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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

IN RE AMGEN INC., SECURITIES LITIGATION

Case No. CV 07-2536 PSG (PLAx)

CORRECTED SECOND CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

REDACTED VERSION

FILED PUBLICLY VIA ECF

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Lead Plaintiff Connecticut Retirement Plans and Trust Funds ("Plaintiff" or "Connecticut"), by its undersigned attorneys, hereby brings this Second Consolidated Amended Class Action Complaint ("Complaint") against Amgen, Inc. ("Amgen" or the "Company"), Kevin W. Sharer, Richard D. Nanula, Roger M. Perlmutter and George J. Morrow (collectively, the "Individual Defendants" and together with Amgen, "Defendants"). The allegations herein are based on Plaintiff's personal knowledge as to its own acts and on information and belief as to all other matters, such information and belief having been informed by the investigation conducted by and under the supervision of its counsel, which included interviews of former employees of Amgen and other persons with knowledge of the matters alleged herein (some of whom have provided information in confidence; these confidential witnesses ("CWs") will be identified herein by number (CW#1, CW#2, etc.)), review and analysis of publicly available information, review and analysis of non-public documents produced in discovery, and consultations with consulting experts. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for continued discovery. On behalf of itself and the class it seeks to represent, Plaintiff alleges as follows:

NATURE OF THE ACTION

1. This action is brought on behalf of a class of purchasers of the publicly traded securities of Amgen who bought their shares between April 22, 2004 and May 10, 2007, inclusive (the purchasers being the "Class" and the timeframe being the "Class Period"). Plaintiff seeks remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). Defendants, with the requisite mental state per the Exchange Act, made a series of materially false and misleading statements and omissions during the Class Period that artificially inflated the value of Amgen's stock; later disclosures and events caused the stock

price to decline, causing Plaintiff and the Class injury during the Class Period and thereafter.

2. Amgen and the Individual Defendants misled and defrauded investors concerning the safety, marketing, and market demand of two of the Company's flagship products—Aranesp® (darbepoetin alfa) ("Aranesp") and Epogen® (epoetin alfa) ("Epogen"). Manufactured by recombinant DNA technology, Aranesp and Epogen are slightly different man-made versions of a human protein that stimulates the production of red blood cells. They are used to combat anemia and thus avoid transfusions in certain patient populations (primarily patients with chronic kidney disease or cancer patients with chemotherapy-induced anemia ("CIA")).

ESAs

3. Both Aranesp and Epogen are members of a drug class known as ESAs. The original clinical trials conducted to obtain initial U.S. Food and Drug Administration ("FDA") approval for ESAs demonstrated that the drugs were effective in helping certain anemic patients build their hemoglobin and red blood cell levels and thereby avoid transfusions. Although the trials collected safety data, as all clinical trials do, they were not designed for the purpose of measuring whether the study drug was as safe as placebo in any clinically meaningful sense. In other words, the trials were not designed to measure, as between study-drug patients and placebo patients, which groups had greater frequency or severity of significant events affecting how patients function or survive. Examples of these significant events or "clinical endpoints" would include cardiovascular events such as heart attacks or strokes, or overall survival rates.

Aranesp

4. Following FDA approval of Epogen (in 1989) and Aranesp (in 2001), several large-scale clinical trials of other ESAs showed an apparent excess of adverse events associated with the use of this class of drugs, namely decreased

overall survival, increased progression of tumor growth and/or increased frequency of cardiovascular events. These "safety signals" raised within the FDA concerns that this class of drugs may, in fact, be less safe than placebo when specifically testing to measure for clinically significant endpoints. In early 2004, concerns over ESA safety caused the FDA to call for a meeting with its advisory board of leading oncology experts – the Oncologic Drugs Advisory Committee, or ODAC. That meeting (the "2004 ODAC Meeting") occurred on May 4, 2004. The Class Period is essentially book-ended by ODAC meetings; it begins in April 2004 with a false statement by Defendant Morrow in response to a question on an earnings call about the then-upcoming 2004 ODAC Meeting, and it ends three years later, with corrective disclosures at a second ODAC meeting held on May 10, 2007 (the "2007 ODAC Meeting").

Lead-Up to 2004 ODAC Meeting

5. Even before the Class Period began, Defendants knew that definitive clinical data on survival rates and other clinically significant endpoints was lacking and that the relevant studies that did exist pointed to significant safety concerns. [redacted] Despite this, in the weeks leading up to the 2004 ODAC Meeting, Defendants misleadingly stressed that the 161 Study and another clinical trial demonstrated that Aranesp' s safety was "comparable to placebo" and that Aranesp was a fundamentally different molecule than Epogen or other ESAs.

Misrepresentations at 2004 ODAC Meeting

6. At the 2004 ODAC Meeting itself, Amgen misled the investing public (not to mention the ODAC panel and the FDA) by [redacted] Yet for its *public* presentation of 161 Study long-term follow-up data, Amgen [redacted] without disclosing that material fact to the public, and Amgen thereby presented a hazard ratio that was *not* statistically significant, misleadingly stating that "no convincing evidence for a significant decrease in overall survival is associated with Aranesp".

DAHANCA 10 Trial

7. Defendants also knowingly concealed material information concerning a clinical trial of Aranesp known as DAHANCA 10. The study was designed to see whether dosing to higher hemoglobin levels could aid in shrinking the tumors of certain cancer patients receiving radiation therapy. The investigators conducting the study halted it early and an interim analysis showed the opposite: cancer patients treated with Aranesp had greater tumor growth than those not receiving Aranesp. Overall survival time also favored those not treated with Aranesp.

8. Defendants knew in mid-October 2006 that DAHANCA 10 had been halted, and they knew by early December 2006 that the study had been officially

terminated early. Defendants did not inform investors of these developments. Information concerning DAHANCA 10 finally reached the market when a newsletter called *The Cancer Letter* published an article concerning the results of the study in mid-February 2007—four months after Defendants had been informed that the study had been halted, and more than two-and-a-half months after Defendants learned that the decision had been made to terminate the study altogether.

The 103 Study

9. Defendants also misled investors concerning another highly material clinical trial of Aranesp known as the 103 Study. Defendants mischaracterized the results of the 103 Study, stating that they were "at best, neutral and ***perhaps*** negative." (Emphasis added.) In fact the study was an abject failure for Aranesp. In patients with anemia of cancer ("AOC," which is anemia caused by a patient's cancer itself rather than by treatments with chemotherapy), those receiving Aranesp did not reduce their need for transfusions and showed significantly shorter survival times compared to patients in the placebo arm of the study. Bluntly, Aranesp patients did not have fewer transfusions but they were more likely to die.

10. In the final months of the Class Period, Defendants signaled to investors that the DAHANCA 10 and 103 Studies were to be narrowly interpreted.

Shift to "On-Label" Safety Story

11. Defendants also reversed their position that Aranesp was safe because unique, and instead repeatedly claimed that Aranesp and Epogen were safe when used in accordance with FDA labeling guidelines (*i.e.*, "on-label"). They further claimed their safety-related statements were supported by clinical trial evidence, when, in fact, they were not.

12. Amgen continued to tout the safety of Aranesp and Epogen, as well as Aranesp's vast untapped potential both to further penetrate the markets in patient populations it was already approved to treat, and grow its sales through expanding

into new patient populations. Given the outstanding core safety problems, these statements were both highly material (Amgen's ESA franchise represented roughly half of Amgen's annual sales revenue) and highly misleading.

The 145 Trial

13. The Aranesp-specific data that Defendants *did* highlight following the disclosures of the 103 and DAHANCA results concerned a clinical trial known as the 145 Study. There, however, Defendants placed greater emphasis on the study than it deserved. The 145 Study was designed as a "superiority" trial, measuring whether small cell lung cancer patients taking Aranesp lived longer than patients on a placebo. Results for the 145 Study were announced in April 2007. Aranesp failed to meet its primary endpoint, but Amgen spun the "neutral" survival results as a net positive development with a significant impact for investors. [redacted]

Marketing Practices

14. Amgen's statements concerning its marketing practices also misled investors. The Company promoted Aranesp and Epogen for unapproved uses and increased per-patient dosages through improper and, in some cases, unlawful means. The Food, Drug, and Cosmetic Act and accompanying regulations prohibit the promotion of a drug for "off-label" uses, *i.e.*, for indications, dosage forms, dose regimens, populations or other use parameters not mentioned in the FDA-approved labeling. Amgen's filings with the Securities and Exchange Commission ("SEC") state repeatedly that "We also manufacture and contract manufacture, price, sell, distribute, and market or co-market our products ***for their approved indications***." (Emphasis added.)

15. However, throughout the Class Period, Amgen encouraged and actively promoted the off-label usage of its products in a variety of unlawful ways, including: training its sales representatives on how to engage physicians in

discussions of the off-label uses of Amgen's products; having its sales force recommend dose increases to achieve excessive target hemoglobin levels; sponsoring pseudo-educational "speaker programs" for doctors and other medical services providers touting the use of Aranesp in off-label settings; and marketing ESAs by showing doctors how they could increase their profits through increased Medicare reimbursements by prescribing larger quantities of the drugs. Amgen also designed rebate programs that improperly incentivized physicians to administer Aranesp when it was not necessary to do so.

The Guilty Plea

16. Amgen's off-label marketing during the Class Period was confirmed in December 2012, when Amgen entered into what the U.S. Department of Justice called "the single largest criminal and civil False Claims Act settlement involving a biotechnology company in U.S. history" to resolve charges that Amgen engaged in the widespread off-label marketing of Aranesp and other Amgen drugs over a period of years that substantially overlaps the Class Period. Amgen pleaded guilty to a misdemeanor count of misbranding of Aranesp, and agreed to pay a total of $762 million to settle criminal and civil off-label marketing charges; the time period covered by a criminal information to which Amgen pleaded guilty—the Sealed Misdemeanor Information in *U.S. v. Amgen, Inc.*, No. 12-CR-760 (SJ) (E.D.N.Y.) dated December 18, 2012 (the "Criminal Information")—spans from the launch of Aranesp in 2001 until at least March 2007. The March 2007 event that curtailed Defendants' off-label marketing efforts was the FDA's imposition of a "black box" warning on the labels for ESAs sold in the U.S., including Aranesp and Epogen, which severely impacted the sale of Amgen's single best-selling product at that time.

The 2007 ODAC Meeting

17. Defendants' ability to mislead the market concerning the safety, marketing and market demand of its ESAs effectively ended on May 10, 2007, the

date of the 2007 ODAC Meeting. Despite Defendants' repeated false assertions that their drugs were "safe" when used in accordance with the FDA-approved label, ODAC panel member Dr. Silvana Martino summed up the breathtaking *lack* of evidence of safety this way:

> The burning question is does this thing actually kill people in the doses that we think are reasonable and appropriate? ***I don't see anything that has approached an answer to that question.***

(Emphasis added.)

18. The FDA emphasized that "no completed or ongoing trial has addressed safety issues of ESAs in cancer patients with chemotherapy-associated anemia using currently approved dosing regimens in a generalizable tumor type." The FDA further noted that "there is no evidence that ESAs improve quality of life or cancer outcomes," and "data continue to accumulate regarding the increased risk of mortality and of possible tumor promotion from the use of ESAs." Dr. Richard Pazdur, Director of the FDA's Office of Oncology Drug Products noted that "***[o]bviously, if we had data at the recommended hemoglobin and there was a therapy-associated death rate associated with it, we wouldn't having this discussion.***" (Emphasis added.) After considering testimony from the FDA, Amgen, and others, ODAC voted overwhelmingly in favor of restricting the use of ESAs and expanding existing warnings.

The Corrective Disclosures

19. Corrective disclosures on three dates removed the artificial inflation in the value of Amgen's stock, causing Plaintiff and the Class injury: (1) following the corrective disclosure of the DAHANCA 10 Trial termination on February 16, 2007, Amgen's share price declined $1.55 per share, or 2.3%, to $66.73; (2) following the corrective disclosure of the "black box" warning on March 9, 2007, Amgen's share price declined $1.31 per share, or 2.1%, to $60.86; and (3)

following the final corrective disclosures at the May 10, 2007 ODAC Meeting, Amgen's share price declined $5.77 per share, or 9.1%, from $63.10 to $57.33 per share on May 10, 2007, and declined an additional $0.97 per share, or 1.7%, from $57.33 to $56.30 per share on May 11, 2007.

The Financial Impact on Amgen

20. The FDA's implementation of further restrictions on the use of ESAs and the expansion of additional warnings had a profound effect on Aranesp's annual US sales, which have declined steadily since their peak in 2006:

ARANESP Annual Sales[1]
($ in millions)

Year	US Sales	% Diff. from Prev. Year
2004	1,533	56%
2005	2,104	37%
2006	2,790	33%
2007	2,154	-23%
2008	1,651	-24%
2009	1,251	-24%
2010	1,103	-12%
2011	986	-11%
2012	782	-21%
2013	747	-4%

PARTIES

A. Plaintiff

21. Lead Plaintiff Connecticut Retirement Plans and Trust Funds consists of six State pension and eight State trust funds. Pursuant to Sections 3-11a, 3-13a(b), 3-13a(c) and 3-13i of the Connecticut General Statutes, State Treasurer Denise L. Nappier is the principal fiduciary for Plaintiff. In this role, the Treasurer was responsible during the Class Period for prudently managing $20.2–25.9 billion in retirement funds for approximately 160,000 teachers, state, and municipal

[1] Amgen Forms 10-K for the years ending 2004-2013.

employees who are pension plan participants and beneficiaries as well as academic programs, grants, and initiatives throughout the State. Plaintiff purchased Amgen common stock at artificially inflated prices during the Class Period and has, accordingly, been damaged by Defendants' wrongful conduct. Attached hereto is a certification reflecting Plaintiff's transactions in Amgen common stock during the Class Period.

