 42%.

67. In January 2001, DaVita charted the percentages of Epogen administrations for patients with specific hematocrit levels. After outlining the percentages of distribution for particular divisions, the chart provides the "DaVita Total": 9.7% of Epogen administrations were for patients who had a hematocrit of less than 30%; 14.8% were for patients between 30 and 32.9%; 27% were for patients between 33 and 36%; and 48.5% of DaVita's Epogen administrations were for patients with hematocrit levels in excess of

36%. In other words, almost half of DaVita's Epogen administrations were for patients with hematocrit levels in excess of the target range.

68. Between 1998 and 2004, DaVita submitted claims to Medicare and was paid $301,774,256 for Epogen administered to patients whose rolling average hematocrit levels were in excess of 37.5%. The $301 million represented 20.08% of DaVita's Epogen charges during that seven-year period. Other for-profit facilities had a lower percentage of patients with rolling average hematocrit levels of more than 37.5%, such as DCI with 7.59%, and Fresenius with 12.90%. As noted in the preceding reference to medical studies, the not-for-profit facilities had considerably lower percentages.

69. Also from 1998 to 2004, the Federal Government's Medicare program paid $137,570,905 to DaVita for Epogen administered to patients whose rolling average hematocrit levels were greater than 40%. The $137 million was 9.15% of DaVita's Epogen billings to Medicare during that same period. Other for-profit facilities had a lower percentage of patients with rolling average hematocrit levels of more than 37.5%, such as DCI with 7.59% and Fresenius with 12.90%.

70. Administration of Epogen under these circumstances was contrary to package labeling instructions, was potentially harmful to patients, was without medical necessity or patient need, and hence constituted false claims. DaVita's increased administration of Epogen to patients with hematocrit levels above the medically-appropriate target levels occurred as part of a scheme to increase revenue. The billings constituted false claims because they were submitted with a pattern of disregard to medical necessity or patient need, contrary to package labeling instructions, and in such

amounts as could be potentially harmful to patients.

(7) Medical Records of DaVita's Patients Confirm that DaVita Administered Epogen with Reckless Disregard for FDA Labels and CMS Guidelines

71. Relator was provided an opportunity to have a sampling of 15 patient files reviewed for Epogen administration in order to determine whether DaVita complies with CMS guidelines and the FDA label. The files were randomly chosen from a list of patients who had at least two billing cycles with a three-month rolling average of hematocrit above 40%, and a summary of the file was provided to Relator for review. Relator found that DaVita disregarded not only the CMS guidelines and FDA label, but also its own protocols for the over-utilization and administration of Epogen.

72. Relator hereafter provides examples of Epogen administration that show periods of three treatment-weeks or more in which DaVita administered treatments to patients with no decreases in dosage despite the fact that the patients had hematocrit levels or 40.0% or higher. Relator found evidence of these extreme practices in 14 of the 15 patient files that were made available for review. Such repeated treatments with no reduction of dosage demonstrate DaVita's pattern and scheme of over-use of Epogen without medical necessity and at risk to the well-being of its patients.

73. Below, Relator also provides the number of times that each patient's average hematocrit level for the preceding three months ("three-month average") was 40.0% or greater. The 40% average was selected because such continued Epogen treatments are dramatically higher than would could be held medically necessary and/or in patients' best interests. Additionally, under current CMS guidelines, the Federal Government no longer pays for Epogen treatments provided to patients with a hematocrit above 39% under

certain circumstances; therefore, the selection of a 40% three-month average demonstrates DaVita's over-administration of Epogen.

74. To protect the privacy interests of the patients whose files have been reviewed, Relator hereafter refers to the patients by their initials. Relator is willing to provide the patients' full names and the available records to DaVita, and will tender this information to the Court under seal, if requested.

75. Patient JA received dialysis treatment from DaVita at its facility, Dialysis Systems of Hammond, in Hammond, Louisiana. During the period of March 23 to April 17, 2002, Patient JA had a hematocrit level of 40.2 to 42.0%, but DaVita administered and submitted false claims to CMS for seven consecutive Epogen treatments of 12,000 units. Patient JA's records also indicate three consecutive months in which his three-month average hematocrit level was above 40.0%.

