

)	
UNITED STATES OF AMERICA)	
[UNDER SEAL],)	CIVIL ACTION NO.
)	
PLAINTIFF,)	
)	
v.)	
)	FILED UNDER SEAL
[UNDER SEAL],)	PURSUANT TO
)	31 U.S.C. § 3730(b)(2)
DEFENDANT.)	
)	

COMPLAINT

CIVIL COVER SHEET

APPENDIX H

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

UNITED STATES OF AMERICA
ex rel. ANGELA KELLY

DEFENDANTS

AMGEN CORPORATION

(b) County of Residence of First Listed Plaintiff: _____
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant: _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE
LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)

Roberta D. Liebenberg
Fine, Kaplan and Black, R.P.C., 1835 Market St., 28th Fl.
Philadelphia, PA 19103 (215) 567-6565

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- X 1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | Plf | Def | Plf | Def |
|---|---|-----|-----|
| 1 Citizen of This State | 1 Incorporated or Principal Place of Business in This State | 4 | 4 |
| 2 Citizen of Another State | 2 Incorporated and Principal Place of Business in Another State | 5 | 5 |
| 3 Citizen or Subject of a Foreign Country | 3 Foreign Nation | 6 | 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excl. Veterans) 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 193 Contract Product Liability 196 Franchise	PERSONAL INJURY 310 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Federal Employers' Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle 355 Motor Vehicle Product Liability 360 Other Personal Injury	PERSONAL INJURY 362 Personal Injury - Med. Malpractice 365 Personal Injury - Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage 385 Property Damage - Product Liability	610 Agriculture 620 Other Food & Drug 625 Drug Related Seizure of Property 21 USC 881 630 Liquor Laws 640 R.R. & Truck 650 Airline Regs. 660 Occupational Safety/Health 690 Other LABOR 710 Fair Labor Standards Act 720 Labor/Mgmt. Relations 730 Labor/Mgmt. Reporting & Disclosure Act 740 Railway Labor Act 790 Other Labor Legislation 791 Empl. Ref. Inc. Security Act	422 Appeal 28 USC 158 423 Writ Removal 28 USC 157 PROPERTY RIGHTS 820 Copyrights 830 Patent 840 Trademark SOCIAL SECURITY 861 HIA (1395m) 862 Black Lung (923) 863 DIWC/DIWW (405(g)) 864 SSID Title XVI 865 TST (405(a)) FEDERAL TAX SUITS 870 Taxes (U.S. Plaintiff or Defendant) 871 IRS - Third Party 26 USC 7609
REAL PROPERTY 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability 290 All Other Real Property	CIVIL RIGHTS 441 Voting 442 Employment 443 Housing/Accommodations 444 Welfare 445 Amer. w/Disabilities - Employment 446 Amer. w/Disabilities - Other 440 Other Civil Rights	PRISONER PETITIONS 510 Motions to Vacate Sentence Habeas Corpus 530 General 535 Death Penalty 540 Mandamus & Other 550 Civil Rights 555 Prison Condition		400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 470 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit 490 Cable/Sat. TV 510 Selective Service 550 Securities/Commodities Exchange 875 Customer Challenge 12 USC 3410 X 890 Other Statutory Actions 891 Agricultural Acts 892 Economic Stabilization Act 893 Environmental Matters 894 Energy Allocation Act 895 Freedom of Information Act 900 Appeal of Fee Determination Under Equal Access to Justice 950 Constitutionality of State Statutes

V. ORIGIN

(Place an "X" in One Box Only)

- X 1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from another district (specify)
6 Multidistrict Litigation
7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing. (Do not cite jurisdictional statutes unless diversity)
31 U.S.C. 3729 et seq.