B. Defendants

22. Defendant Amgen is a global biotechnology company. According to its website (www.amgen.com), the Company "discovers, develops, manufactures and markets human therapeutics based on advances in cellular and molecular biology." Amgen markets its products in the areas of supportive cancer care, nephrology, inflammation and oncology. As of the close of the Class Period, the Company's principal products were Aranesp, Epogen, Neulasta® (pegfilgrastim) ("Neulasta"), Neupogen® (filgrastim) ("Neupogen") and Enbrel® (etanercept). The Company markets its principal products to healthcare providers, including clinics, dialysis centers, hospitals and pharmacies. Amgen is a Delaware corporation with its principal place of business at One Amgen Center Drive, Thousand Oaks, California.

23. Defendant Kevin W. Sharer ("Sharer") was, at all relevant times, Amgen's President, Chief Executive Officer and Chairman of the Company's Board of Directors. Sharer became Amgen's Chairman in April 2000. Sharer was a direct and substantial participant in the fraud, who also profited from the sale of Amgen securities at artificially inflated prices during the Class Period and received substantial revenue-based bonuses and other compensation that was artificially increased by the wrongful conduct set forth herein. In addition, Sharer signed and certified, as required by Section 906 of the Sarbanes-Oxley Act of 2002 ("SOX"), the Company's Annual Reports on Form 10-K for the years 2004, 2005 and 2006, which the Company filed with the SEC during the Class Period and which

contained materially false and misleading statements and/or omissions. Sharer also certified, as required by Section 906 of SOX, the Company's Form 10-Qs for the second and third quarters in 2004, for the first, second and third quarters in 2005 and 2006, and for the first quarter in 2007, which the Company filed with the SEC during the Class Period and which contained materially false and misleading statements and/or omissions.

24. Defendant Richard D. Nanula ("Nanula") was the Company's Chief Financial Officer from the beginning of the Class Period through the date of his resignation from Amgen on April 10, 2007. Nanula was a direct and substantial participant in the fraud, who also profited from the sale of Amgen securities at artificially inflated prices during the Class Period and received substantial revenue-based bonuses and other compensation that was artificially increased by the wrongful conduct set forth herein. In addition, Nanula signed the following documents that the Company filed with the SEC during the Class Period and which contained materially false and misleading statements and/or omitted to state material facts: the Company's Annual Report on Form 10-K for the years 2004, 2005 and 2006 and the Company's Form 10-Q for the second and third quarters in 2004 and for the first, second and third quarters in 2005 and 2006. Nanula also certified, as required by Section 906 of SOX, the Company's Annual Reports on Form 10-K for the years 2004, 2005 and 2006 and the Company's Form 10-Qs for the second and third quarters in 2004 and for the first, second and third quarters in 2005 and 2006, which the Company filed with the SEC during the Class Period and which contained materially false and misleading statements and/or omissions.

25. Defendant Roger M. Perlmutter ("Perlmutter") was, at all relevant times, the Company's Executive Vice President of Research and Development. Perlmutter was a direct and substantial participant in the fraud, who also profited from the sale of Amgen securities at artificially inflated prices during the Class

Period and received substantial revenue-based bonuses and other compensation that was artificially increased by the wrongful conduct set forth herein.

26. Defendant George J. Morrow ("Morrow") was, at all relevant times, the Company's Executive Vice President of Global Commercial Operations. Morrow was a direct and substantial participant in the fraud, who also profited from the sale of Amgen securities at artificially inflated prices during the Class Period and received substantial revenue-based bonuses and other compensation that was artificially increased by the wrongful conduct set forth herein.

CONTROL PERSON ALLEGATIONS

27. The Individual Defendants, because of their positions of control and authority as senior executive officers and a director of the Company, had access to the adverse undisclosed information about its business, operations, products and prospects through their access to internal corporate documents and information (including information concerning Aranesp and Epogen), conversations and associations with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof, and reports and other information provided to them in connection therewith.

28. The Individual Defendants participated in drafting, preparing, and/or approving the public reports and other statements and communications complained of herein and knew of, or were deliberately reckless in disregarding, the material misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature.

29. The Individual Defendants, as senior executive officers and a director of the Company, were able to and did control the content of the various SEC filings, press releases, and other public statements pertaining to the Company during the Class Period. The Individual Defendants were provided with copies of the documents and statements alleged herein to be materially false and misleading prior to or shortly after their issuance or had the ability and opportunity to prevent

their issuance or cause them to be corrected. As specified herein, the Company's SEC filings complained of herein were signed by the Individual Defendants and contained certifications by Defendants pursuant to §302 of SOX. Accordingly, the Individual Defendants are responsible for the accuracy of the public reports, releases, and other statements detailed herein and are primarily liable for the misrepresentations and omissions contained therein.

30. As senior officers and controlling persons of a publicly-held company whose securities were, during the relevant time, registered with the SEC pursuant to the Exchange Act, traded on the NASDAQ stock market and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's performance, operations, business, products, and prospects, and to correct any previously issued statements that were or had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. The Individual Defendants' wrongdoing during the Class Period violated these specific requirements and obligations.

31. Each of the Individual Defendants is liable as a primary participant in a wrongful scheme and course of business that operated as a fraud and deceit on purchasers of Amgen securities during the Class Period, which included the dissemination of materially false and misleading statements and concealment of material adverse facts. The scheme: (i) deceived the investing public regarding Amgen's performance, operations, business, products and prospects, and the true value of Amgen securities; and (ii) caused Plaintiff and other members of the Class to purchase Amgen securities at artificially inflated prices, which fell as the truth concerning Aranesp and Epogen ultimately became known.

32. In making the statements complained of herein, Defendants, who were all senior officers and controlling persons of Amgen, were acting on behalf of the

Company in the regular course of business. Therefore, each of the statements made by the Individual Defendants is attributable to the Company.

JURISDICTION AND VENUE

33. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§ 78j(b) and 78t(a)] and Rule l0b-5 promulgated thereunder by the SEC.

34. The Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 27 of the Exchange Act [15 U.S.C. § 78aa].

35. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b).

36. In connection with the acts alleged in this Complaint, Defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mail, interstate telephone communications, and the facilities of the national securities markets.

FACTUAL ALLEGATIONS

A. Overview of ESAs and the ESA Market

37. Erythropoiesis is the process by which the body produces erythrocytes, or red blood cells. Red blood cells contain hemoglobin, a protein that functions primarily in the transport of oxygen from the lungs to the tissues of the body. Hemoglobin levels are expressed in grams (g) per deciliter (dL) of whole blood. An adequate supply of red blood cells is necessary to oxygenate the body.

38. Anemia, a condition in which the blood is deficient in red blood cells or hemoglobin, impairs the body's ability to transfer oxygen to the tissues. Anemia has many potential causes, including an iron-poor diet, excessive bleeding, certain cancers, certain cancer treatments, and kidney or liver failure.

39. A necessary step in the erythropoietic process is the production of erythropoietin, a protein made in the kidneys that stimulates red blood cell

formation. In the early 1980s, Amgen scientists cloned the gene for erythropoietin, a discovery that led eventually to the Company's commercialization of man-made versions of erythropoietin – epoetin alfa, which Amgen markets in the U.S. as Epogen, and darbepoetin alfa, which Amgen markets in the U.S. as Aranesp. Hoffmann La-Roche manufactures another ESA, epoetin beta, which it markets in Europe as NeoRecormon. Because epoetin alfa, darbapoetin alfa, and epoetin beta, like endogenous erythropoietin, stimulate red blood cell formation, they are referred to as erythropoiesis-stimulating agents, or ESAs. Erythropoietin and its man-made copies are also sometimes referred to as EPO.

40. While epoetin alfa was still in development, Amgen entered into a Product License Agreement ("PLA") with a subsidiary of Johnson & Johnson ("J&J"). Amgen granted J&J an exclusive license under Amgen's patents to market and sell Amgen-manufactured epoetin alfa in the U.S. for anemia in humans resulting from all treatments except in the dialysis and diagnostics settings.

41. In 1989, the FDA approved Epogen for the treatment of anemia associated with chronic renal failure ("CRF"), including end stage renal disease patients and patients not on dialysis. The treatment for more severe cases of anemia in CRF patients had been whole blood or red cell transfusions. Epogen therapy was to elevate or maintain the red blood cell level and to reduce the need for transfusions in these patients.

42. Through its own research and testing, J&J obtained FDA approval to market epoetin alfa to treat and reduce the need for transfusions in patients undergoing treatment for other diseases. Between 1991 and 1996, J&J secured FDA approvals to market epoetin alfa for persons who develop anemia as a consequence of chemotherapy for cancer, treatment of HIV infection with the pharmaceutical zidovudine, chronic kidney diseases in pre-dialysis patients, and in anemic patients scheduled to undergo elective, non-cardiac, non-vascular surgery. J&J markets its Amgen-manufactured product under the name Procrit® ("Procrit").

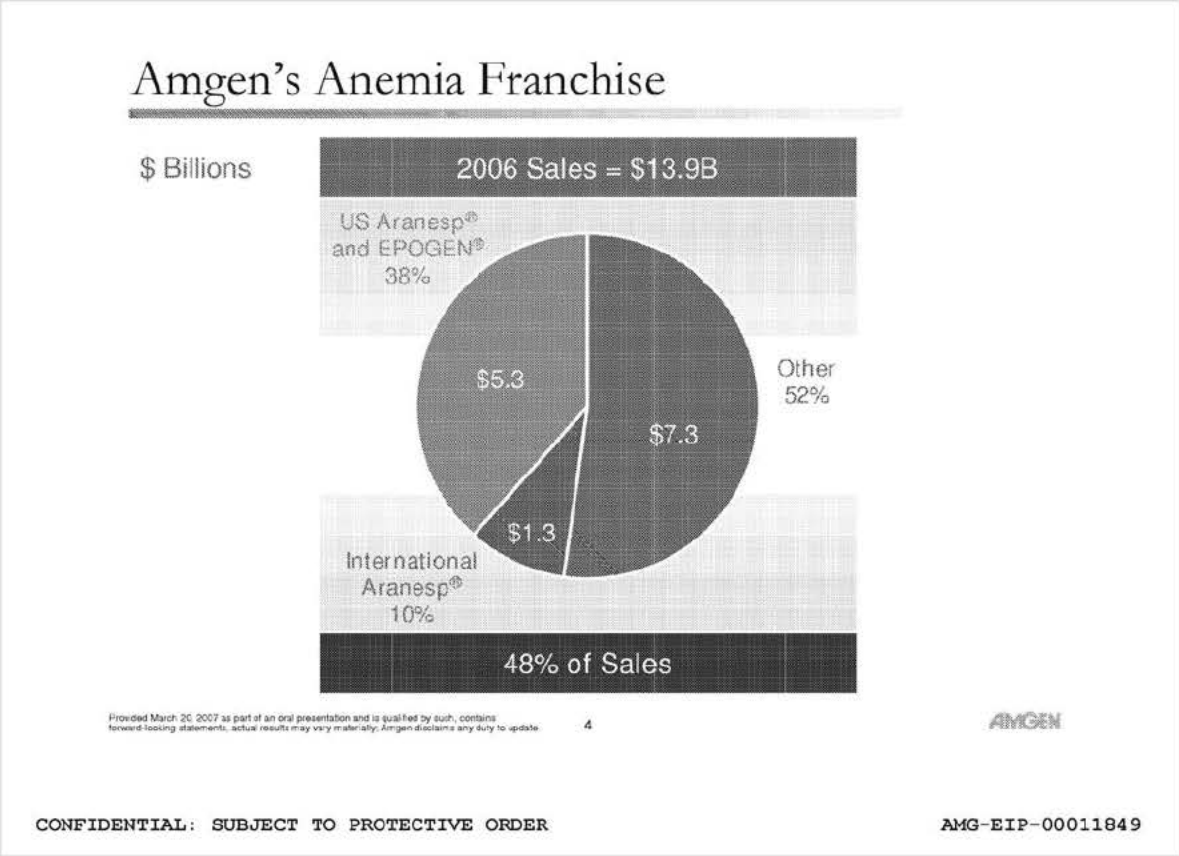
43. Except for the difference in their marketing names, the Epogen and Procrit products are identical, as are their FDA-approved labels listing indications, warnings and other information. Pursuant to the PLA, however, Amgen is precluded from expanding its Epogen franchise to take advantage of the indications for epoetin alfa obtained by J&J.

44. Amgen's solution to that limitation was to develop a new ESA, darbepoetin alfa, or Aranesp. In Amgen's internal documents, darbepoetin alfa is sometimes referred to as Novel Erythropoiesis Stimulating Protein, or NESP. The molecular structure of darbepoetin alfa is slightly different from that of epoetin alfa and lasts longer in the bloodstream. The clinically significant impact was that darbepoetin alfa needed to be administered less often than epoetin alfa. The commercially significant impact was that Amgen could now market a product in the lucrative oncology market and otherwise seek to expand its ESA franchise in ways the PLA precluded it from doing with Epogen.