76. Patient WC received dialysis treatment from DaVita at ACQ-Owensboro Dialysis Center in Owensboro, Kentucky. From April 24 to May 10, 2004, Patient WC received nine Epogen treatments of 8,500 units, even though his hematocrit was 41.1%. For the period of July 14 to August 9, 2004, DaVita administered and submitted false claims to CMS for 12 Epogen treatments of 3,800 units to Patient WC, despite his hematocrit level ranging from 42.0 to 42.3%. Also, Patient WC received five noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

77. Patient AD received dialysis treatment from DaVita at Hemacare Dialysis or PDI Cadieux in Detroit, Michigan. During the time period of October 5 to October 31,

2001, Patient AD had a hematocrit level of 46.5%, but DaVita provided and submitted false claims to CMS for 12 Epogen treatments. For each of the 12 Epogen administrations, Patient AD received 1,000 units of Epogen. Patient AD's records also indicate eight noncontiguous months in which her three-month average hematocrit level was above 40.0%.

78. Patient ERG received dialysis treatment from DaVita at Dialysis Center of Anson in St. Wadeboro, North Carolina. For the period October 27 to November 22, 2004, Patient ERG had hematocrit levels ranging from 40.5 to 48.3% (increasing over the course of the treatment period). Nevertheless, DaVita administered and submitted false claims to CMS for 12 consecutive Epogen treatments of 20,000 units per treatment. Also, Patient ERG received five noncontiguous months of treatment in which her three-month average hematocrit level was above 40.0%.

79. Patient CMH received dialysis treatment from DaVita at Dialysis Care of Kannapolis South in Kannapolis, North Carolina. From March 29 to April 19, 2003, Patient CMH had a hematocrit level of 44.4 to 44.7%, yet during that period, she was administered ten treatments of Epogen. For each treatment, Patient CMH received 14,000 units of Epogen. On April 21 through May 7, 2003, Patient CMH had a hematocrit of 42.9 to 44.4%, but DaVita provided and submitted false claims to CMS for eight treatments of Epogen at 13,000 units. Additionally, Patient CMH received six noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

80. Patient JCH received dialysis treatment from DaVita at Ocala South Unit in Lady Lake, Florida. From September 28 to October 28, 2002, Patient JCH had a

hematocrit level of 44.1 to 46.2%. During that period, DaVita administered and submitted false claims to CMS for 14 consecutive Epogen treatments of 8,100 units. Patient JCH's records also indicate nine noncontiguous months in which his three-month average hematocrit level was above 40.0%.

81. Patient AJL received dialysis treatment from DaVita at Hopewell Dialysis Center in Hopewell, Virginia. During the time period of September 25 to October 13, 2004, Patient AJL had a hematocrit level ranging from 42.0 to 46.8%, yet she received six consecutive administrations of Epogen. For each treatment, Patient AJL received 12,000 units of Epogen. Also, Patient AJL received three consecutive months of treatment in which her three-month average hematocrit level was above 40.0%.

82. Patient JTL received dialysis treatment from DaVita at Tomball Dialysis Center in Tomball, Texas. From May 10 to May 24, 2003, Patient JTL had a hematocrit level of 40.2 to 42.3%, but DaVita administered and submitted false claims to CMS for seven Epogen treatments of 6,000 units. In October and November 2003, Patient JTL had a hematocrit level of 41.1 to 42.6%. During that period, she received ten Epogen treatments of 9,000 units per treatment.

83. Patient ML received dialysis treatment from DaVita at Santa Ana Dialysis Center #875 in Santa Ana, California. From July 2 through July 21, 2003, Patient ML had a hematocrit of 40.2%, but DaVita administered and submitted false claims to CMS for nine consecutive Epogen treatments of 10,000 units per treatment. For the period of November 17 through December 10, 2003, Patient ML had a hematocrit of 43.2 to 44.1%, but she received ten Epogen treatments of 4,000 units per treatment. Similarly, from April 24 to

May 22, 2004, Patient ML had a hematocrit level of 41.1 to 43.5%. During that period, she received 13 treatments of 6,000 units per treatment. Additionally, Patient ML received five noncontiguous months of treatment in which her three-month average hematocrit level was above 40.0%.