Brief description of cause:

Violation of Federal Civil False Claims Act

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION DEMAND \$
UNDER F.R.C.P. 23 Unascertained

CHECK YES only if demanded in complaint
JURY DEMAND: X Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions)

JUDGE

DOCKET NUMBER

DATE

SIGNATURE OF ATTORNEY OF RECORD

11/30/07

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

UNITED STATES DISTRICT COURT

APPENDIX F

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: See attached

Address of Defendant: See attached

Place of Accident, Incident or Transaction: Eastern District of Pennsylvania

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?
(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes ☐ No ☐

Does this case involve multidistrict litigation possibilities? Yes ☐ No ☐

RELATED CASE, IF ANY:

Case Number: _____ Judge: _____ Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes ☐ No ☐
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes ☐ No ☐
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes ☐ No ☐

CIVIL: (Place ☒ in ONE CATEGORY ONLY)

A: Federal Question Cases:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☒ All Other Federal Question Cases
(Please specify)

B: Diversity Jurisdiction Cases:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
(Please specify)

ARBITRATION CERTIFICATION

(Check appropriate Category)

I, Roberta D. Liebenberg, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 11/30/07

Roberta D. Liebenberg
Attorney-at-Law

31738
Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 11/30/07

Roberta D. Liebenberg
Attorney-at-Law

31738
Attorney I.D.#

Designation Form (Continued)

Address of Plaintiff:

UNITED STATES OF AMERICA

Angela Kelly
4409 Winding Creek Rd.
Manlius, NY 13104

Address of Defendant:

Amgen Corporation
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

CASE MANAGEMENT TRACK DESIGNATION FORM

UNITED STATES OF AMERICA
ex rel. ANGELA KELLY

v.

AMGEN CORPORATION

CIVIL ACTION

NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1.03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a case management track designation form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

- (a) Habeas Corpus – Cases brought under 28 U.S.C. §2241 through §2255. ()
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ()
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ()
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ()
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)
- (f) Standard Management – Cases that do not fall into any one of the other tracks. ()

11/30/07

Date

Roberta D. Liebenberg

Attorney-at-law

Plaintiff/Relator Angela Silva

Attorney for

(215) 567-6565

Telephone

(215) 568-5872

FAX Number

rliebenberg@finekaplan.com

E-Mail Address

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DEFENDANT.)	
)	

COMPLAINT

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA
EX REL.

ANGELA KELLY

PLAINTIFF,

v.

AMGEN CORPORATION

DEFENDANT.

CIVIL ACTION NO.

**FILED UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730(b)(2)**

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff and qui tam relator Angela Kelly, through her counsel Sanford, Wittels & Heisler, LLP, for her Complaint against Amgen Corporation (hereinafter “Defendant,” “Amgen” or “Company”), alleges as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent statements, records, and claims made and caused to be made by the Defendant and/or its agents and employees in violation of the Federal False Claims Act, 31 U.S.C. §3729 et seq., (“the FCA” or “the Act”).

2. This qui tam case is brought against Defendant for (a) conducting a fraudulent inducement campaign that foreseeably caused false or fraudulent claims, and (b) through such fraudulent activities, promoting the off-label use of pharmaceuticals. As a direct result of Defendant’s improper practices, the federal Treasury has been damaged in a substantial amount yet to

to be determined.

3. In order to gain a competitive edge over other pharmaceutical manufacturers and increase sales and revenue, Defendant Amgen initiated a coordinated nationwide sales campaign to entice and induce doctors and hospitals to purchase and use Amgen's products for off-label purposes in addition to the products' approved uses.

4. This campaign, however, involved not only sharpening pharmaceutical representatives' marketing and promotional pitches, but also paying illegal kickbacks to hospitals and physicians who purchased and used Amgen's products.

5. Specifically, Amgen was able to increase its market share by rewarding and bribing doctors and hospitals who were "big [Amgen] prescribers" or purchasers.

6. As a result of this illegal kickback scheme, a substantial number of Medicare and Medicaid patients have been given excessive and/or inappropriate medications, often to the detriment of the patients' health. As a result, the Medicare and Medicaid programs have incurred substantially increased costs.

II. PARTIES

7. Angela Kelly is a resident of Manlius, New York. From 2002 through 2005, Ms. Kelly was employed as an Oncology Pharmaceutical Representative ("Representative") for Amgen's Philadelphia, Pennsylvania territory.

8. Defendant Amgen Corporation is headquartered in Thousand Oaks, California. Amgen is a leading human therapeutics company in the biotechnology industry.

III. JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331. It also has subject-matter jurisdiction pursuant to 31 U.S.C. §3732, which specifically provides for jurisdiction over actions brought under 31 U.S.C. §§3729 and 3730.

10. There has been no statutorily relevant public disclosure of the “allegations or transactions” in this Complaint.

11. This Court has personal jurisdiction over Defendant Amgen pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because Defendant has at least minimum contacts with the United States. Moreover, Defendant can be found in and transacts – or has transacted – business in the Eastern District of Pennsylvania.

12. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because Defendant can be found in and transacts – or has transacted – business in the Eastern District of Pennsylvania.

IV. BACKGROUND

A. FALSE CLAIMS ACT

13. The FCA was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub. L. 99-562, 100 Stat. 3153. Congress enacted the 1986 amendments to enhance and modernize the Government’s tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government frauds to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government’s behalf.

14. The Act provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from \$5,500 up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the federal Government.

15. The Act allows any person having information about false or fraudulent claims to bring an action for herself and the Government, and to share in any recovery (“Relator”). The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time). Based on these provisions, qui tam plaintiff and relator Angela Kelly seeks through this action to recover damages and civil penalties arising from the Defendant’s knowing fraud on the U.S. Government.

B. ANTI-KICKBACK STATUTE

16. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult-to-detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to over-utilization or poor quality of care.

17. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of

any item for which payment may be made under a federally funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, pharmaceutical companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend products or procedures that may be paid for by a federal health care program. The law prohibits not only bribes and rebate schemes, but also any payment by a company for a purpose of inducing a physician to utilize the company's pharmaceuticals.

18. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider in federal health care programs. Hospitals and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law. Violation of the Anti-Kickback statute can result in exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7). Any party convicted under the Anti-Kickback statute must be excluded from federal health care programs (i.e., not allowed to bill for services rendered) for a term of at least five years. 42 U.S.C. §1320a-7(a)(1). In the absence of an actual conviction, the Secretary of the Department of Health and Human Services ("HHS") may nonetheless exclude a provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agency(ies) to exclude that provider from the State health program) and may impose administrative sanctions of \$50,000 per kickback violation if it determines that the provider has violated the statute. 42 U.S.C. §1320a-7(b).

V. **ALLEGATIONS**

A. **DEFENDANT AMGEN ILLEGALLY MARKETS ITS PRODUCTS TO PHYSICIANS**

1. **Amgen Corporation**

19. Amgen is a Fortune 500 biotechnology company with facilities in thirty-five countries, including the United States. Upon information and belief, Amgen has more than 20,000 employees worldwide.

20. According to Amgen's website, Amgen was originally founded in 1980 and pioneered the development of novel and innovative products based on advances in recombinant DNA and molecular biology.

21. Amgen introduced two of the first biologically derived human therapeutics, Epogen and Neupogen, which, Amgen's website claims, became the biotechnology industry's first blockbusters. Amgen's products treat patients with chronic kidney disease, cancer, anemia, rheumatoid arthritis and other autoimmune diseases.

22. In 2006, the Company's annual revenue was over \$14 billion.

2. **Amgen Trains its Representatives to Give Kickbacks to Doctors and Hospitals Who Use Amgen Drugs Off-Label**

23. During Ms. Kelly's four-year tenure with Amgen, the Company made clear to its Representatives that they were to help maximize the Company's market share by providing doctors and hospitals with kickbacks and rebates in exchange for the use of Amgen products.

24. Ms. Kelly's manager, Donna Mackinley, advised the Representatives that understanding rebates and kickbacks was the most important part of their jobs. She warned them that the failure to partake in this illegal scheme would result in the loss of their jobs, stating, "this is what

what you need to do if you want to keep your job.”

25. Amgen managers trained Representatives on how to encourage doctors and hospitals to use more Aranesp and Neulasta. Both of these drugs are purchased by doctors and hospitals on an as-needed basis and injected in the patient at the medical facility.

26. Amgen also devoted increasing amounts of time at its quarterly regional meetings to explaining the margin between the price of a drug being purchased and the amount being reimbursed.

27. At one national meeting in December of 2004, District Manager Donna Mackinley instructed Representatives, including Ms. Kelly, that they would have “to learn how to do what [Ms. Kelly’s sales partner Steven] DeNucci does if [they] wanted to make [their] quotas.” Specifically, Ms. Mackinley stated that Representatives would have to learn to how to properly explain the margin and Amgen’s incentive rebates to Amgen’s clients, i.e. physicians or hospitals, to achieve sales goals.