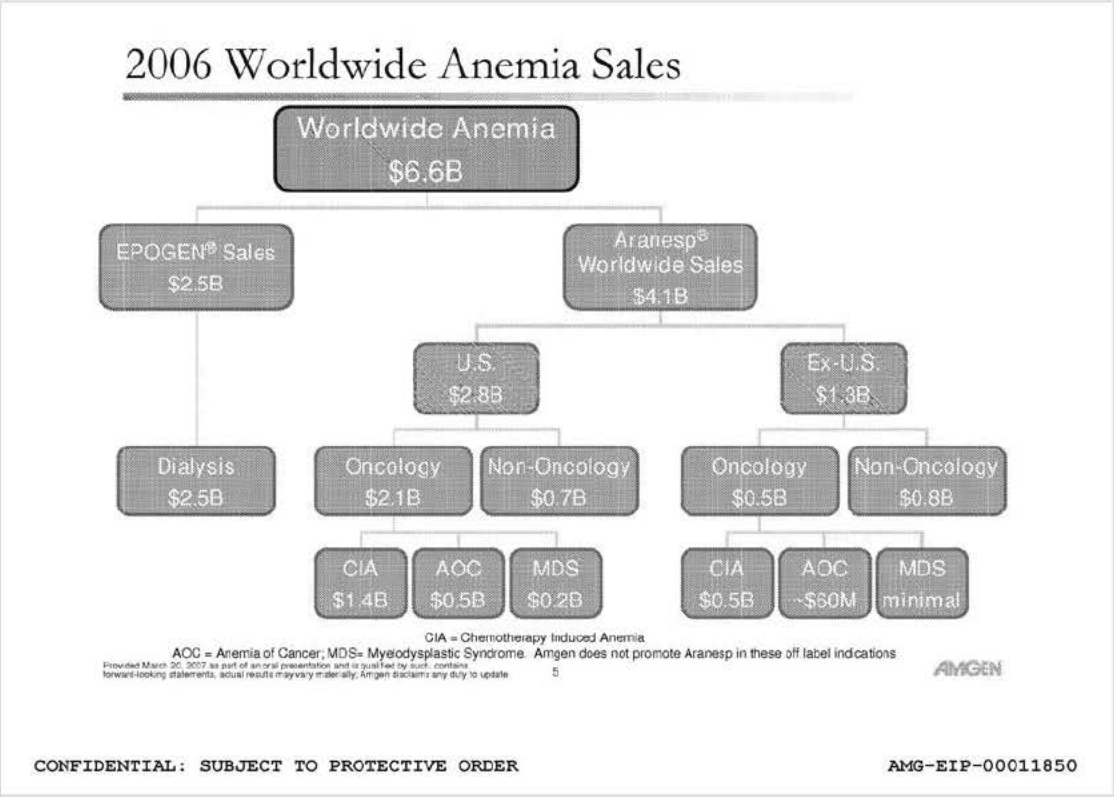
45. The PLA between Amgen and J&J, entered into when Amgen was still a struggling start-up hungry for capital, has allowed J&J to reap billions of dollars from sales of Procrit. As described in a *Forbes* article entitled "Amgen's Enemies" dated October 14, 2006, Amgen "sidestepped" the PLA through its development of Aranesp so it could reclaim the market it had given to J&J.

46. In 2001, the FDA awarded Amgen approval to market Aranesp for the treatment of anemia associated with chronic renal failure ("CRF"), including patients on dialysis (end stage renal disease) and patients not on dialysis. In 2002, Amgen secured approval to market Aranesp for the treatment of anemia associated with cancer chemotherapy, commonly referred to as chemotherapy-induced anemia, or CIA. By early 2004, Aranesp had a 45% share of domestic non-dialysis ESA share to Procrit's 55%; by the close of the Class Period, Amgen had overtaken J&J and controlled over half this market.

47. Amgen's ESA franchise has been core to its survival and its success. Now a Fortune 200 company, Amgen is the largest biotechnology company in the world, and generated $14.3 billion in revenues in 2006. According to an investor presentation made by Defendant Morrow in March 2007, approximately half of Amgen's 2006 revenues came from sales of Epogen and Aranesp:



48. *The New York Times* once described Epogen as the "best-selling drug ever created by biotechnology." However, by 2006, according to Morrow's presentation, Amgen's sales of Aranesp had far surpassed its sales of Epogen, with $4.1 billion in worldwide sales compared with Epogen's $2.5 billion:



49. By 2006, Aranesp accounted for more than 60% of the Company's ESA sales, with the single largest contributor of Aranesp sales being almost $2 billion worldwide for use in patients with chemotherapy induced anemia.

B. Early Safety Signals With ESAs

50. The clinical testing conducted to obtain FDA approval for Epogen, Procrit and Aranesp established that subjects who were administered the study drug were less likely to require transfusions than subjects who were administered a placebo. The trials were not designed to assess, as a primary endpoint, the overall survival rates of participants or other clinically meaningful metrics.

51. Several early studies observed an association between ESA therapy and cardiovascular events. The original FDA-approved labels for both Epogen and Aranesp warned that they may increase the risk of cardiovascular events, including death, that higher risk of cardiovascular events may be associated with higher hemoglobin and/or higher rates of rise of hemoglobin, and that hemoglobin level should be managed to avoid exceeding a target level of 12 g/dL.

52. At the time Procrit was approved for treating anemia associated with cancer chemotherapy in 1993, the FDA also noted that epoetin alfa could potentially serve as a growth factor for malignant tumors. Amgen and J&J therefore agreed to conduct a study (N93-004) to rule out a decrease of 15 percent in the overall tumor response rate after chemotherapy with epoetin alfa when compared with patients receiving chemotherapy alone. Amgen and J&J terminated the study early due to slow accrual rates. The study did meet its objective, but there was also a higher incidence of vascular (extracardiac) adverse events in the group receiving epoetin alfa, and the median duration of survival was 10.5 months among epoetin alfa-treated subjects compared with 10.4 months among placebo-treated subjects.

53. In the late 1990s and early 2000s there were several larger-scale clinical tests performed on ESAs, including the "Normal Hematocrit" Study, ENHANCE and BEST.

54. The Normal Hematocrit Study, published in 1998, was a randomized controlled study of CRF patients with established heart disease. The study compared anemic patients targeted to increase their hemoglobin to either low level or a normal level. The study was stopped by its data safety monitoring board because of a higher rate of vascular thrombosis (the formation of blood clots within blood vessels) in patients randomized to the normal-level group. Patients in that group also had a higher, although not statistically significantly higher, rate of nonfatal heart attacks and death.

55. In 2003, data from two large-scale clinical trials testing ESAs on cancer patients in Europe, ENHANCE and BEST, raised concerns over the safety of the entire ESA class. In the ENHANCE trial (also known as the "Henke" trial), patients with head and neck cancer dosed with Hoffmann-La Roche's epoetin beta product Neorecormon had substantially shorter progression-free survival and overall survival than the placebo group. The Breast Cancer Erythropoietin

Survival Trial ("BEST") (also known as INT-76 or the "Leyland-Jones" trial) was stopped after only four months because of increased mortality in breast cancer patients receiving an epoetin alfa product called Eprex manufactured by a J&J company for marketing outside the U.S.

56. ENHANCE involved 351 patients; BEST involved over 900. By contrast, the data set used by the FDA in 1993 to approve the use of epoetin alfa for cancer patients with chemotherapy-induced anemia consisted of pooled data from six clinical trials, none of which was designed to measure clinical outcomes as a primary endpoint, and which had a combined study population of 131 patients.

57. Both ENHANCE and BEST studied ESAs marketed in Europe but not approved by the FDA for use in the U.S., evaluated patient populations for which ESAs had not been approved in the U.S., and dosed to high target hemoglobin levels. While these distinctions prevented the studies from providing definitive evidence of a safety problem involving Epogen or Aranesp, they did prompt substantial safety concerns on the part of the FDA, given the absence of any compelling countervailing evidence. In other words, according to the FDA there were no large, well-controlled clinical trials measuring survival, tumor growth or other clinically significant metrics using approved ESAs in approved populations and targeting approved hemoglobin levels to show that ESAs were at least as safe as a placebo. The earlier epoetin alfa and darbepoetin alfa clinical trials measuring study-drug and placebo transfusion percentages were not designed to measure clinically significant outcomes and did not provide data robust enough to address the negative safety signals raised by ENHANCE and BEST.

C. Amgen Misled Investors Concerning the Safety Profile of Its ESAs

58. The allegations concerning the misrepresentations and/or omissions made by Defendant Morrow on April 22, 2004 were previously upheld by the Court in its Order GRANTING in part and DENYING in part Defendant's Motion to Dismiss the Consolidated Amended Complaint dated February 1, 2008 ("MTD

Opinion"). *See* October 2007 Complaint (Dkt. No. 109) ¶¶ 136-137 (alleging claims concerning April 22, 2004 statement); MTD Opinion at 13-16 (upholding claims concerning the safety of ESAs, including Defendant Morrow's April 22, 2004 statements).

1. The 2004 ODAC Meeting

(a) Defendant Morrow's April 22, 2004 Misrepresentations

59. In light of the safety signals raised by the ENHANCE and BEST trials, in May of 2004 the FDA convened a meeting of leading experts in the field of oncology – the Oncologic Drugs Advisory Committee, or ODAC – to seek its counsel as to what should be done (the "2004 ODAC Meeting").

60. In the weeks leading to the 2004 ODAC Meeting, Amgen held a conference call with analysts on April 22, 2004 to discuss its earnings for the first quarter of 2004. Defendants Sharer, Nanula and Morrow participated for Amgen. Specifically concerning the ODAC Meeting, they were asked "Could you comment on a FDA meeting that I've heard about I believe several weeks from now where they're going to look into the safety of Aranesp and other erythropoietic products and what the scope of that meeting would be?" Defendant Morrow, Amgen's Executive Vice President of Global Commercial Operations, responded as follows:

> Yes, this is the oncology. It's called the ODAC meeting. It's going to be held on May 4. And it really was called due to the two studies that were done on Eprex and Neorecormon in Europe where there was an issue about long-term survival in cancer populations.
>
> So we had answered and recognized the risen issue for Tobin, Alpha, and Beta. Just as a reminder, those products were used off-label at higher hematocrit levels than dictated by the label. And we also feel there was some potential study design flaws.

> And so we're anxious to learn more about those studies during this meeting as well.
>
> Now we had decided to participate in that meeting 'cause the focus was not on Aranesp and as Roger said late last year, ***there is no signal associated with Aranesp.*** We've had two p[ro]spective randomized placebo controlled trials. ***And the safety for Aranesp has been comparable to placebo.***
>
> We continue to investigate with well-designed studies on Aranesp and we're working closely with the FDA on this issue. But just as a reminder, it's two weeks away so that's pretty much all we know today.

(Emphasis added.)

(b) Facts Establishing That the April 22, 2004 Statements or Omissions Are Untrue or Misleading, and Giving Rise to a Strong Inference of Scienter

61. The following misrepresentations and/or omissions of material fact were made in April 2004:

(a) Defendant Morrow's April 22, 2004 statement that "***there is no [safety] signal associated with Aranesp***"; and

(b) Defendant Morrow's April 22, 2004 statement that "***the safety for Aranesp has been comparable to placebo***."

62. These two distinct misrepresentations were materially false or misleading when made. They give rise to a strong inference that Defendants Morrow and Amgen acted with scienter because they misrepresented or omitted the material adverse facts set forth below, or created a false impression as to the facts presented and statements made by authorized senior officers of Amgen whose scienter is imputable to Amgen itself.

(i) [redacted]

63. Contrary to Morrow's statement that "there is no signal associated with Aranesp", [redacted]

64. One of the two "p[ro]spective randomized placebo controlled trials" about which Defendant Morrow spoke in his April 22, 2004 statement was Protocol 20000161, or the 161 Study, a multicenter, blinded, placebo-controlled, randomized study of Aranesp for the treatment of anemia in subjects with lymphoproliferative malignancies receiving chemotherapy. [redacted]

[redacted]

One of the central tenets of the scientific method is the primacy of a pre-specified plan for analyzing data. Deviating from pre-specified criteria with post hoc data mining to present data in a more favorable light is an unscientific and unacceptable departure from the scientific method. Adherence to the scientific method with respect to the 161 Study long-term follow-up thus required Amgen to adhere to a consistent methodology for determining overall survival.

69. [redacted]

[redacted]

(ii) [redacted]

[redacted]

[redacted]

74. Accordingly, Defendant Morrow knew or was deliberately reckless in disregarding that at the time of his April 22, 2004 statement, [redacted]

75. The gravity of the 161 Study long-term follow-up results would have been obvious to Morrow, a senior executive at a biotechnology company. Moreover, during the Class Period, Defendant Morrow publicly demonstrated his facility with hazard ratios and what they mean. At an analyst conference in March of 2007, Morrow discussed why it matters whether a hazard ratio confidence interval "crosses 1" in the context of a different clinical trial of another drug: "The hazard ratio, basically, is the probability of having [an] event in the active arm . . . And since the confidence interval does not cross 1, it's a statistically significant event"; "Here the hazard ratio is 1.08. The confidence interval crosses 1, so that is not a statistically significant difference." Applying this criteria to the data cited above, patients who took Aranesp in the 161 Study [redacted].

76. As more fully alleged *infra* in ¶ 254, the disclosure correcting these misrepresentations and/or omissions of material fact was a substantial proximate cause of the stock drop on May 10 and 11, 2007.

2. Amgen's May 4, 2004 Statements in Connection With the ODAC Meeting

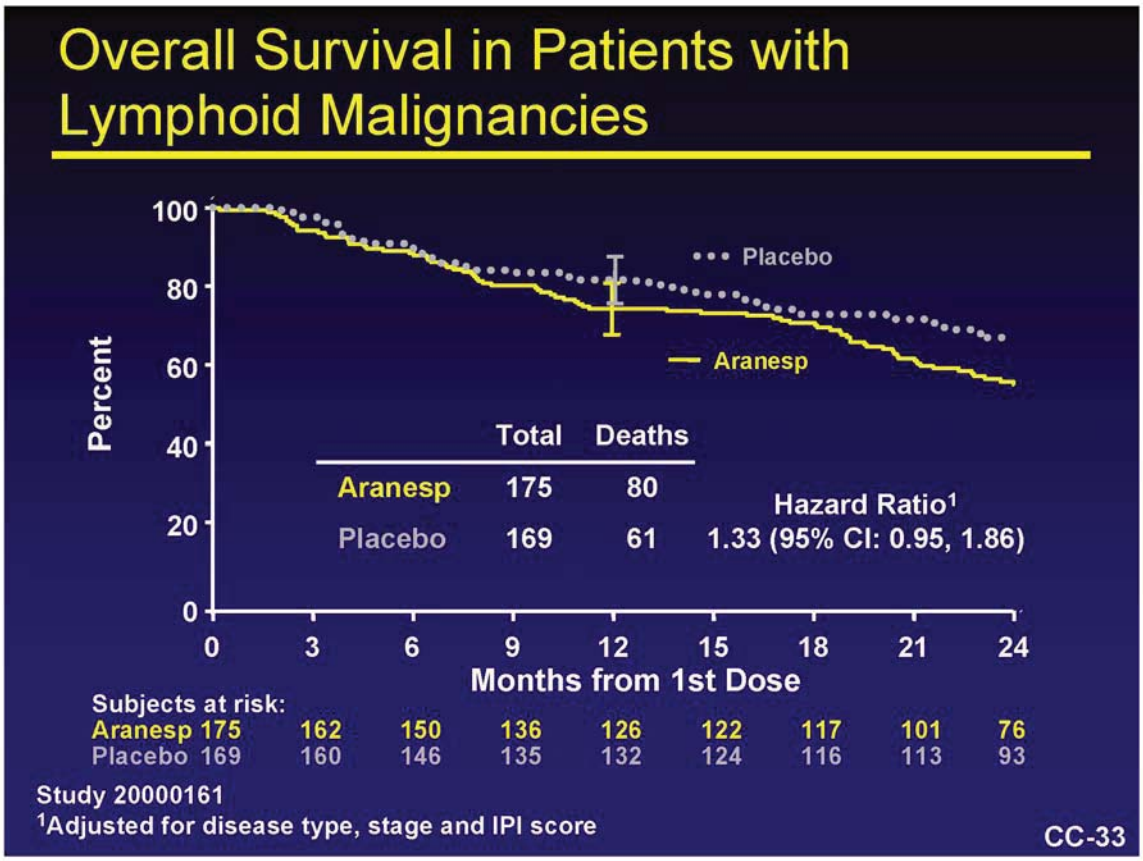
(a) Untrue or Misleading Statements or Omissions of Material Facts

77. In its "briefing book" for the 2004 ODAC Meeting, Amgen stated as follows:

> The recent INT-76 [BEST] and ENHANCE studies . . . employed treatment regimens that were outside the currently-approved labeling and guidelines. The results from these studies are not in keeping with previous epoetin oncology studies that have examined survival outcomes, and ***such findings have not been observed with Aranesp therapy.*** (Emphasis added.)