84. Patient MML received dialysis treatment from DaVita at Grand Blanc Dialysis Center #156 in Grand Blanc, Michigan. For the period of July 17 to August 4, 2004, Patient MML had a hematocrit level of 41.7 to 43.2% (increasing throughout the treatment period). During that interval, she received nine Epogen treatments of 6,000 units per treatment. From August 7 through September 6, 2004, Patient MML had a hematocrit level of 41.7 to 44.7%. For that period, Patient MML received 14 Epogen treatments of 5,400 units per treatment. Additionally, Patient MML received six consecutive months of treatment in which her three-month average hematocrit level was above 40.0%.

85. Patient ML received dialysis treatment from DaVita at Loma Vista Dialysis Center in El Paso, Texas. From November 15 to December 3, 2003, Patient RL had a hematocrit level of 42.3 to 44.1%. During that period, DaVita administered and submitted false claims to CMS for nine Epogen treatments of 10,000 units. As an aside, the same treatment continued for six additional administrations after Patient RL's hematocrit level decreased to 39.9%. From March 27 to April 28, 2004, Patient RL had a hematocrit of 43.5 to 45.0% (increasing throughout this period), but she received 15 Epogen treatments of 2,800 units per treatment. Patient RL received seven consecutive months of treatment in which her three-month average hematocrit level was above 40.0%.

86. Patient FM received dialysis treatment from DaVita at Complete Dialysis North in Coral Springs, Florida. From November 22 to December 15, 2003, Patient FM had a hematocrit level of 41.1 to 45.3% (increasing during the treatment period). During that period, DaVita administered and submitted false claims to CMS for 11 Epogen treatments of 1,000 units per treatment. From December 17, 2003 through May 5, 2004, Patient FM received 55 Epogen treatments even though his hematocrit was always between 40.8 and 45.3%. During that four-and-a-half month period, DaVita never withheld or reduced a treatment. Also, Patient FM received 11 noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

87. Patient EMR received dialysis treatment from DaVita at Medcenter Dialysis Center #917 in Houston, Texas. From April 21 to May 26, 2003, Patient EMR had a hematocrit level of 40.2 to 42.0%, but DaVita administered 15 Epogen treatments of 1,800 units per treatment. For the period of February 25 through March 22, 2004, Patient EMR had a hematocrit level of 44.1 to 44.7%, but he received 12 consecutive treatments of Epogen at 5,600 units per treatment. From July 24 through August 9, 2004, Patient EMR had a hematocrit level of 40.2 to 41.1%, but DaVita administered and submitted false claims to CMS for eight Epogen treatments at 10,000 units per treatment. From August 11 through September 20, 2004, Patient EMR had a hematocrit level ranging from 41.1 to 44.1 %, but he received 18 Epogen treatments at 7,500 units per treatment. Also, Patient EMR received 19 noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

88. Patient RR received dialysis treatment from DaVita at Peninsula Dialysis Center in Newport News, Virginia. From March 3 to April 7, 2004, Patient RR had hematocrit levels from 40.8 to 43.8% (increasing throughout the treatment period). During that time, DaVita administered and submitted false claims to CMS for 17 Epogen treatments to Patient RR with 6,500 units in each treatment. Additionally, Patient RR received two consecutive months of treatment in which his three-month average hematocrit level was above 40.0%.

89. Patient TES received dialysis treatment from DaVita at Dialysis Care of Rowan County in Salisbury, North Carolina. Patient TES received 15 noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

90. For each of the patients referenced above, CMS guidelines and FDA label indications dictate that Epogen administration should have been reduced or held because the target hematocrit level of 36% had been greatly exceeded. In each of these cases, however, DaVita administered the Epogen without reductions. Without regard to medical necessity or patient need, DaVita submitted false claims to the Federal Government for its repeated treatment of these patients and received payment based on its fraudulent charges. These randomly sampled patient files, which were from different regions and treatment periods, demonstrate DaVita's systematic, nationwide pattern of over-utilization of Epogen without regard to medical necessity or patient need.