28. Amgen’s Regional Managers created cost calculators (in Microsoft Excel spreadsheets) which they distributed throughout the country. Ms. Kelly and the other Representatives would use these cost calculators in front of the doctor or hospital staff, to calculate the margin and rebate the doctor or hospital would receive from Amgen and to compare these amounts with what the doctor or hospital would get if they used a drug from another company. This constitutes “selling on the margin,” which is an illegal practice.

29. During the years 2004 and/or 2005, Ms. Kelly and other Pharmaceutical Representatives in her territory attended national and regional meetings, ostensibly to discuss Amgen “policy” with their managers. However, more time was devoted at these meetings to discussing how to make the company more profitable by providing rebates or kickbacks than was devoted to clinical issues.

30. During these “policy” meetings, Ms. Kelly’s manager instructed her and the other Pharmaceutical Representatives to put more emphasis on kickbacks and financial benefits than the clinical merit of the drug. Amgen trained Representatives to point out to doctors or hospital representatives that the less he or she used Amgen drugs, the smaller the rebates and kickbacks would be.

31. Exhibit 5, attached hereto and incorporated in this Complaint, includes documents that Amgen trained its Representatives to give to doctors and hospitals. These documents show each doctor’s kickback earnings in a given time period and whether those kickbacks had been paid. Page 1 of Exhibit 5 is a printout indicating that Mainline Oncology Hematology Associates at Lankenau Hospital were entitled to a \$141,442.43 check from Amgen as a reward for purchasing Amgen drugs. This kickback is based on purchases of Amgen drug that were made from 1/1/05-2/28/05. This physician’s office was entitled to receive a check for 25% of their Aranesp purchases and 21% of their Neulasta and Neupogen purchases. Because the kickbacks are based on a percent of the amounts purchased, physicians were induced to use more Amgen drugs, often inappropriately. Other printouts in Exhibit 5 show that various medical practices were entitled to rebate amounts ranging from \$14,943.12 in a two-month period to \$338,611.36 in a two-month period.

32. Amgen management sent Ms. Kelly and the other Representatives weekly reports so they could track doctors and hospitals’ weekly purchases of Amgen products. This allowed the Representatives to calculate the amount of rebate each doctor or hospital had earned and then use the information to motivate the doctor or hospital to “maximize their contract” by reaching a higher kickback tier. As a physician or hospital moved to a higher tier, it would get a larger percent of their purchases kicked back to them in the form of a physical check.

33. Exhibit 2 consists of charts showing the weekly sales amounts for each of Amgen's practices.

34. Amgen managers also encouraged Representatives to show doctors and hospitals, on a cost calculator in Representatives' laptops or in print-outs the breakdown of the total potential profit that could be made if such doctors and hospitals purchased and used Amgen drugs. Representatives were expected to be able to use these cost calculators to illustrate that the total profit consisted of both the margin between the purchase price of the drug and the amount reimbursed, coupled with the rebate (kickback) that Amgen would give them. Calculations were presented for both Amgen product and the competitor in order to illustrate that more money could be made using Amgen drugs.

35. Exhibit 3a contains examples of the material that Amgen would send the Representatives to give to the doctor with their rebate check. These handouts were used to convince doctors to buy and use more Amgen drugs by showing them that if they used more drugs, they could reach a higher tier, therefore increasing the kickback. Exhibit 3a, Page 1 shows that Bryn Mawr Medical Specialists earned a check for \$531,787.60 from Amgen for a three-month period (written calculations). Ms. Kelly's district manager at Amgen trained and encouraged Ms. Kelly to do such a calculation in front of the doctor. See also Exhibit 3a, Pages 2-10. The rebate checks issued in March of 2005 to all Amgen contracts accounts for the amounts shown in this exhibit. These checks were hand delivered to the doctors' offices via the Amgen Representative instead of mailed in order to give the Representative another opportunity to sell Amgen drugs based on the financial benefit.

36. Amgen managers instructed the Representatives not to leave any evidence of their illegal practices behind. For this reason, the cost calculator that the Representatives used to induce the doctors and hospitals does not have the Amgen logo on it.

37. In obedience to the instructions provided by management, Ms. Kelly and her partner Steven DeNucci and other Amgen Representatives offered doctors and hospitals large rebates and kickbacks to motivate them to use Amgen's drugs.