78. At the 2004 ODAC Meeting, Amgen spokesman David Parkinson, M.D., Vice President, Oncology Clinical Development, presented 161 Study long-term follow-up data, stating as follows: "On this slide, we observe no convincing evidence for a significant decrease in overall survival in association with Aranesp therapy. Again, the hazard ratio is above 1, but the confidence interval extends below 1."

79. The accompanying slide, entitled "Overall Survival in Patients with Lymphoid Malignancies," contained a Kaplan-Meier curve and stated: "Hazard Ratio 1.33 (95% CI: 0.95, 1.86)" with a footnote explaining that the hazard ratio was "Adjusted for disease type, stage and IPI score":



80. Defendants, in footnote 1 of the above graph, stated "Adjusted for disease, stage and IPI score." Defendants failed to disclose that [redacted]

(b) Facts Establishing That Statements or Omissions Are Untrue or Misleading, and Giving Rise to a Strong Inference of Scienter

81. The following misrepresentations and/or omissions of material fact were made at or in connection with the May 4, 2004 ODAC Meeting:

(a) Amgen's statement in its briefing book that "such findings have not been observed with Aranesp therapy"; and

(b) Amgen's omission of a material fact that [redacted]

[redacted]

82. These misrepresentations and/or omissions of material fact were materially false or misleading when made. They give rise to a strong inference that Defendant Amgen acted with scienter because it misrepresented or omitted the material adverse facts set forth below, or created a false impression as to the facts presented and statements made by authorized senior officers whose scienter is imputable to Amgen itself.

83. Each of the statements alleged herein that was made by a senior officer of Amgen other than the Individual Defendants was made at the direction of and/or otherwise authorized by Defendants.

84. At the 2004 ODAC Meeting, Amgen picked up where Defendant Morrow left off by continuing to rely on the 161 Study to justify Aranesp's safety. Contrasting the negative safety signals in the BEST and ENHANCE trials with Amgen's own clinical trial experience with Aranesp, Amgen stated in its briefing book that "such findings have not been observed with Aranesp therapy." That statement is demonstrably false for the same reasons why Morrow's April 22, 2004 statement is false. In fact, [redacted]. *See* ¶¶ 69-75.

85. But for the 2004 ODAC Meeting Amgen went even further, presenting summary data from the 161 Study long-term follow-up to bolster its claims of Aranesp's safety. The data Amgen presented appeared to demonstrate that overall patient survival did not favor placebo-treated patients over Aranesp-treated patients by a statistically significant margin. However, to arrive at that result, [redacted]

86. [redacted]

89. Similarly, the statement by Dr. Parkinson misled the audience of regulators, ODAC members, cancer patients, health care providers, investors and others in stating "[o]n this slide, ***we observe no convincing evidence for a significant decrease in overall survival in association with Aranesp therapy. Again, the hazard ratio is above 1, but the confidence interval extends below 1.***" [redacted] Parkinson knew or was deliberately reckless in disregarding that he was utilizing data and delivering a

message that created a false impression of safety and misrepresented and understated Aranesp's risk.

90. The above statements were also false or misleading because they affirmatively created an impression of a state of affairs that differed in a material way from the one that actually existed.

91. The above statements were also false or misleading because Amgen, the Individual Defendants, and Amgen's representatives at the 2004 ODAC Meeting, had access to or actual knowledge of information contradicting the veracity of the statements when the statements were made.

92. As more fully alleged *infra* in ¶ 254, the disclosure correcting these misrepresentations and/or omissions of material fact was a substantial proximate cause of the stock drop on May 10 and 11, 2007.

3. Defendants' Actionable Omissions Concerning the DAHANCA 10 Trial

93. The allegations concerning Amgen's omissions regarding the DAHANCA 10 Trial were previously upheld in the Court's MTD Opinion. *See* Complaint (Dkt. No. 109), at ¶¶ 129-134 (alleging claims concerning DAHANCA 10 Trial omissions; MTD Opinion at 21-23 (upholding claims concerning DAHANCA 10 Trial omissions).

(a) Untrue or Misleading Statements or Omissions of Material Facts

94. Amgen made actionable omissions of material fact when it failed to timely disclose the fact of, and reasons for, the halting and termination the DAHANCA 10 Trial of Aranesp. On October 18, 2006, the DAHANCA investigators temporarily halted the study "due to information about potential unexpected negative effects related to immunohistochemical estimation of the so-called EPO receptor."[redacted] On or about December 1, 2006, Overgaard

informed Amgen that the trial had been terminated early. [redacted]

95. Amgen did not disclose any information concerning developments in the DAHANCA 10 Trial to investors. On February 16, 2007, a periodical called *The Cancer Letter* disclosed recent developments to the market when it published an article about the halting and unplanned termination of the DAHANCA 10 Trial.

(b) Facts Establishing That Statements or Omissions Are Untrue or Misleading and Giving Rise to a Strong Inference of Scienter

96. Purportedly to address the concerns raised by the FDA over ESA safety, at the 2004 ODAC Meeting, Amgen presented its "Pharmacovigilance Program," five planned or ongoing trials selected by Amgen to test Aranesp in different tumor treatment settings. David Parkinson, M.D., Amgen's Vice President, Oncology Clinical Development, asserted that the Pharmacovigilance Program was "a responsible and credible approach to definitively resolving the questions raise[d] in this morning's meeting." Thus, Amgen represented these trials as important baselines for future safety judgments by both the FDA and investors.

97. One of the five clinical trials in the Pharmacovigilance Program was a trial of Aranesp sponsored by the Danish Head and Neck Cancer Group ("DAHANCA"). This study, SE-2002-9001 (the "DAHANCA 10 Trial"), was to test Aranesp in subjects with head and neck cancer, and, specifically, to test whether dosing to high hemoglobin levels (above the label) could aid in shrinking the tumors of such cancer patients when receiving radiation therapy.

98. By virtue of its inclusion in the Pharmacovigilance Program, the DAHANCA 10 Trial was held out by Amgen as material to a resolution of the

FDA's concerns over safety signals with ESAs. Indeed, the study's Principal Investigator, Dr. Jens Overgaard, appeared and spoke at the 2004 ODAC Meeting as a guest of Amgen. Because the DAHANCA 10 Trial was held out by Amgen as a purportedly "responsible and credible" way to "definitively resolv[e] the questions raise[d]" about ESA safety at the 2004 ODAC Meeting, statements about ESA safety, disclosure of the DAHANCA 10 Trial's halting and termination were necessary to make the statements Defendants made, in the light of the circumstances under which they were made, not misleading.

99. On February 16, 2007, *The Cancer Letter* reported that the DAHANCA 10 Trial had been temporarily halted back in October 2006, and permanently terminated on December 1, 2006, because it showed "significantly inferior therapeutic outcome from adding Aranesp to radiation treatment of patients with head and neck cancer." Under the banner "Amgen Didn't Tell Wall Street About Results Of Danish Study," the article continued: "Several Wall Street sources who monitor Amgen confirmed that they have been awaiting these results and were not aware of them until hearing about the closing of the trial from this reporter." *The Cancer Letter* further stated that "even informed observers have been largely unaware that the Danish study was temporarily stopped on Oct. 18, 2006, and that the decision not to resume the study was made on Dec. 1, 2006, and posted on the Web by the principal investigator, Jens Overgaard."

100. Because Amgen had communicated to the market that the DAHANCA 10 Trial was part of Amgen's response to the FDA's inquiry, and that the results of the trial would be part of a resolution of the FDA's concerns about the safety of ESAs when used on label, Amgen had a duty to inform the market about material developments concerning the trial, including its being halted or prematurely terminated. These material facts were not disclosed: First, that DAHANCA had shown that tumor growth and mortality had increased at the dosage levels prescribed to such an extent that the trial had to be halted. Second,

that one of the five baseline studies set forth by Amgen as "tests" for the safety of Aranesp was now gone, with only four left. Third, the DAHANCA cessation meant there would be no support for the *expansion* of Aranesp sales based on the drug being used for a *new* purpose, *i.e.*, to shrink the tumors of cancer patients receiving radiation therapy—the purpose for which the test originally was designed. Thus, *The Cancer Letter* reported that "[e]xperts say that the hypothesis underlying the study—that avoidance of anemia would result in a better radiation effect—now appears to be disproved."

101. For these reasons the termination was highly material to investors. Indeed, *The Cancer Letter* reported that the study result had been "eagerly awaited by physicians, investors, regulators, and payers around the world."

102. The reason for the termination, and the fact of the termination, also were material to investors, because the interim trial result showed a statistically significant difference to the disfavor of Aranesp in terms of tumor progression.

103. After the article was published, Amgen hastily arranged an analyst call for later that same day. According to Defendant Perlmutter's statement during the conference call, the call was justified because "enough people had called us." Defendant Sharer admitted the problem: "In retrospect, it would have been ideal to mention that the DAHANCA 10 study was stopped as well as the status of the other FDA-approved pharmacovigilance trials. We will do that, going forward." Such admission is imputable to Amgen.

104. Defendants had numerous opportunities to disclose the halting and termination of the DAHANCA 10 Trial (and, for that matter, the 161 Study long-term follow up results, which were finalized in 2005), including:

(a) in its November 20, 2006 website posting defending the safety of Aranesp and Epogen in response to news about the CHOIR and CREATE trials (*see* ¶¶ 108-109);

(b) in its December 4, 2006, stating, *inter alia*, that "EPOGEN and Aranesp are effective and safe medicines when administered according to the Food and Drug Administration (FDA) label" (*see* ¶ 110);

(c) during Amgen's January 25, 2007, earnings conference call, when Amgen released top-line results of the 103 Study and otherwise discussed the issue of ESA safety (*see* ¶¶ 121-122).

105. As more fully alleged *infra* in ¶ 243, the disclosure correcting the omissions of these material facts was a substantial proximate cause of the stock drop on February 16, 2007.

4. Defendants Amgen, Sharer, Morrow and Perlmutter and Other Authorized Officers Misrepresented the Safety of Amgen's ESAs Through 2006 and 2007

106. The allegations concerning these statements were previously upheld by the Court in its MTD Opinion. *See* October 2007 Complaint (Dkt. No. 109) ¶¶ 108-149 (alleging claims concerning the safety of ESAs); MTD Opinion at 20 (upholding claims concerning the safety of ESAs).

(a) Untrue or Misleading Statements or Omissions of Material Facts

107. As adverse clinical trial results began to appear in late 2006, Amgen repeatedly asserted that substantial clinical evidence supported the purported safety of Epogen and Aranesp when prescribed in accordance with FDA-approved dosing guidelines when in fact they knew such evidence did not exist one way or the other.

108. On November 20, 2006, the Company posted a statement titled "Amgen Responds to CHOIR and CREATE Clinical Trial Data" on the "Featured Content" page of its website. CHOIR and CREATE were clinical trials of ESAs on chronic kidney disease patients; the results of both studies were published in the November 16, 2006 issue of the *New England Journal of Medicine*. The CHOIR data safety monitoring board terminated the study early due to findings of an

increased risk of death and cardiovascular hospitalization in patients assigned to achieve a target hemoglobin of 13.5 g/dL with epoetin alfa. The study's primary hypothesis was that anemia correction to 13.5 g/dL in patients with chronic kidney disease would decrease mortality and cardiovascular morbidity, but the study showed the opposite. In CREATE, patients with chronic kidney disease and mild to moderate anemia were randomized to treatment with epoetin beta to either a high or a low target hemoglobin. On November 16, 2006, Roche Pharmaceuticals announced that the CREATE results "clearly show that there is no additional cardiovascular benefit from treating to higher hemoglobin levels in this patient group."

109. Attempting to reaffirm the safety of Aranesp and Epogen for their on-label uses, Amgen's November 20, 2006 website posting stated in relevant part:

> A very substantial body of evidence, developed over the past 17 years, demonstrates that anemia associated with chronic kidney disease ***can be treated safely*** and effectively with EPOGEN® and Aranesp®, ***when administered according to the Food and Drug Administration (FDA)-approved dosing guidelines***. In particular, the FDA-approved labels for both drugs define regimens aimed at achieving a hemoglobin target not to exceed 12 g/dL. (Emphasis added.)

110. Amgen addressed additional negative reports of its ESA drugs' safety on December 4, 2006, when it issued a press release titled "Amgen Responds to Reports About Use and Safety of EPOGEN and Aranesp in CKD Anemia Therapy." In this press release, the Company stated:

> Amgen [] today posted to its corporate web site documents intended to clarify Amgen's position on the use of EPOGEN(R) (Epoetin alfa) and Aranesp(R)

> (darbepoetin alfa) and to correct what the company believes are misleading and inaccurate news reports regarding the use of its drugs.
>
> . . . .
>
> ***EPOGEN and Aranesp are*** effective and ***safe medicines when administered according to the Food and Drug Administration (FDA) label***. (Emphasis added.)