F. DaVita's Capture and Use of Epogen Overfill for Increased Profits

(1) Purpose of Overfill in Epogen Vials

91. General guidelines for injections outlined in the United States Pharmacopeia ("USP") require that Epogen vials have an excess volume, which is sufficient to permit withdrawal and administration of the labeled fill volumes. The USP test to determine if a vial meets this requirement specifies that the contents of the test vial be drawn into a dry hypodermic syringe fitted with a 21-gauge needle not less than one inch in length. The contents of the syringe are then discharged, without emptying the needle, into a graduated cylinder. The volume measured cannot be less than the labeled volume.

92. To meet the vial filling requirement, the USP generally recommends a 0.1 mL overfill for a labeled fill volume of 1.0 mL and a .15 mL overfill for a labeled fill volume of 2.0 mL. Taking into account the Epogen vial-closure system and the filling variance in vial-filling equipment, Amgen deteremined that a "target" fill volume of 1.168 mL for a single-dose vials and 2.168 mL for the 2 mL multidose vials would assure that the labeled fill volume of Epogen could be readily withdrawn. Before the overfill percentages were essentially equalized, multi-use vials were "overfilled" by approximately 12 percent, while the single-use vials were "overfilled" by as much as 25 percent.

(2) FDA Labels - 1993 and 1999

93. The 1993 and 1999 FDA Label specify that the single-dose 1mL vials of Epogen contain no preservatives. They further specify: "Use only one dose per vial; do not re-enter the vial. Discard unused portions." The vials also are labeled for "single-use only."

(3) Risks to Patients Caused by Multiple Entries into Single Dose Vials

94. To avoid potential infection risks to the patient, Amgen's official position is and has been that single-dose vials cannot be pooled and re-used. Instead, the potentially contaminated overfill in single-use vials should be discarded after the single dose has been withdrawn. In undated correspondence with DaVita's clinicians in approximately 2000, Amgen noted:

> As supplied, EPOGEN in single dose vials is a sterile solution. Although multidose vials with preservative are available, single dose vials **DO NOT** contain a preservative. Once a syringe has entered a single dose vial, the sterility of the product can no longer be guaranteed. The instructions provided in the labeling for the product under the section 'Preparation and Administration of EPOGEN' state: '*Single-dose 1mL vial contains no preservative. Use one dose per vial; do not re-enter vial. Discard unused portions*.'

(emphasis in original).

95. In other correspondence with clinicians, Amgen noted that it "cannot and will not condone unsafe practices that may be utilized to capture any overfill, such as the pooling of unused portions of the Single-Dose Preservative-Free vials of Epogen."

96. Amgen advised DaVita of the health risks associated with the capturing of overfill. For example, such practices resulted in at least one CDC-reported case of Serratia liquefaciens sepsis "in a dialysis unit where EPOGEN had been extrinsically contaminated by personnel during pooling of the overfill of the single use vials." On a separate occasion, Amgen advised dialysis clinics that it was aware of at least 21 episodes of bacteremia or pyrogenic reactions under similar circumstances.

97. Because of such risks, many states prohibit multiple entries into single-use vials in their pharmaceutical laws and regulations. Under the circumstances, multiple

entries into Epogen vials are contrary to the recommended use and good medical practice.

(4) Despite its Official Prohibition on Re-entry into Single Dose Vials, Amgen Instructed DaVita on the Financial Benefits of Epogen Overfill

98. Despite its official position that overfill could not be utilized through a reentry into single dose vials, Amgen employees such as Relator taught DaVita's employees to make multiple entries into the single use vials, to extract the overfill, to administer this "captured" overfill to patients, and to bill the Federal Government at the regular price for the captured overfill.

99. Amgen's sales representatives (including Relator) provided DaVita's staff with visual aids to show the profit that could be earned by using 10% overfill from Epogen vials. Relator used this type of visual aid during his sales calls to clinics, including DaVita-owned clinics. Through techniques such as this, Amgen's sales representatives marketed the sale of Epogen single-use vials based on its unnaturally and illegally high profitability.

100. In part from training by Amgen employees like Relator, DaVita's dialysis clinics were aware 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 the Federal Government as though it came from new vials.