38. Representatives would directly or indirectly raise the topic of how much profit the doctor or hospital would make by accepting kickbacks. For example, during "business reviews" with key accounts, Ms. Kelly's sales partner, Steven DeNucci, would use such words as "margin" and "spread" to explain the difference between the purchase price of the drug and the reimbursement that the doctor or hospital could receive from the insurance carriers. In this manner, Mr. DeNucci was able to induce doctors and hospitals to partake in the company's illegal scheme while also protecting the Company. The "spread" or "margin" means the amount between what the doctor or hospital paid for the drug and what the insurance company would reimburse for that drug.

39. During the first quarter of 2004, the management teams also began holding special meetings designed to teach Representatives how to calculate and explain the margin or "spread" and rebates. At the meetings, Representatives would be required to role play a meeting with a doctor or hospital representative.

40. In the spring of 2005, a number of district and regional wide conference calls took place where selling based on financial benefit was the main topic. Representatives also received emails illustrating how to use cost calculators in front of the client to show the client how much money clients could get from Amgen if they used a specific amount of a drug.

41. Amgen management asked Mr. DeNucci to hold a conference call to train Amgen Representatives to use reimbursement charts. Exhibit 1 includes the charts Mr. DeNucci used to show doctors and hospital staff the rebates (kickbacks) they could receive for using a given Amgen drug. In Exhibit 1, page 1, the column labeled "25% Rebate" represents the amount a doctor or

hospital would get for each dosage of Aranesp they used in comparison with the rebate associated with Procrit (Epoetin Alfa). Exhibit 1, Page 2 compares the rebate associated with using Neupogen and that associated with using Neulasta; the column labeled “21% Rebate” represents the rebate check a doctor or hospital would receive.

42. Exhibit 1, Page 3 is an example of a cost calculator shown to doctors and hospitals to encourage the use of Amgen drugs. This particular chart demonstrates how a doctor could receive a higher kickback if that doctor used 300mcg of Aranesp versus 200mcg of Aranesp (in other words, it shows that if a doctor used 200mcg, the doctor would only get a \$178.80 rebate, whereas if the same doctor used 300mcg, the doctor would receive a \$268.20 rebate).

43. In mid-2004, Amgen assigned Ms. Kelly to Mr. DeNucci’s meetings with key clients. The purpose of this assignment was to teach Ms. Kelly how to properly handle presenting kickback checks to clients and to train her on how to show doctors and hospitals how they could earn more money from Amgen by using more Amgen drugs.

44. At one such meeting in early 2005, Ms. Kelly and Mr. DeNucci met with Dr. Steven Cohen of Bryn Mawr Medical Specialists office. At that meeting, Mr. DeNucci encouraged Dr. Cohen to use an off-label weekly dosage of 300mcg of Aranesp in order to double his purchases of that drug. Aranesp is only indicated to be used 150-200 mcg every other week.

45. On several occasions, Ms. Kelly sat with clients over lunch with her manager and witnessed her manager encouraging doctors and hospitals to push patients’ hemoglobin levels higher by using higher doses of Aranesp (because using more Aranesp would mean higher kickbacks for the doctors and hospitals).

46. After she left her employment with Amgen, Ms. Kelly learned that the FDA has issued a warning that overutilizing Aranesp actually increases tumor growth.

47. While Ms. Kelly's partner, Mr. DeNucci, was encouraged by Amgen management to continue these practices and was even made a mentor, other Representatives who were not as comfortable selling in this fashion were made to feel that they were underperforming.

3. Amgen's Development and Off-Label Promotion of Aranesp, a Drug Used to Treat Anemia

48. One of Amgen's major research investments in the 1980s was Procrit. Procrit was initially indicated for reduction of anemia in patients with renal failure, but could also be used by cancer patients who developed anemia during chemotherapy. Procrit is given subcutaneously or intravenously through injection.

49. At the end of the research phase for Procrit, Amgen reached a marketing agreement with Johnson & Johnson ("J&J"). Under that agreement, J&J would be able to market Procrit for use by cancer patients who developed anemia from chemotherapy; Amgen would be permitted to market the drug under the name "Epogen" for patients with renal failure.