111. On February 16, 2007, Amgen held a conference call with analysts to discuss the DAHANCA 10 Trial in response to the premature termination of the study reported earlier that day in *The Cancer Letter*. Defendant Sharer told analysts "[w]e strongly believe, as we have consistently stated, ***that Aranesp and Epogen are safe and effective medicines when used in accordance with label indications.***" (Emphasis added.)

112. On March 1, 2007, Amgen participated in the Goldman Sachs "In Your Office" Call. During that conference, Defendant Sharer stated that "[w]hen we look at the totality of the data***, we believe our products are safe and effective when used on-label."*** (Emphasis added.) Defendant Morrow added: ***"As a reminder, there is a large body of evidence in our labeled indications that support, as Kevin said, the safe and effective use of Aranesp."***

113. On March 9, 2007, the FDA announced that it would mandate what is commonly referred to as a "black box" warning or "boxed warning" on the label for ESAs, including Aranesp and Epogen. The FDA imposed the black box warning on ESAs as a result of increased safety concerns arising from negative results in several "off-label" clinical trials including the DAHANCA 10 Trial (*see* ¶¶ 93-104) and the 103 Study (*see* ¶¶ 121-122 below). The boxed warning cautioned against the use of ESAs in the off-label settings studied in the clinical trials described in the warning.

114. In response to the black box warning regarding off-label usage, on March 9, 2007, Amgen issued a statement titled "Amgen's Statement on the Safety of Aranesp® (darbepoetin alfa) and EPOGEN® (Epoetin alfa)." In relevant part, the statement misleadingly stated:

> Aranesp® (darbepoetin alfa) and EPOGEN® (Epoetin alfa) have ***favorable risk/benefit profiles*** in approximately four million patients with chemotherapy-induced anemia or CKD ***when administered according to the FDA-approved dosing guidelines***. (Emphasis added.)

(b) Facts Establishing That Statements or Omissions Are Untrue or Misleading and Giving Rise to a Strong Inference of Scienter

115. The following misrepresentations and/or omissions of material fact were made with respect to the safety of Amgen's ESAs in 2006 and 2007:

(a) Amgen's November 20, 2006 statement that "anemia associated with chronic kidney disease can be treated safely and effectively with EPOGEN® and Aranesp®, when administered according to the Food and Drug Administration dosing guidelines";

(b) Amgen's December 4, 2006 statement that "EPOGEN and Aranesp are … safe medicines when administered according to the Food and Drug Administration (FDA) label";

(c) Defendant Sharer's February 16, 2007 statement "that Aranesp and EPOGEN are safe and effective medicines when used in accordance with label indications";

(d) Defendant Sharer's March 1, 2007 statement that "we believe our products are safe and effective when used on-label";

(e) Defendant Sharer's March 1, 2007 statement that "there is a large body of evidence in our labeled indications that support … the safe and effective use of Aranesp"; and

(f) Amgen's March 9, 2007 statement that "Aranesp … and EPOGEN® … have favorable risk/benefit profiles … when administered according to the FDA-approved dosing guidelines";

116. These statements were materially false or misleading when made and give rise to a strong inference that Defendants Sharer and Amgen acted with *scienter* because they misrepresented or omitted the material adverse facts set forth below, or created a false impression as to the facts presented and statements made by authorized senior officers of Amgen whose scienter is imputable to Amgen itself.

117. As alleged above, as trial after trial generated bad results for Aranesp, Amgen changed its message in 2006 to "safe when used on label". This statement was designed as a shield against further bad results using off label dosing regimes from other ongoing trials.

118. Amgen and the Individual Defendants were deliberately reckless in disregarding that there was simply no substantial evidence from on label dosage trials that would provide a reasonable basis for these statements repeatedly made in 2006 and up to the 2007 ODAC Meeting.

119. As more fully alleged *infra* in ¶ 254, the disclosure correcting these misrepresentations and/or omissions of material fact was a substantial proximate cause of the stock drop on May 10 and 11, 2007.

5. The Misrepresentations and/or Omissions of Defendants Amgen, Morrow and Perlmutter Regarding the 103 Study

120. The allegations concerning Defendant Perlmutter's January 25, 2007 statement was previously upheld by the Court in its MTD Opinion. *See* October

2007 Complaint (Dkt. No. 109) ¶¶ 23-24 (alleging claims regarding the 103 Study); MTD Opinion at 23-24 (upholding claims regarding the 103 Study).

(a) Untrue or Misleading Statements or Omissions of Material Facts

121. On January 25, 2007, *i.e.*, after Defendants had learned the results of the DAHANCA 10 Trial but before *The Cancer Letter* exposed those results, and long after the 161 Study long-term follow-up was completed, Amgen held a conference call to discuss its fourth quarter 2006 earnings. On that call the Company also announced the results of a clinical trial testing Aranesp in 939 patients with anemia of cancer (AOC). Internally Amgen referred to this trial as Study 20010103 or the 103 Study.

122. On the January 25 earnings call, Amgen described the results as "neutral and ***perhaps*** negative." (Emphasis added.) Defendant Perlmutter, Amgen's Executive Vice President of Research and Development, described the results of the 103 Study as follows:

> Let me now turn to Aranesp. In Aranesp, we received in the fourth quarter data from our Phase III study in the anemia of cancer setting. Now, this is an attempt to expand the label for Aranesp to include patients with anemia that is not secondary to chemotherapy but, in fact, is attributed to the cancer itself. The Phase III study evaluated anemic patients who had active malignancy who are not receiving chemotherapy or radiotherapy and in whom it was not planned to provide chemotherapy or radiotherapy in the near future.
>
> These individuals understandably are gravely ill, and in this patient population, one can expect that there would be a high frequency of adverse events. The study

> was designed to show, as we had previously shown in Phase II studies, that Aranesp could reduce the frequency of transfusions and improve quality of life. With respect to the transfusion-end point, the study did not meet its primary end point.
>
> We did not show a statistically significant reduction in transfusions in this patient population at the 16-week end point. Moreover, we did see a statistically significant adverse effect of Aranesp on overall mortality in this patient population, and so ***we conclude that the risk benefit ratio for Aranesp in these extremely ill patients with anemia secondary to malignancy is, at best, neutral and perhaps negative.*** (Emphasis added.)

(b) Facts Establishing That Statements or Omissions Are Untrue or Misleading and Giving Rise to a Strong Inference of Scienter

123. The following misrepresentation and/or omission of material fact were made with respect to the 103 Study: Defendant Perlmutter's January 25, 2007 statement that "the risk benefit ratio for Aranesp in this extremely ill patients with anemia secondary to malignancy is, at best, neutral and perhaps negative".

124. This statement was materially false or misleading when made and gives rise to a strong inference that Defendants Amgen and Perlmutter acted with *scienter* because they misrepresented or omitted the material adverse facts set forth below, or created a false impression as to the facts presented and statements made by authorized senior officers of Amgen whose scienter is imputable to Amgen itself.

125. No one within Amgen reasonably could have believed the spin Amgen put on the 103 Study results when they were announced in January 2007. It was a failure – Aranesp patients did not have fewer transfusions but they were

more likely to die. The key result of the 103 Study, as later described by the FDA, was that it "demonstrated significantly shorter survival in cancer patients receiving ESAs as compared [to] those receiving transfusion support." Defendants, however, sought to minimize the results of the 103 Study.

126. Perlmutter's statement was also misleading because he knew or was deliberately reckless in not knowing that the 103 Study was likely to carry great weight with the FDA; the target hemoglobin level, 12 g/dL withhold at 13 g/dL, was consistent with the instructions on Aranesp label. In other words, "the 103 Study was more akin to what the FDA was looking for in 2004, since it involved on-label rather than off-label dosages." MTD Opinion at 24. Indeed, the FDA believed in 2004 that it had obtained Amgen's commitment to conduct studies consistent with Aranesp's label. The FDA's briefing book for the 2004 ODAC Meeting states that "[i]n discussion with both firms [i.e., Amgen and J&J], FDA has requested ***and both firms have agreed*** to conduct adequately designed trials that will assess whether, ***when administered in accordance with current labeling***, there is evidence of tumor stimulation or impairment in survival (due to tumor stimulation, thrombotic events, or any cause) with Epogen/Procrit or Aranesp." (Emphasis added.)

127. [redacted]

[redacted]

128. Perlmutter's minimization of the importance of the 103 Study on January 25, 2007 was also misleading because he omitted to state material facts necessary to make the statements not misleading, namely the 161 Study long-term follow-up and DAHANCA 10 Trial results.

129. As more fully alleged *infra* in ¶ 254, the corrective disclosure of this misrepresentation and/or omission of material fact was a substantial proximate cause of the stock drop on May 10 and 11, 2007.

6. The Misrepresentations and/or Omissions of Defendants Amgen, Sharer and Perlmutter Concerning the 145 Study

(a) Untrue or Misleading Statements or Omissions of Material Facts

130. On April 19, 2007, Amgen announced that the 145 Study, an Amgen-run clinical trial that examined Aranesp's use in treating small-cell lung cancer ("SCLC") patients, found that Aranesp did not increase the risk of death in patients receiving chemotherapy.

131. In Amgen's April 19, 2007 press release, the following statement is attributed to Defendant Perlmutter: "These results contribute to the growing body of evidence on ESA safety, ***reinforcing the neutral impact of ESAs on survival in cancer patients suffering from chemotherapy-induced anemia***." (Emphasis added.)

132. During Amgen's April 23, 2007 earnings conference call with Wall Street analysts, Defendant Sharer further stated:

> It is certainly our very, very strong conviction that our products are very safe when used on label. ***The new 145 data is obviously reinforces that point of view.*** (Emphasis added.)

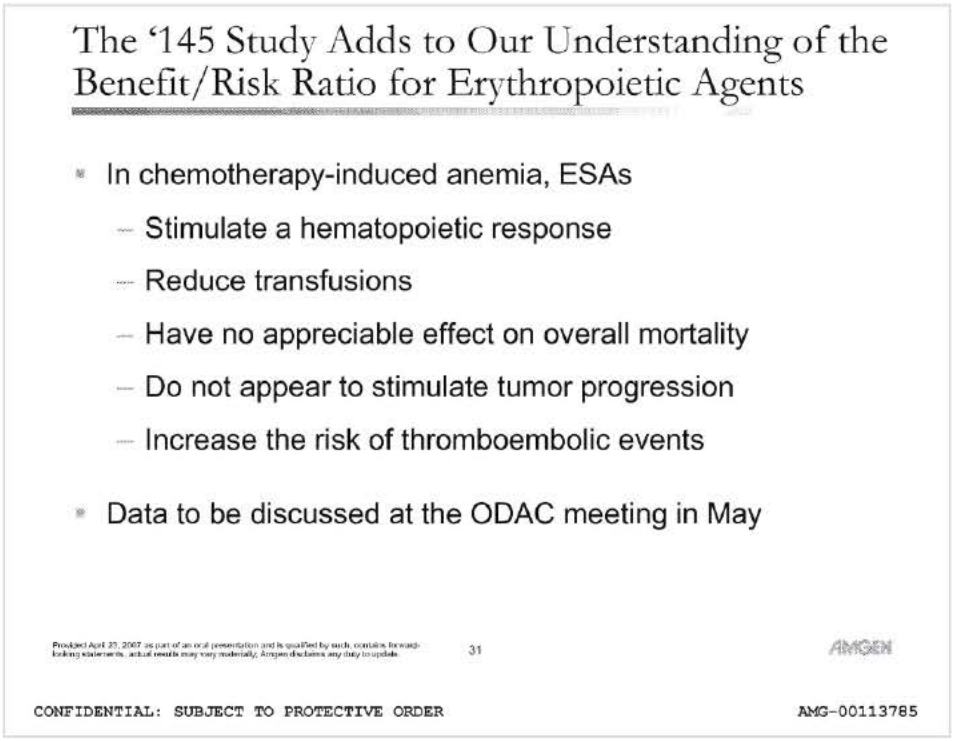
133. On that same conference call with Wall Street analysts, Defendant Sharer again addressed the safety of Amgen's ESAs. He stated:

> The overwhelming conclusion that -- that I reach and others have reached in looking at all that data is that on label ***our drugs are certainly safe***.
>
> * * *
>
> ***It is certainly our very, very strong conviction that our products are very safe when used on label.*** The new 145 data is obviously reinforces that point of view. (Emphasis added.).

134. On that same call, Defendant Perlmutter stated as follows:

> So looking out across the totality of studies ***we can see the 145 study adds substantially to our understanding of the benefit-risk ratio for Erythropoietic agents*** In chemotherapy-induced anemia, ESAs unquestionably stimulate hematopoietic and reduce transfusions, and indeed that's what's listed on our label, and that's how we originally attained approval for Aranesp in this indication. ***ESAs have no appreciable effect on mortality in chemotherapy-based anemia***, they do not appear to stimulate tumor progress, they do increase the progression of thromboembolic events and the totality of these data will be discussed in the ODAC meeting in May. (Emphasis added.)

135. Accompanying Perlmutter's remarks was the following slide:



136. On May 3, 2007, Amgen Executive Vice President and Chief Financial Officer Bob Bradway (who replaced Defendant Nanula in April 2007) stated as follows on a call with securities analysts:

> I wanted to point out that the recent studies to which so much attention has been paid examined off-label hemoglobin targets and indications. ***The 145 study, in particular, strengthens our conviction, again, that our ESA products are safe when used on-label."*** (Emphasis added.)

137. On May 8, 2007, Amgen Vice President, Investor Relations, Arvind Sood said the following on a call with investors:

> There was a recent study that was done. It's just known as Study 145 in chemotherapy induced anemia patients, which is an approved indication for ARANESP and this particular study showed that using ESAs in these patients does not have any meaningful impact from a mortality

> standpoint, ***which further reinforces our conviction that these products, the ESA products are indeed safe when they're used on label.***
>
> . . . .
>
> Now Study 145, this is a study that I've noted as a 600 patient study in small cell lung cancer patients ***I think adds to our understanding in a substantial way in terms of the benefit-risk profile for ESAs. And this particular study once again confirms that ESAs*** do indeed simulate hematopoietic response. They do reduce transfusions and in this particular study in a statistically significant way, they ***have no appreciable affect [sic] on overall mortality*** and they do not appear to stimulate tumor progression, which has been one of the big concerns that has been postulated.
>
> They do increase the risk of thromboembolic events but this is a risk that is well known with the use of ESAs and a point that I've noted before, that we expect to have a more fulsome discussion of this data at the upcoming ODAC. (Emphasis added.)