(5) DaVita's Capture and Use of Epogen Overfill

101. Since on or about 1992, DaVita instructed its employees to make multiple entries into single-use vials of Epogen to capture the overfill, and Relator believes that these instructions may have been reduced to writing. DaVita combined the overfill from multiple vials to form additional doses of Epogen and the "recaptured," additional doses of Epogen were administered to patients and were billed to the Federal Government as if

they came from new vials. Such multiple entries into single-use vials were a violation of standard medical practice and many state laws. The practice also violated the government's conditions of coverage, which required use of medications according to their labels or consistent with good medical practice, and also the required disclosure and the passing along of pricing discounts to the Federal Government.

102. DaVita was so interested in the volume of Epogen that it could obtain from pooling and selling the overfill from single-use vials that, as part of its business model, it tracked the volume of Epogen "captured" through this process. In fact, DaVita regularly generated reports that tracked the amount of Epogen captured by its facilities per month. Such reports demonstrate—with surprising clarity—that DaVita administered more Epogen than it had in its inventory.

103. In just one report for DaVita's Atlantic region, the high volume of captured overfill and the over-charging for Epogen to the Federal Government becomes very clear. The report also demonstrates that DaVita's facilities captured, administered, and sold Epogen overfill as a part of a company-wide effort to generate undue income and to mislead CMS and the Federal Government.

Facility	Monthly	Epogen	Usage	Year-to-Date	Epogen	Usage
	Units Administered	Units from Inventory	Volume Captured	Units Administered	Units from Inventory	Volume Captured
Atlantic Stars Region 1	32,811,000	29,878,000	9.82%	205,887,420	187,465,000	9.83%
Atlantic Stars Region 2	44,802,100	41,524,000	7.89%	248,542,200	229,758,000	8.18%
Atlantic Stars Region 3	48,242,300	40,349,000	19.56% (likely inflated by clerical error)	255,146,400	228,184,000	11.82% (likely inflated by clerical error)
Atlantic Stars Region 4	50,018,300	47,750,000	4.75%	173,724,100	162,890,000	6.65%
Atlantic Stars Region 5	43,123,300	40,190,000	7.30%	198,957,800	182,974,000	8.74%
Atlantic Stars Region 6	63,473,600	58,770,000	8.00%	307,413,000	284,700,000	7.98%

104. DaVita's strategic use of overfill in Epogen vials—knowledge gained from Amgen sales representatives such as Relator—is the only way that DaVita could so consistently administer more Epogen to patients than it had in its inventory. DaVita's careful tracking of Epogen capture by year, month, and facility—combined with the powerful financial incentives to use as much Epogen as possible—indicates its calculated misuse of Epogen for the maximization of profit.

105. The Federal Government did not foresee that outpatient dialysis facilities would attempt to submit Epogen doses for which they had not paid. Therefore, DaVita's outpatient dialysis facilities were not required to submit figures for the Epogen units purchased as well as the units administered on their cost reports. This effectively prevented the Federal Government from tracking DaVita's misuse of Epogen overfill.

(6) DaVita Urged Medical Care Providers to Prescribe Dosages that Would Include an Assumed, Constant Overfill

106. In the course of his research on DaVita's handling of overfill, Relator has uncovered that DaVita changed its practice of handling overfill in approximately 2005. At or about that time, DaVita acquired Gambro, another for-profit dialysis center. Gambro also was manipulating its charges for Epogen overfill, albeit in a different manner than DaVita.

107. Prior to its acquisition by DaVita, Gambro had implemented protocols that assumed a constant, guaranteed overfill in the single-dose vials of Epogen and involved the administration of multiple, single-dose vials in order to achieve a desired dose. As previously noted, multi-use vials had roughly half the overfill volume of single-dose vials, so Gambro and DaVita used single-dose vials in order to profit from the administration of the higher overfill in the single dose vials. Gambro assumed that all Epogen doses had a constant overfill and calculated the overfill amount at different times to be between 10% and 15%. For example, at one point, a single dose vial of 3,000 units of Epogen was assumed to have 3,300 units, and at a different time, 3,450 units, and at yet another time, 3,330 units. Administering the assumed overfill amount, Gambro protocols changed the required doses of Epogen accordingly, and the physicians were asked to follow the corporate Epogen protocol.