50. Subsequent to entering into this agreement, Amgen decided to market Epogen to oncology patients as well as patients with renal failure. In order to avoid running afoul of its agreement with J&J, Amgen altered the formula of Epogen slightly by using Chinese hamster ovary cells rather than cells from humans enabling the drug to be dosed every other week instead of weekly. This benefited the patient in that it required fewer injections and should have benefited the healthcare system by reducing the financial burden of having to reimburse hospitals and physicians for administering the drug by 50%. Amgen called this modified version of Procrit "Aranesp."

51. Aranesp was subsequently approved by the FDA for the treatment of anemia associated with chronic renal failure, and for the treatment of anemia developed in patients with certain malignancies as a result of concomitantly administered chemotherapy.

52. Unlike Procrit, however, the FDA did not approve Aranesp for use in patients with MDS (Myelodysplastic Syndrome), a hematological condition marked by ineffective production of blood cells.

53. This left doctors and hospitals with two options for on-label use: (1) using Procrit for all cancer patients with or without MDS, or (2) using Procrit for cancer patients with MDS and Aranesp for cancer patients without MDS. If, however, a doctor or hospital was willing to use Aranesp off-label, the doctor or hospital could use it for both MDS and non-MDS cancer patients, thereby increasing the doctor or hospital's Amgen kickbacks.

54. The off-label use of Aranesp would substantially increase Amgen's sales and market share of the product.

55. As the competition between Johnson & Johnson and Amgen grew, Amgen would offer contracts that would give kickbacks to doctors and hospitals as they reached different "purchasing tiers." In other words, as doctors and hospitals purchased more Amgen drugs, Amgen gave the doctors kickback checks for more money.

56. Amgen trained its Representatives to use reimbursement spreadsheets (cost calculators) to convince doctors and hospitals that even though Procrit was sometimes more appropriate or at least was on-label, using Procrit instead of Aranesp would result in a loss of profit for the physician or hospital, i.e., lower reimbursements and lower rebates.

57. Exhibit 6 shows how an Amgen Representative calculated the rebate associated with using the off-label dosing of Aranesp. Exhibit 6, Page 3 demonstrates how an Amgen representative compared 217 shots/quarter of Aranesp with 217 shots/quarter of Procrit, even though the proper conversion ratio of procrit to Aranesp is 2:1. In other words, if a physician were using 217 shots of Procrit/quarter, he should use approximately 108 shots of Aranesp for the same efficacy. This

practice was intended to show the doctor or hospital that using Aranesp off-label in higher doses and weekly would result in a much higher profit from insurance reimbursement and kickbacks.

58. Amgen also trained Representatives on how to instruct doctors and hospitals to code off-label usage of its medications in a way that would allow doctors and hospitals to receive reimbursement from insurance companies, Medicare, and Medicaid. Ms. Kelly's sales partner, Steven DeNucci, gave doctors and hospitals detailed explanations of how to get insurance companies (including Medicare) to cover off-label usage. Ms. Kelly's manager encouraged Mr. DeNucci to share his knowledge with the other Representatives in that district.

59. Amgen Representatives were furnished with clinical studies justifying off-label use in order to maximize profit. Once a medical practice used only Amgen drugs, Amgen would elevate that practice to the next tier on Amgen's contract, increasing the practice's kickbacks. For instance, Representatives were given papers detailing studies done in Europe suggesting that Aranesp was as beneficial as Procrit for patients with MDS, even though the FDA had not approved it for this purpose.

60. Ms. Kelly's manager, Donna Mackinley, told Ms. Kelly and other Representatives that it was important to be able to refer to these clinical papers when speaking with doctors and hospitals as part of an off-label marketing campaign designed to promote Aranesp. These papers gave doctors and hospitals the information they needed to fight with insurance companies, including Medicare, for reimbursement.

61. Exhibit 7 is an example of how Amgen trained Representatives to use these papers to encourage off-label dosing.

62. According to Amgen's website, Aranesp is now one of Amgen's principal products.

4. Neulasta and the Bundling of Neulasta with Aranesp

63. Neulasta is an Amgen-created drug, which is FDA-approved for use in decreasing the incidence of infection. Neulasta is not indicated for concomitant use with weekly or biweekly chemotherapy regimens. Neulasta was approved by the FDA to be used one time per chemotherapy cycle (approximately every twenty-one days) thus significantly decreasing the number of patient injections.