(b) Facts Establishing That Statements or Omissions Are Untrue or Misleading and Giving Rise to a Strong Inference of Scienter

138. The following misrepresentations and/or omissions of material fact were made with respect to the 145 Study:

(a) Amgen's April 19, 2007 statement that the 145 Study reinforces "the neutral impact of ESAs on survival in cancer patients suffering from chemotherapy-induced anemia";

(b) Defendant Sharer's April 23, 2007 statement that "[t]he new 145 data … obviously reinforces that point of view [that Amgen's products are very safe when used on label]";

(c) Defendant Sharer's April 23, 2007 statements that "our drugs are certainly safe" and "[i]t is certainly our very, very strong conviction that our products are safe when used on label";

(d) Defendant Perlmutter's April 19, 2007 statement that "we can see the 145 Study adds substantially to our understanding of the benefit-risk ratio for Erythropoietic agents …";

(e) Bradway's May 3, 2007 statement that "[t]he 145 Study, in particular, strengthens our conviction, again, that our ESA products are safe when used on label"; and

(f) Sood's May 8, 2007 statement that the 145 Study "further reinforces our conviction that these products, the ESA products are indeed safe when they're used on label."

139. These statements were materially false or misleading when made and give rise to a strong inference that Defendants Amgen, Sharer and Perlmutter and Bradway and Sood acted with scienter because they misrepresented or omitted the material adverse facts set forth below, or created a false impression as to the facts presented and statements made by authorized senior officers whose scienter is imputable to Amgen itself.

140. Defendants and Bradway and Sood knew or were deliberately reckless in disregarding the non-generalizability of the 145 Study. Instead, they misleadingly elevated the significance of the 145 Study, creating the false impression that its results supported the broad conclusion that ESAs are safe.

141. [redacted]

[redacted][2]

[redacted]

[2] Emphasis added.

147. [redacted].

148. Defendants' statements and the statements of Bradway and Sood were also false and/or misleading because, as described above, they created an impression of a state of affairs that differed in material ways from the one that actually existed.

149. The foregoing statements were also false and misleading because Defendants had access to or actual knowledge of information contradicting the veracity of the statements when the statements were made.

150. As more fully alleged *infra* in ¶ 254, the disclosure correcting these misrepresentations and/or omissions of material fact was a substantial proximate cause of the stock drop on May 10 and 11, 2007.

7. Defendants Amgen, Sharer, Nanula, and Morrow Misrepresentations and/or Omissions Regarding Amgen's Marketing Practices

151. The allegations concerning these statements were previously upheld by the Court in its MTD Opinion. *See* October 2007 Complaint (Dkt. No. 109) ¶¶ 156-162 (alleging claims concerning all marketing-related statements; MTD Opinion at 25-29 (upholding claims concerning all marketing-related statements).

(a) Untrue or Misleading Statements or Omissions of Material Facts

152. During the Class Period, Amgen repeatedly misrepresented that its marketing practices complied with FDA regulations, including the FDA's prohibition on marketing drugs for off-label uses.

153. In Amgen's public filings, Defendants represented:

> We . . . conduct research, preclinical testing, and clinical trials [and] we manufacture and contract manufacture . . .

> our product candidates. We also manufacture and contract manufacture, price, sell, distribute, and market or co-market our products ***for their approved indications***. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, including Europe. (Emphasis added.)

154. The foregoing representation was made in Amgen's Forms 10-K for the fiscal years ended 2004, 2005, and 2006 and Forms 10-Q for the fiscal quarters ended June 30, 2004, September 30, 2004, March 31, 2005, June 30, 2005, September 30, 2005, March 31, 2006, June 30, 2006, and September 30, 2006. All of these Forms 10-K and 10-Q were signed by Defendants Sharer and Nanula.

155. Amgen and several of the Individual Defendants also repeatedly affirmed Amgen's compliance with FDA regulations governing marketing of off-label uses in public statements during the Class Period.

156. On December 4, 2006, in a press release titled "Amgen Responds to Reports About Use and Safety of EPOGEN and Aranesp in CKD Anemia Therapy," the Company affirmed, "Amgen only promotes the use of EPOGEN and Aranesp consistent with the FDA label."

157. The following month, on January 25, 2007, Defendant Morrow stated that "our promotion [of Epogen] ***has always been strictly according to our label***, we do not anticipate a major shift in clinical practice." (Emphasis added.)

158. During the same call, Defendant Sharer again falsely affirmed Amgen's adherence to FDA rules barring marketing of off-label uses. Addressing an analyst's question about the safety of Epogen, he inaccurately asserted that the CHOIR study, which showed adverse health effects from use of Procrit (J&J's equivalent of Epogen), was of limited relevance because it "was for a hemoglobin

above ***what we dose, and what we promote and what's on the label.***" (Emphasis added.)

(b) Facts Establishing That Statements or Omissions Are Untrue or Misleading and Giving Rise to a Strong Inference of Scienter

159. The following misrepresentations and/or omissions of material fact were made with respect to Amgen's marketing practices of ESAs:

(a) Amgen's statements in its Forms 10-Ks and 10-Qs filed during the Class Period that "[w]e also … sell, distribute and market or co-market our products for their approved indications";

(b) Amgen's December 4, 2006 statement that "Amgen only promotes the use of EPOGEN and Aranesp consistent with the FDA label";

(c) Defendant Morrow's January 25, 2007 statement that "our promotion [of EPOGEN] has always been strictly according to our label"; and

(d) Defendant Sharer's January 25, 2007 statement that Epogen is marketed for "what's on label."

160. These statements were materially false or misleading when made and give rise to a strong inference that Defendants Amgen, Morrow and Sharer acted with scienter because they misrepresented or omitted the material adverse facts set forth below, or created a false impression as to the facts presented and statements made by authorized senior officers whose scienter is imputable to Amgen itself.

161. At the same time the FDA was questioning whether ESAs were safe for *approved* indications and populations, Amgen was pushing Aranesp for *unapproved* indications and populations. Amgen's unparalleled success in marketing ESAs was due in part to its practice of promoting unapproved uses and increased per-patient dosages through improper and, in some cases, unlawful means.

162. Although physicians may prescribe drugs for off-label uses, the law prohibits drug manufacturers from marketing or promoting their drugs for

unapproved uses. A manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

163. Acknowledging the "extensive regulation" of drug marketing by the FDA and other regulatory authorities, Amgen repeatedly affirmed in its Class Period filings with the SEC that "[we] manufacture and contract manufacture, price, sell, distribute, and market or co-market our products ***for their approved indications***." (Emphasis added.)

164. Notwithstanding the prohibitions against off-label marketing, Amgen developed a sophisticated and multifaceted scheme to circumvent the rules and grow sales.

165. In December 2012, Amgen pleaded to a misdemeanor Criminal Information for "misbranding" in violation of 21 U.S.C. §§ 331(a) and 333(a)(1) in connection with its off-label marketing of Aranesp. By pleading guilty Amgen admitted that it had introduced into interstate commerce a drug that was "misbranded," in that its labeling lacked adequate directions for intended uses and dosages that were not approved by the FDA. *See* Criminal Information ¶¶ 11-13, 22, 41. The conduct that constituted the misbranding, as charged in the Criminal Information, involved Amgen's promotion of Aranesp in three off-label areas that were not approved by the FDA: (i) the off-label "QM" (once a month) dosage for the treatment of anemia in CRF patients; (ii) the off-label "Q2W" (once every 2 weeks) starting dosage for the treatment of anemia in CIA patients; and (iii) the off-label use in the treatment of AOC. *Id.* ¶ 41. Although the guilty plea occurred long after the Class Period, the off-label marketing conduct that constituted the Aranesp misbranding occurred *during* the Class Period – specifically, between September 2001 and March 2007, inclusive. *Id.* ¶¶ 22, 41. Amgen's corporate representative, who was duly authorized by Amgen's Board of Directors to enter

the guilty plea on its behalf, stated as follows at the December 18, 2012 plea hearing:

> ***We agree that on occasions within the time frame charged in the Information*** and in particular, shortly after the launch of Aranesp in 2003 and 2004 . . . Amgen introduced into interstate commerce Aranesp that was misbranded because it did not contain adequate directions for an intended use. . . .
>
> Specifically, ***during that time frame, Amgen intended that certain customers use Aranesp in a manner that was not yet approved by the FDA.*** Thus, the FDA-approved label for Aranesp did not contain adequate directs for that intended use.

Plea Hearing Transcript at 19:7-12; 21-25.

166. Further, the Criminal Information to which Amgen pleaded guilty provides detailed factual allegations of Amgen's off-label marketing in the three off-label areas that formed the factual basis for Amgen's guilty plea for misbranding. In entering its guilty plea, Amgen's corporate representative specifically agreed to the "sufficiency of the factual basis" for the offense charged. Plea Transcript at 19:4-6. Accordingly, the factual allegations in the Criminal Information that support the misbranding charge, which Amgen admitted by pleading guilty, further evidence Amgen's widespread off-label marketing schemes during the relevant time period and directly contradict Defendants' statements above that Amgen marketed its products only for their approved indications and only in accordance with the FDA label during that time frame. *See, e.g.*, ¶¶ 152-158 below.

167. Thus, in pleading guilty, Amgen admitted to engaging in off-label marketing of Aranesp during a time period when *all* of Defendants' marketing-

related statements in ¶¶ 152-158 were made. Accordingly, such statements were false and misleading because Amgen affirmatively created an impression that it was conforming to legitimate and sustainable business activities, a state of affairs that differed in a material way from that which actually existed.

168. Plaintiff's allegations that Amgen's off-label marketing schemes emanated from its national office (*see* ¶¶ 170, 173, 177-179, 193 and *compare* to October 1, 2007 Complaint ¶¶ 86, 89-91, 101, 157) together with other allegations in the Complaint, such as the widespread and lucrative nature of Amgen's off-label marketing (*see* ¶¶ 170-178), and Defendants' various statements in press releases, SEC filings, and earnings calls affirming that Amgen only promoted Aranesp and Epogen in accordance with the FDA label, support a strong inference that Amgen executives were aware of this marketing scheme or acted with deliberate recklessness. *See* MTD Opinion at 27.

169. Moreover, Amgen's admissions at the December 18, 2012 hearing during the entry of its guilty plea further support a strong inference that Amgen was aware of and intended that its employees engage in off-label marketing of Aranesp during the relevant time period. In particular, Amgen's corporate representative stated that "during that time frame [September 2001 through March 2007], ***Amgen intended*** that certain customers use Aranesp in a manner that was not yet approved by the FDA." Plea Hearing Transcript at 19:21-23 (emphasis added). He further stated:

> On occasions, ***Amgen's sales employees evidenced Amgen's intent*** that the customers engage in a new intended use of Aranesp by distributing to them scientific literature and reprints of Aranesp listed in compendia that discuss that use, such as new dosing regimens of the type described in the Information, and did so under circumstances where the FDA label did not contain

> adequate directions for the new intended use, as the term "adequate directions for use" is defined in the FDA regulations.

Id. at 20:1-9 (emphasis added).

170. Similarly, the Criminal Information to which Amgen pleaded guilty includes the following factual allegations in support of the misbranding charge, which also demonstrate Amgen's scienter with respect to Aranesp off-label marketing:

> As part of its strategy to increase sales of Aranesp, ***AMGEN instructed its sales representatives*** to distribute laminated reprints of the Aranesp compendia listing for the QM dose to health care professionals ***with the intent*** that the health care professionals would use Aranesp for QM dosing, for which they would be reimbursed. (¶ 26)
>
> . . . .
>
> Senior AMGEN sales executives promoted the use of the Freedom Time chart and the attendant sales messages to AMGEN sales ***representatives across the United States and provided incentives to sales representatives who were able to convert accounts from Procrit to Aranesp.*** In response to an email showing that the Freedom Time chart and sales messages were being circulated to regional sales directors, district sales managers and sales representatives across the country, ***the Senior National Sales Director in Nephrology wrote to a regional sales director, senior marketing executives and others:*** "Great direction to your team. Thanks for sharing. This is a great way to follow up from our management [sic] call. (¶ 28)

> . . . .
>
> In reality, AMGEN trained its sales representatives to elicit questions from doctors about QM dosing that AMGEN believed gave the sales representative the necessary cover to provide the doctors with the off-label QM studies because ***Amgen intended that the drug be used for the off-label QM dosing***, notwithstanding that Aranesp labeling lacked adequate directions for use for the off-label QM dosing. (¶ 29)
>
> . . . .
>
> A year after the FDA approved Aranesp for the treatment of CIA, AMGEN sought and obtained a listing in the USPDI concerning the use of Aranesp to treat AOC, providing the USP-DI with information about two AOC studies. ***Senior AMGEN sales executives treated the USP listing as the functional equivalent of FDA approval.*** AMGEN's internal marketing materials trumpeted that Aranesp in AOC was the "next big thing" and ***would give AMGEN a "fifty-one percent market share."*** AMGEN instructed its sales representatives to distribute laminated reprints of the USP-DI listing for Aranesp to treat AOC to health care professionals ***with the intent*** that the health care professionals would use Aranesp for AOC. (¶ 38) (All emphasis added.)

171. Finally, in Amgen's plea agreement, as part of calculating the applicable fine range under the United States Sentencing Guidelines (specifically, its "culpability score"), Amgen agreed that "an individual within high-level personnel participated in, condoned, or was willfully ignorant of the offense." This

admission further supports the strong inference that Amgen knew of or recklessly disregarded its Aranesp off-label marketing during the relevant time.