108. For example, under the Gambro protocol, if the patient required 7,700 units of Epogen, the protocol mandated administration of said dose out one vial of 3,000 units and one of 4,000 units, rather than administration from one multi-dose vial. Assuming that there was 10% guaranteed overfill, Gambro billed the Federal Government for 7,700 units,

but, because the 10% overfill was “free,” only used 7,000 units from its inventory. At other times, when the assumed overfill was 11%, Gambro changed the protocol for example to 7,770 units, which were still administered from a combination of the 4,000 unit vial and 3,000 unit vial. Although Gambro purchased the vials of 7,000 units, it billed the Federal Government for 7,770 units.

109. Due to the discrepancy between the billed dose and the labeled dosages, it is likely that patients did not actually receive the amount of Epogen that was billed. As in the above example, the labels on the two vials showed 7,000 units available, but the billing records show that 7,700 units were administered.

110. Davita allowed the aquired Gambro Clinics to continue with the same protocols for Epogen, and in 2007, DaVita adopted this protocol for all of its dialysis centers with small modifications.

111. DaVita’s revised Epogen protocol exposed patients to unnecessary risks arising from the use of multiple vials, syringes, and injections. The protocol mandates up to five vial combinations in order to achieve a desired dose. On the other hand, if DaVita’s staff had drawn the dosage from a multi-dose vial of Epogen, patients would have required only one syringe and one injection. The use of multi-use vials of Epogen would have served the best medical interests of DaVita’s patients, but DaVita placed profit from the billing for “free” product ahead of its patients’ interests.

112. Such a practice not only continued DaVita’s scheme of over-utilization of Epogen in an attempt to maximize revenue, but it also created a new problem: DaVita’s charging for medication that it did not provide. DaVita billed for a constant, guaranteed

overfill with no assurance that its staff could pull that much overfill from the vials. As indicated in the chart above, most of DaVita's clinics were not able to pull a full 10% of overfill from each single dose vial. Therefore, by billing as if 10% to 15% overfill was provided in such dosages, DaVita was fraudulently billing for medication that had not been administered.

113. Similar to the practice of pooling overfill for administration in subsequent treatments, the prescription and administration of the overfill resulted in windfall profits to DaVita that it did not report to the Federal Government as a discount or rebate for the proper computation of the sales price.

114. DaVita's protocols for Epogen administration, which mandates the use of multiple single-dose vials, multiple syringes, and multiple injections is in stark contrast with other DaVita protocols, which emphasize minimizing the number of vials and syringes and injections for patient and staff safety. DaVita's Epogen protocols, past and present, show disregard to patients' welfare and are geared only to maximize profits.

(7) DaVita's Use of Epogen Overfill Conflicts with its Practice of Wasting Other Medications, Such as Zemplar, for which the Federal Government Pays DaVita by the Vial

115. DaVita's manipulation and use of overfill stands in stark contrast to its wasteful practices in the administration of other drugs, such as Zemplar. Not coincidentally, the Federal Government paid DaVita for Zemplar by the vial, as opposed to its payment for Epogen by the dosage.

116. With Zemplar and other medicines for which it was paid by the vial, DaVita made no effort to collect overfill or to maximize the utility of each vial of medicine. To the

contrary, DaVita decreased dosages and increased the number of treatments. DaVita also directed that its clinics should discard the unused portion of the vials, even if other patients were readily available to receive the unused portion of the single-use vial. This enabled DaVita to maximize its charges for the single-use vials, a practice that conflicts with its misuse of Epogen overfill.

117. DaVita's abusive practices in the administration of drugs, such as Zemplar, illustrate that billing guidelines and profit motives dictate the treatment regimen (including the frequency and dosage of treatment) of drugs billed separately to the Federal Government.

V. CAUSES OF ACTION

A. Count One: DaVita Violated the Fraud and Abuse Statutes by Not Disclosing Discounts and Other Remuneration Arising From its Epogen Purchases

118. The allegations of Paragraphs 1 through 117 are incorporated herein by reference.

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

120. As noted above, compliance with all applicable laws and regulations is a condition of coverage for the Federal Government's reimbursement of dialysis treatments. 42 C.F.R. § 405.2135; 42 C.F.R. § 494.20.