64. Upon information and belief, Amgen marketed Neulasta for off-label use.

65. Amgen trained and strongly encouraged Representatives to market the drug for weekly or bi-weekly use in order to increase sales. This meant that a \$2,800.00 drug that was intended to be used approximately one time every twenty-one days, was now being used one time every seven or fourteen days, tripling the burden of reimbursement for Medicare and Medicaid.

66. Amgen rewarded doctors and hospitals who purchased Neulasta for off-label use by paying them higher kickbacks.

67. Beginning in early 2003 and continuing through Ms. Kelly's employment at Amgen, Amgen instructed Representatives on how to bundle the Neulasta rebate with the Aranesp rebate. Representatives were trained to say, "Doctor, let me show you how you can maximize your contract." The Representatives would then explain that if that doctor would use the Aranesp (often off-label) instead of Procrit, the doctor or hospital would move to a higher tier on his or her contract with Amgen and get higher rebates on Aranesp and Neulasta instead of the much lower rebate for using some Aranesp, some Procrit and Neulasta.

68. If a doctor or hospital used Procrit, such a doctor or hospital would sacrifice a large Neulasta rebate. In this manner, Amgen was able to induce doctors and hospitals to choose Aranesp over Procrit, even if it was not the best clinical choice.

69. Amgen managers emailed Representatives spreadsheets showing the Representatives how to explain kickbacks to doctors and hospitals using phrases such as, “If you use Aranesp and Neulasta for all of your chemo patients, you will reach tier 7 of our purchasing contract. That will give you 25% back on all of your total purchases of Neulasta and 30% on Aranesp in addition to the margin on reimbursement from insurance carriers like Medicare.”

70. Doctors were also punished financially for buying some drugs from one company and others from another. Representatives would show doctors and hospitals how the extra Procrit that doctor used put him or her in a lower tier on the contract with Amgen. Amgen Representatives would then take the dollar amount of the Procrit purchases and add them to the Aranesp purchases in the Cost Calculator to illustrate how much money the doctor was leaving on the table by continuing to use Procrit with no regard for which drug was the better clinical choice. In this manner Amgen was able to increase its market share.

71. As set forth above, Defendant routinely provides illegal kickbacks to physicians to induce them to use their products off-label.

72. Because compliance with the anti-kickback statutes is a condition of payment, claims for reimbursement for medications used by a physician who has received a kickback or at a hospital that has received a kickback from Defendant are not eligible for reimbursement by Medicare.

73. Accordingly, kickback-tainted claims for reimbursement are false claims within the meaning of the Federal False Claims Act.

COUNT I

Violation of the False Claims Act, 31 U.S.C. §3729(a)(1)-(2), (7)

74. Plaintiff realleges and incorporates by reference the allegations in the preceding paragraphs of this Complaint.

75. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729 et seq.

76. As described above, Defendant has, through its off-label marketing campaign and the use of illegal kickbacks, caused physicians to use Amgen's medications unnecessarily, in cases where less costly medications (or no medication) would otherwise have been used.

77. Through the acts described above, Defendant knowingly made, used, and caused to be made and used false records and statements in order to obtain reimbursement from the United States for Amgen medications.

78. The United States, unaware of the falsity or fraudulence of the statements, records or claims made or submitted by Defendant, its agents, and employees, approved, paid and continues to approve and pay claims that otherwise would not have been approved or paid, and has not recovered funds that would otherwise have been recovered.

79. Through the acts described above, Defendant knowingly presented, or caused to be presented, false or fraudulent claims, to the United States Government, in order to obtain government reimbursement for health care services provided under Medicare.

82. As a result of these false claims, the United States has been damaged and continues to be damaged in an amount yet to be determined.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendant as follows:

1. that Defendant cease and desist from violating 31 U.S.C. §3729 et seq.;
2. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. §3729;

3. that Plaintiff be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

4. that Plaintiff be awarded all costs of this action, including attorneys' fees and expenses; and

5. that the United States and Plaintiff recover such other and further relief as the Court deems just and proper.

6. that Plaintiff be awarded the maximum amount she is entitled to, pursuant to 31 U.S.C. §3730(h) of the False Claims Act to make her whole, including two times the amount of back pay, interest on the back pay, and compensation for any special damages sustained, including litigation costs and reasonable attorneys' fees.

VII. DEMAND FOR JURY TRIAL

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

Dated: November 30, 2007

Respectfully submitted:



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