172. A key element in the scheme was the day-to-day interaction between the Amgen sales force and the doctors with whom they met. The FDA does not regulate the practice of medicine and federal regulations do not prohibit physicians from prescribing drugs for unapproved, off-label uses. Drug companies are permitted to provide information regarding such uses *in response to doctors' inquiries*. Amgen sales representatives were expected and encouraged to respond to doctor inquiries with detailed information about the various unlabeled uses to which Aranesp could be put. Indeed, Amgen sales representatives were trained to prompt doctors to ask questions that would permit them to begin the off-label dialog—a marketing technique referred to as "reactive" marketing. Amgen gave its sales representatives training on the different types of questions to ask ("Problem Questions," "Situation Questions" or "Implication Questions") to best steer doctors into discussions of the potential off-label uses of Aranesp. The Criminal Information to which Amgen pleaded guilty in December 2012 similarly alleges that Amgen trained its sales representatives to elicit questions about off-label uses of Aranesp "under the guise of 'reactive' marketing" in order to justify providing physicians marketing materials that supported such off-label uses. *See* Criminal Information ¶¶ 29, 34, 28.

173. Effective "best practices" for off-label sales techniques were shared throughout the Country. CW#1, a former Amgen district sales manager based in Florida, was provided with a sales aid by his regional manager that was first written for Amgen sales personnel in Arizona (referred to in the document as the "Phoenix Storm"). It provides an "expanded list" of "excellent questions" for Amgen sales personnel to pose to Amgen customers, *e.g.*: "What is keeping you from using Aranesp in all your MDS/HIV/CIA patients?"; "What can I do to help you to remember to use Aranesp in your MDS/HIV/CIA patients?"; "Why have

you not tried Aranesp in your MDS/HIV/CIA patients?"; and "How can we break you of this habit you have developed? Can we come up with a list of MDS/HIV/CIA pts that you can target to try Aranesp?" (MDS stands for myelodysplastic syndrome, an illness frequently tied to leukemia and often resulting in anemia. No ESA has been approved by the FDA for the treatment of MDS, and Aranesp has not been approved for HIV-infected patients.)

174. According to CW#2, a former Amgen sales representative and interim district manager in Houston, Amgen ostensibly repudiated the off-label promotion of Aranesp and Epogen but provided its sales staff with detailed information about off-label uses in the form of "color-coded spreadsheets, Power Point presentations and unpublished study results," to insure that they "were prepared to discuss any off-label topic." CW#2 stated that Amgen was seeking "hard, fast and heavy to promote off-label uses for Aranesp." The Criminal Information to which Amgen pleaded guilty in December 2012 similarly alleges that Amgen provided its sales representatives with marketing materials designed to illegally promote unapproved, off-label dosages and uses for Aranesp. *See* Criminal Information ¶¶ 26, 28-29, 32-35, 38-39.

175. Sales representatives were also required to carry "Proof Source Binders" on all sales calls to promote Aranesp and/or Epogen. As described above, the poor results of the 103 Study (conducted on patients with anemia of cancer) and DAHANCA 10 (conducted on patients with head and neck cancer) were publicized in January and February 2007, respectively. CW#3, a former Amgen Health Systems manager based in Ohio, attended a two-day "corporate, national" meeting soon thereafter, on or around March 13 and 14, 2007, in Orlando, Florida. At that meeting, attendees, including sales representatives in Amgen's Oncology Business and Corporate Accounts units, were given explicit instructions to return, on-the-spot, their Proof Source Binders so that they could be destroyed. In addition to the binders, the Company collected from employees all

documents concerning anemia of cancer (AOC), an off-label use, so that they too could be destroyed. The Company kept written records tracking, for each employee, what documents they brought to the meeting and turned over to the Company.

176. The Criminal Information to which Amgen pleaded guilty in December 2012 similarly alleges that Amgen "encouraged its sales representatives to use off-label studies to promote Aranesp for the treatment of AOC" and "to distribute laminated reprints of the USP-DI listing for Aranesp to treat AOC to health care professionals with the intent that the health care professionals would use Aranesp for AOC." ¶ 38. Amgen did so even though as early as 2001, the "FDA told AMGEN that it required a robust study of safety in AOC patients before it could approve Aranesp for that use." ¶ 39. "AMGEN nevertheless promoted Aranesp for the treatment of AOC using the less-robust studies that would have been insufficient to gain FDA approval." *Id.*

177. Another component of Amgen's scheme to evade off-label marketing restrictions and thus boost its sales was its "speakers program." Speakers program events were ***not*** accredited continuing medical education seminars held under the auspices of an independent medical association. They were dinners, paid for by Amgen, at which an "expert" speaker, paid by Amgen, would talk about off-label uses of Aranesp to physicians and other medical services providers in attendance, who were *also* paid by Amgen. An Amgen document describes "Clinical Round Table" dinners held for clinicians and administrators who were to receive a $1,000 honorarium "***paid from marketing budget***" upon the Company's receipt of the attendee's program evaluation (emphasis added).

178. CW#1 also described in detail how Amgen retained a doctor named Jeffrey Patton to make presentations to doctors throughout the Southeast sales region (Tennessee, Kentucky, Georgia, Missouri, Michigan, Alabama, Louisiana, and Florida) regarding the off-label use of Aranesp to treat MDS. As a result of

Dr. Patton's presentations and other marketing efforts by Amgen, as much as 20% of all Aranesp sales within the district managed by CW#1 came from off-label administration for the treatment of MDS. According to a slide in one of Dr. Patton's presentations, the Aranesp market in Tennessee alone had off-label sales of almost 40%:

Chemotherapy Induced Anemia	50%
Anemia of Chronic Renal Insufficiency	11%
Anemia of Chronic Disease	***17%***
Anemia Secondary to MDS	***22%***

(Emphasis added to off-label uses.)

179. CW#4, a former oncology sales representative at Amgen in New Jersey, confirmed the use of speakers to advance off-label uses. CW#4 explained that Amgen would sponsor "speaker programs" for doctors, clinic managers, and pharmaceutical directors and that at these programs, Amgen would arrange for one speaker to discuss the "on-label" use of Aranesp, while a second speaker would discuss "off-label" uses.

180. Although Amgen sells its ESAs to medical providers such as dialysis and oncology clinics, it is largely dependent on the federal government for its revenue stream. Indeed, as reported by *Forbes*, Medicare spent $1.75 billion on Epogen in 2005, more than on any other drug. As explained by Amgen's 2006 Form 10-K filed with the SEC:

> In the United States, dialysis providers are primarily reimbursed for EPOGEN® by the federal government through the End Stage Renal Disease Program ("ESRD Program") of Medicare. The ESRD Program reimburses approved providers for 80% of allowed dialysis costs; the remainder is paid by other sources, including patients, state Medicaid programs, private insurance, and to a

> lesser extent, state kidney patient programs. The ESRD Program reimbursement rate is established by federal law and is monitored and implemented by the Center for Medicare & Medicaid Service ("CMS"). Most patients receiving Aranesp®, Neulasta® and NEUPOGEN® for approved indications are covered by both government and private payer healthcare programs.

181. During the Class Period a change occurred in how medical services providers are reimbursed by Medicare for their coverage-eligible purchases. Prior to January 1, 2005, Amgen and other drug companies were required under Medicare Part B to report average wholesale prices ("AWP") for their drugs to the Centers for Medicare and Medicaid Services ("CMS"). Purchasers of the drugs like doctors and other medical services providers were reimbursed by CMS based on these "posted prices" and not actual transaction prices. Purchases at prices less than the posted AWP created a "spread" resulting in a profit source for doctors.

182. Pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003, companies now have to report actual net transaction prices (including rebates and other discounts) rather than AWP. The reimbursement formula is now calculated as "average sale price" or ASP, plus six percent.

183. Amgen sales representatives also solicited business by marketing a Medicare "spread." This was straightforward, and more lucrative to doctors before the law changed from AWP pricing to ASP pricing in 2005. Getting reimbursed in amounts that exceed the drug's purchase price resulted in profit for the doctor. Amgen representatives also marketed a different kind of "spread," namely the financial benefits associated with dosing patients to higher target hemoglobin levels or dosing patients in ways that reached the same target hemoglobin levels but that required more Epogen or Aranesp to do it. Simply put, doctors could

make more (through reimbursements) or save more (through greater discounts or rebates) by using more of Amgen's ESAs in their patients.

184. One example of sales representatives' efforts to drive increased drug dosages was reported by the *Boston Globe*, in an article dated October 24, 2006, titled "Some See Profiteering in Clinics' Use of Drug." The article detailed Amgen's efforts to encourage doctors to administer Epogen intravenously, rather than subcutaneously. The article explained that subcutaneous injection requires a substantially smaller dose to achieve the same therapeutic effect. The article quoted one physician as stating that "Amgen sales representatives have told him he could boost his earnings by following the lead" of clinic operators who administer Epogen intravenously, thereby increasing his use of the drug.

185. CW#5 shared one of Amgen's largest accounts and specifically stated that Amgen promoted off-label use by encouraging doctors to prescribe higher doses of Epogen and Aranesp than had been approved by the FDA.

186. CW#2 also reported that Amgen had a company-wide practice of encouraging dosages higher than those approved by the FDA. CW#2 explained that Amgen sales representatives gave doctors dosing recommendations, and that Amgen's management created incentives to increase dosages – referred to as "dose driving" – by reviewing sales representatives' performance based on the size of the dosages prescribed by the doctors with whom they worked. CW#2 stated that in response to Amgen's monitoring of dose sizes, sales representatives would sometimes accelerate dosing late in a fiscal quarter to meet their sales quotas.

187. Other former sales representatives reported that Amgen also promoted increased use of Epogen and Aranesp by encouraging doctors to give patients high dosages of the drugs. CW#1, a former district sales manager in Western Pennsylvania, recalled that Amgen's management applied immense pressure down the chain of command to district managers, such as himself, and sales representatives to meet ever increasing sales quotas, essentially forcing the sales

force to encourage the inappropriate administration of Epogen or Aranesp in order to meet their sales goals. The Criminal Information to which Amgen pleaded guilty in December 2012 similarly alleges that Amgen promoted the administration of Aranesp with dosing regimens not approved by the FDA. *See* Criminal Information ¶¶ 25-29, 32-35. As the December 19, 2012 Department of Justice ("DOJ") press release announcing Amgen's criminal guilty plea explained, the two off-label dosing schemes outlined in the Criminal Information involved unapproved ***higher*** doses being administered on a less frequent basis: "off-label, unapproved doses [] ***were larger*** and less frequently administered than those approved by the FDA for these patient populations." For example, starting in approximately January 2005, "Senior AMGEN sales executives promoted the use of [a marketing document called] the Freedom Time chart and the attendant sales messages to AMGEN sales representatives across the United States and provided incentives to sales representatives who were able to convert accounts from Procrit to Aranesp." Criminal Information ¶ 28. The Freedom Time chart was created by an Amgen sales representative to help promote the off-label "QM" (once a month) dose of Aranesp "by highlighting the alleged lifestyle benefits to patients and economic benefits to doctors" that flowed from the less frequent off-label dose (versus on-label doses that were administered more frequently). *Id.* At its sentencing hearing, Amgen specifically confirmed the allegations in the Criminal Information regarding the Freedom Time chart:

> As [counsel for the DOJ] indicated, this was a chart created by a sales rep. . . . This absolutely shouldn't have happened. . . . And this sales rep created a third column that said, here is the lower cost if you dose it QM, or once a month. . . . ***What we acknowledge is, because QM use is not an FDA-approved use***, this shouldn't have been created or at least -- let me re-speak. ***This shouldn't***

> ***have been shared with customers***. . . . Where the guardrails fell down in this case was, ***there's evidence collected by the government that this chart was shown to customers.***

December 19, 2012 Sentencing Transcript at 14:15 – 16:4. (Emphasis added.)

188. In another example of Amgen's off-label dosing schemes from Amgen's guilty plea, Amgen told its sales representatives that one of the "keys to success" was the "ability to maintain provider confidence in the [off-label] 200 mcg Q2W dose" in CIA patients. Criminal Information ¶ 33. Moreover, Amgen's internal marketing documents openly stated that the "launch strategy" for Aranesp in the oncology field was to "build a compelling clinical study around [the off-label dose of] 200 mcg 2QW" and to "utilize [an off-label study that supported the Q2W dose] on each call to solidify Q2W dosing with the 200 mcg." in CIA patients. *Id.* ¶ 32. Indeed, Amgen's promotion of the off-label Q2W dose in CIA patients "was so pervasive that some sales representatives were unaware that the Q2W starting dose was an off-label dosage." *Id.* ¶ 33

189. Amgen greatly enhanced the effectiveness of its efforts to drive dosing higher by providing extremely large financial incentives for prescribing physicians to increase their usage of the drugs. Unlike prescription drugs purchased by patients through other chains of distribution such as community pharmacies and mail order, Epogen and Aranesp are purchased by the physicians, clinics, hospitals or other facilities that administer them. Accordingly, pharmaceutical companies such as Amgen offer may offer discounts and rebates on their purchases.

190. *The New York Times* reported on May 9, 2007 that the total ESA drug payments by Amgen to one group of six oncologists was in the millions of dollars. Six oncologists were reportedly paid $2.7 million by Amgen for prescribing $9 million of Amgen's drugs in 2006. In another reported occurrence, one large

kidney dialysis chain made 25 percent of its revenue from the ESA drugs and an even bigger share of its profits.

191. As discussed briefly above, Amgen's incentive payment program tied rebates on Neupogen or Neulasta (white blood cell-boosting drugs used in oncology practices) to purchases of Aranesp. This tying arrangement prompted strong opposition from some doctors, who felt that Amgen was attempting to interfere with their medical judgment. In an open letter to the Chairman and Members of the Committee on Ways and Means, for a December 6, 2006 Hearing on Patient Safety and Quality Issues in End Stage Renal Disease Treatment, Noshi Ishak, owner and medical director of a New Hampshire kidney center wrote:

> This is a total disgrace to the practice of medicine. It is shameful to allow rebates for achieving larger volume for the use of a drug. It is shameful that the physician is forced to increase the dose of EPO for a patient who has hemoglobin of 10.8 or 10.9 so the center can meet the rebate threshold yet he knows that it will not do the patient any good.