121. DaVita violated 42 U.S.C. §§ 1320a-7a & 7b in that:

a. DaVita purchased Epogen from Amgen at a reduced, rebated price;

b. DaVita failed to disclose or pass on the discounts and rebates to the Federal Government, either in its bills for Epogen or in HCFA-265;

c. The undisclosed discounts and rebates constituted prohibited remuneration under 42 U.S.C. §§ 1320a-7a & 7b, because the discounts and rebates were paid by Amgen in exchange for DaVita's purchase of Epogen, which was then reimbursed by the Federal Government.

122. DaVita also violated 42 U.S.C. §§ 1320a-7a & 7b in that:

a. Amgen provided anemia management training and support to DaVita's staff. Amgen provided this service free of charge to DaVita and thereby saved it substantial training expenditures each year;

b. The anemia management training that Amgen provided to DaVita constituted prohibited in-kind remuneration under 42 U.S.C. §§ 1320a-7a & 7b because it was provided in exchange for DaVita's purchase of Epogen, which was then reimbursed by the Federal Government.

123. DaVita violated 42 U.S.C. §§ 1320a-7a & 7b in that:

a. DaVita received and administered overfill as "free" product;

b. DaVita failed to disclose or pass on the savings associated with the administration of overfill to the Federal Government, either in its bills for Epogen or in compliance with HCFA-265;

c. The undisclosed savings resulting from the administration of overfill

constituted prohibited remuneration under 42 U.S.C. §§ 1320a-7a & 7b, because the "free" product was provided by Amgen in exchange for DaVita's purchase of Epogen, which was then reimbursed by the Federal Government.

124. Because DaVita falsely certified that it was in compliance with Federal, state and local laws and regulations when in fact it was violating 42 U.S.C. §§ 1320a-7a & 7b, and because such certification was a condition of coverage, DaVita violated 31 U.S.C. § 3729 by knowingly submitting false claims for Epogen to the Federal Government.

125. In return for making these misrepresentations to the Federal Government, DaVita rewarded itself with higher profits in the form of volume discounts, rebates, and kickbacks from Amgen as well as the profit on Epogen that it administered without a sound medical basis for doing so. The United States Treasury has been financially damaged by DaVita's wrongful withholding of its savings and undue profit.

B. Count Two: Fraudulent Over-Administration of Epogen

126. The allegations of Paragraphs 1 through 125 are hereby incorporated by reference. The facts and circumstances demonstrate DaVita's scheme of submitting false claims and its large volume of Epogen sales arising from the wrongful practices.

127. In violation of 31 U.S.C. § 3729(a)(1), Defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States. Alternatively, the Defendant presented or caused to be presented such claims with reckless disregard or deliberate ignorance of their truth or falsity.

128. DaVita violated 31 U.S.C. § 3729 in that it knowingly submitted claims for Epogen administered without regard to medical necessity or patient need as described

above, and by doing so, it was not in compliance with Federal, state, and local laws and regulations, nor was it using the drug consistent with its label or good medical practice, both of which are conditions for reimbursement by the Federal Government.

129. Through procedures, practices, and/or protocols intended to result in the over-administration and over-utilization of Epogen without regard to guidelines for hematocrit level and without regard to medical necessity or patient need, DaVita knowingly submitted false claims for Epogen to the Federal Government.

130. DaVita violated 31 U.S.C. § 3729 in that it knowingly submitted claims for Epogen administered without regard to medical necessity or patient need. DaVita violated conditions for reimbursement by the Federal Government, because it was not in compliance with Federal, state, and local laws and regulations, and it was not using Epogen consistent with its label or good medical practice. In addition to identifying the basic nature, framework, and procedures underlying DaVita's fraudulent scheme, Relator has addressed specific instances of fraud from a random sampling of patient files. Relator will identify additional, specific instances of fraud after engaging in discovery and receiving information under the exclusive control of DaVita.

131. DaVita's submission of false claims, in turn, caused the Federal Government to pay DaVita for medical claims based on false certifications that DaVita had complied with all applicable laws or because DaVita should not have been paid for the administration of Epogen under the circumstances. This resulted in financial injury to the United States Treasury from paying claims that otherwise should not have been paid because they were fraudulently procured and unnecessary.

C. Count Three: Fraudulent Overcharge for Captured Overfill

132. The allegations of Paragraphs 1 through 131 are incorporated herein by reference. The facts and circumstances demonstrate DaVita's scheme of submitting false claims to the Federal Government and its large volume of Epogen sales arising from the wrongful practices.

133. DaVita submitted a substantial volume of false claims to Medicare based on its charges for captured overfill. DaVita received the "captured" medication from distributors free of charge but then billed the Federal Government as if DaVita paid for it in full. In return for making these misrepresentations, DaVita rewarded itself with higher profits from the Federal Government's payments for DaVita's administration of "captured" medication.

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

135. By billing for medication in a manner that was inconsistent with its package insert, by billing for overfill medication, and by billing the Federal Government for more medication than was actually administered to patients, DaVita knowingly submitted false claims for Epogen.

136. DaVita violated 31 U.S.C. § 3729 in that it knowingly submitted claims for Epogen administered as described above. By doing so, DaVita violated conditions for

governmental reimbursement because it was not in compliance with Federal, state, and local laws and regulations, and it was not using Epogen consistent with its label or good medical practice. In addition to identifying the basic nature, framework, and procedures underlying DaVita's fraudulent scheme, Relator has addressed specific instances of fraud based on DaVita's administration of more Epogen than it had in its inventory. Relator will identify additional, specific instances of fraud after engaging in discovery and receiving information under the exclusive control of DaVita.

137. DaVita's submission of false claims, in turn, caused the Federal Government to pay DaVita for claims either based on false certifications that DaVita had complied with all applicable laws or for which DaVita was not entitled to be paid. The United States, unaware of the falsity of the claims and/or statements made by DaVita, and in reliance on the accuracy of DaVita's claims and statements, paid for Epogen by the federally-funded health insurance programs, including Medicare. If the United States had known that the bills presented by DaVita for payment were false, misleading, and fraudulent, payment would not have been made for such claims. The result was injury to the United States Treasury from paying DaVita's medical claims that otherwise would not have been paid.

D. Count Four: DaVita Submitted False Cost Reports

138. The allegations of Paragraphs 1 through 137 are hereby incorporated by reference. The facts and circumstances demonstrate DaVita's scheme of submitting false claims and its large volume of Epogen sales arising from the wrongful practices.

139. Each year, DaVita submitted a cost report known as HCFA-265 to the Health Care Finance Administration. HCFA-265 was required from all dialysis facilities that bill

to the Federal Government and included a certification of DaVita's adherence to federal laws and regulations. The tender of cost data and the certification in HCFA-265 were conditions of coverage. 42 C.F.R. § 405.2138; 42 C.F.R. § 494.180(h)(3).

140. Defendant falsely certified its compliance with federal, state, and local laws and regulations, and because such certification was a condition of coverage by Medicare, Defendant violated 31 U.S.C. § 3729(a)(2) in that it knowingly submitted false claims to Medicare.

VI. PRAYER

WHEREFORE Relator, Ivey Woodard, prays that this Court:

(1) Assess a civil penalty of not less than $5,500 and not more than $11,000 against DaVita, Inc., as provided by 31 U.S.C. § 3729(a), for each and every false claim as a result of its charges to the Federal Government for the administration of Epogen in violation of applicable FDA label and CMS guidelines;

(2) Assess a civil penalty of not less than $5,500 and not more than $11,000 against DaVita, Inc., as provided by 31 U.S.C. § 3729(a), for each and every false claim as a result of its charges to the Federal Government for the administration of Epogen from overfill;

(3) Assess a civil penalty of not less than $5,500 and not more than $11,000 against DaVita, Inc., as provided by 31 U.S.C. § 3729(a), for each and every false claim as a result of its charges to the Federal Government without disclosure of remuneration and discounts that DaVita had received from Amgen;

(4) Award damages in the sum of three times the amount fraudulently billed to

the Federal Government as set forth herein, as provided by 31 U.S.C. § 3729(a), plus interest;

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

(6) Exclude DaVita, Inc. from participation in all Federal health care programs; and

(7) For such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

Relator hereby demands a jury trial.

Dated: January 15, 2010.

By: /s/ Mitchell A. Toups

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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 Federal Rule of Civil Procedure 4(d)(4), true and correct copies of the foregoing were served on all counsel identified below by certified mail, return receipt requested on this 15th day of January, 2010:

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