192. According to several confidential witnesses, Amgen marketed Epogen and Aranesp by explicitly discussing the financial benefits of prescribing high volumes of these products with physicians and other medical services providers, in violation of Medicare regulations.

193. CW#2 and CW#4 separately explained that Amgen's national office provided spreadsheets and other tools to enable sales representatives to discuss the economics of Amgen drugs with doctors, clinic business managers, and their accountants. CW#5 also confirmed that Amgen provided sales representatives with detailed documentation that allowed them to calculate the "margin and spread," *i.e.*, the profit that a medical practice could earn using particular Amgen drugs in combination. CW#5 noted that while Amgen always included the caveat

in its materials that representatives were not supposed to communicate these numbers to doctors, Amgen devoted extensive time to training its representatives on how to use the spreadsheets and perform the necessary calculations, with the clear expectation that sales representatives would make use of these materials when speaking with doctors, administrators and other personnel.

194. The Criminal Information to which Amgen pleaded guilty in December 2012 similarly alleges that Amgen encouraged its sales force to use marketing materials such as the Freedom Time chart with physicians to promote the off-label QM dosing of Aranesp by, *inter alia*, highlighting the purported "***economic benefits to doctors***" that followed from converting patients from the approved, more frequent dosing to the off-label, less frequent QM dosing. ¶ 28. (Emphasis added). At Amgen's sentencing hearing on December 19, 2012, Amgen specifically admitted that the Freedom Time chart "was an improper document" that "shouldn't have been telling doctors about the money that they could save . . . using this dosing regimen that was not on-label." Sentencing Transcript at 24:4-8.

195. Amgen's activities continued unabated until near the end of the Class Period, when its practices began to draw scrutiny from the press and, as noted above, from the government. In addition to the *Boston Globe* article, *Forbes* reported on Amgen's marketing practices and highlighted the financial incentives that Amgen granted prescribing physicians. The article further reported that as a result of these financial incentives, "dosing levels have crept up by a factor of four over the past decade, though some doubt that this makes dialysis patients live longer. The higher doses have the side effect of fattening the bank accounts of both Amgen and the clinics that choose the prescriptions."

196. Defendants' statements were also false and/or misleading because, as described above, they created an impression of a state of affairs that differed in material ways from the one that actually existed. In addition, as also described,

supra, in the foregoing paragraphs, in certain respects the statements were literally false.

197. The foregoing statements were also false and misleading because Defendants had access to or actual knowledge of information contradicting the veracity of the statements when the statements were made.

198. As more fully alleged *infra* in ¶ 244, the disclosure correcting these misrepresentations and/or omissions of material fact was a substantial proximate cause of the stock drop on March 9, 2007.

8. The Misrepresentations and/or Omissions of Defendants Amgen, Sharer, Morrow and Nanula Regarding Potential for Market Growth, Revenues and Earnings

199. The allegations concerning the statements in paragraphs 201-204 were previously upheld by the Court in its MTD Opinion. *See* October 2007 Complaint (Dkt. No. 109) ¶¶ 150-155, (alleging claims regarding market growth potential); MTD Opinion at 16-20 (upholding claims regarding market growth potential). The allegations in ¶¶ 206-219 concerning these statements were previously upheld by the Court in its MTD Opinion. *See* October 2007 Complaint (Dkt. No. 109) ¶¶ 164-177 (alleging claims regarding revenues and earnings); MTD Opinion at 28 (upholding claims regarding revenues and earnings).

(a) Untrue or Misleading Statements or Omissions of Material Facts Regarding Potential for Market Growth

200. Notwithstanding the serious safety concerns posed by ESAs and Amgen's illegal off-label and other improper marketing practices with respect to its ESAs, Defendants repeatedly asserted that the drugs held significant growth potential.

201. On July 22, 2004, Amgen issued an earnings release and held a conference call with Wall Street analysts to discuss its second quarter 2004 results. In response to a question from an analyst, Defendant Morrow stated: "You know, ***right now we really see a lot of growth potential in the anemia market***, and one of

the things we have to do is get beyond these products being used as replacements for transfusions and products that treat fatigue." (Emphasis added.)

202. Commenting further on Amgen's pharmacology program on the same conference call, Defendant Sharer added that "[w]e also continue to move forward on a variety of clinical studies with Aranesp, which we believe has ***strong growth potential***." (Emphasis added.)

203. On November 10, 2004, Amgen participated in the CIBC World Markets 15th Annual Healthcare Conference call. Defendant Nanula commented on Aranesp's potential going forward, stating:

> what we think the big opportunity going forward and have for a while is [] continued market penetration. I think both we and our competitor, but I can really speak for ours, we are investing heavily in the marketplace to continue to grow in while we are working at gaining share in the new ASP environment, which we'll talk about in a moment, I think the market growth will become more important versus market share gains as in the past . . . We also have additional indications that we are seeking in Aranesp, so we are highly focused on growing this market, we think it has plenty of room to grow as it's experienced in the last few years too.
>
> . . .
>
> ***[W]e think the market has plenty of room to grow….***
>
> (Emphasis added.)

204. On March 16, 2005, Amgen participated in the SG Cowen & Co. 25th Annual Health Care Conference. Dr. Anthony Gringeri, Amgen's Senior Director of Scientific Research and Licensing Operations, commented on Aranesp's potential for growth as follows:

> . . . I wanted to highlight that this drug which has now been on the market for a little over 3 years has been highly successful in treating anemia in a variety of indications. And we're very concerned that anemia remains a risk factor, both in renal disease and in other areas. You'll see from the first bullet on this slide that more patients with chronic kidney disease still die before they reach dialysis. ***So there is a large population of patients that needs to be reached. And we feel that Aranesp is an ideal treatment option for these patients.***

205. On Amgen's January 25, 2007 earnings call, Defendant Morrow gave overall positive guidance for future ESA sales:

> In 2007, we will once again focus on anemic chronic kidney disease and chemotherapy induced patients not currently being treated. ***This pool of several 100,000 patients has and will continue to be the primary driver of Aranesp growth.*** We're also pleased with the level of differentiation achieved versus the first generation EPOs. This will serve us well as we defend against [Indiscernible] in Europe later this year. ***Roger did discuss the anemia of cancer, clinical findings and it's far too early for us to asses[s] any potential impact on the marketplace.*** (Emphasis added.)

(b) Untrue or Misleading Statements or Omissions of Material Facts Regarding Revenues and Earnings

206. The following misrepresentations and/or omissions of material fact were made with respect to the potential market growth and revenues and earnings for Amgen's ESAs:

(a) Defendant Morrow's July 22, 2004 statement that "right now we really see a lot of growth potential [for ESAs] in the anemia market";

(b) Defendant Sharer's July 22, 2004 statement that "[w]e also continue to move forward on a variety of clinical studies with Aranesp, which we believe has strong growth potential";

(c) Defendant Nanula's November 10, 2004 statement that "we think the [Aranesp] market has plenty of room to grow …";

(d) Gringeri's March 16, 2005 statement that "a large population of patients… needs to be reached. And we feel that Aranesp is an ideal treatment option for these patients;" and

(e) Defendant Morrow's January 25, 2007 statement that "[t]his pool of several 100,000 patients has and will continue to be the primary driver of Aranesp growth."

207. The foregoing misrepresentations concerning safety problems with ESAs, nondisclosure of the risk of adverse action by ODAC and the FDA, misrepresentations and omissions concerning adverse clinical trial results, and misrepresentations concerning marketing practices all rendered Amgen's financial statements false and misleading during the Class Period.

208. In its press release dated July 22, 2004 and Form 8-K dated July 28, 2004, Amgen reported adjusted earnings per share of $0.62, net income of $748 million, and revenues of $2.6 billion for the second fiscal quarter of 2004. The same amounts were subsequently reported in the Form 10-Q filed by Amgen for such quarter.

209. In its press release dated October 20, 2004 and Form 8-K dated October 26, 2004, Amgen reported adjusted earnings per share of $0.64, net income of $236 million, and revenues of $2.7 billion for the third fiscal quarter of 2004. The same amounts were subsequently reported in the Form 10-Q filed by Amgen for such quarter.

210. In its press release dated January 27, 2005 and Form 8-K dated February 2, 2005, Amgen reported adjusted earnings per share of $0.58, net income of $689 million, and revenues of $2.9 billion for the fourth fiscal quarter of 2004. The same amounts were subsequently reported in the Form 10-K filed by Amgen for 2004.

211. In its press release dated April 21, 2005 and Form 8-K dated April 22, 2005, Amgen reported adjusted earnings per share of $0.72, net income of $854 million, and revenues of $2.8 billion for the first fiscal quarter of 2005. The same amounts were subsequently reported in the Form 10-Q filed by Amgen for such quarter.

212. In its press release dated July 19, 2005 and Form 8-K dated July 25, 2005, Amgen reported adjusted earnings per share of $0.88, net income of $1.0 billion, and revenues of $3.2 billion for the second fiscal quarter of 2005. The same amounts were subsequently reported in the Form 10-Q filed by Amgen for such quarter.

213. In its press release dated October 19, 2005 and Form 8-K dated October 25, 2005, Amgen reported adjusted earnings per share of $0.85, net income of $967 million, and revenues of $3.2 billion for the third fiscal quarter of 2005. The same amounts were subsequently reported in the Form 10-Q filed by Amgen for such quarter.

214. In its press release dated January 26, 2006 and Form 8-K dated February 1, 2006, Amgen reported adjusted earnings per share of $0.75, net income of $824 million, and revenues of $3.3 billion for the fourth fiscal quarter of 2005. The same amounts were subsequently reported in the Form 10-K filed by Amgen for 2005.

215. In its press release dated April 18, 2006 and Form 8-K dated April, 24, 2006, Amgen reported adjusted earnings per share of $0.91, net income of $1.0 billion, and revenues of $3.2 billion for the first fiscal quarter of 2006. The same

amounts were subsequently reported in the Form 10-Q filed by Amgen for such quarter.

216. In its press release dated July 20, 2006 and Form 8-K dated July 24, 2006, Amgen reported adjusted earnings per share of $1.05, net income of $14 million, and revenues of $3.6 billion for the second fiscal quarter of 2006. The same amounts were subsequently reported in the Form 10-Q filed by Amgen for such quarter.

217. In its press release and Form 8-K dated October 23, 2006, Amgen reported adjusted earnings per share of $1.04, net income of $1.1 billion, and revenues of $3.61 billion for the third fiscal quarter of 2006. The same amounts were subsequently reported in the Form 10-Q filed by Amgen for such quarter.

218. In its press release and Form 8-K dated January 25, 2007, Amgen reported adjusted earnings per share of $0.90, net income of $833 million, and revenues of $3.84 billion for the fourth fiscal quarter of 2006. The same amounts were subsequently reported in the Form 10-K filed by Amgen for 2006.

219. In its press release and Form 8-K dated April 23, 2007, Amgen reported adjusted earnings per share of $1.08, net income of $1.1 billion, and revenues of $3.69 billion for the first fiscal quarter of 2007. The same amounts were subsequently reported in the Form 10-Q filed by Amgen for such quarter.

220. All of the above Form 10-Q's and Form's 10-K's filed by Amgen were signed by Defendants Sharer and Nanula (with the exception of the Form 10-Q for first fiscal quarter of 2007, which was signed by Sharer and Bob Bradway, Amgen's CFO who replaced Nanula in April 2007).

(c) Facts Establishing That Statements or Omissions Are Untrue or Misleading and Giving Rise to a Strong Inference of Scienter

221. These statements were materially false or misleading when made and give rise to a strong inference that Defendants Amgen, Sharer, Morrow and Nanula acted with *scienter* because they misrepresented or omitted the material adverse

facts set forth below, or created a false impression as to the facts presented and statements made by authorized senior officers of Amgen whose scienter is imputable to Amgen itself.

222. Defendants lacked any reasonable basis for projecting growth in sales of Aranesp or Epogen during the Class Period in light of the serious safety concerns associated with ESAs and the substantial risk that greater limitations would be placed on the use of ESAs by the FDA in light of Amgen's failure to conduct the clinical trials recommended by ODAC in 2004. Put another way, Defendants' growth projections were untenable because they had every reason to believe that Amgen's "anemia franchise" was in serious jeopardy given all that Defendants knew or were reckless in disregarding about the evolving safety profile of ESAs and the risk of adverse regulatory action by the FDA. At its 2004 meeting, ODAC had specifically requested certain clinical studies be conducted to resolve the outstanding safety issues regarding its ESAs; Amgen, however, knew that it had not conducted or even attempted to conduct the requested trials, resulting in a substantial risk that ODAC would recommend, and the FDA would adopt, restrictions on the sale and use of Epogen and Aranesp when it next met to evaluate the drugs. Defendants' growth projections were also false and/or misleading in light of Amgen's unsustainable illegal marketing practices during the Class Period.

223. Similarly, the statements regarding revenues and earnings set forth in paragraphs 200 through 220 were false and misleading because Amgen's misrepresentations concerning safety problems with ESAs, nondisclosure of the risk of adverse action by ODAC and the FDA, misrepresentations and omissions concerning adverse clinical trial results, and misrepresentations concerning marketing practices deceived investors as to the quality and nature of Amgen's revenue and earnings. In fact, such matters caused Amgen's revenue and earnings from ESAs to be at significantly greater risk of diminishing due to (i) later

determinations that existing on- and off-label uses of the drugs were either unsafe or ineffective, (ii) regulatory action to limit or prohibit such uses, and (iii) increased enforcement preventing continued marketing in violation of FDA law and regulations.

224. In light of Defendants' illegal marketing practices, which have now been confirmed by Amgen's December 2012 guilty plea, "Defendants misled investors by implicitly and falsely warranting that there were no illegal practices contributing to that success." MTD Opinion at 28.

225. Defendants' statements were also false and/or misleading because, under rules and regulations promulgated by the SEC under the Exchange Act, including Item 303 of Regulation S-K, Defendants also had a duty to report, among other things, all "known trends" and (i) whether those trends have had or are reasonably expected to have a material unfavorable impact on revenue; and (ii) the extent of any such impact on revenue. Indeed, the SEC has stated that Item 303 is "intended to give the investor an opportunity to look at the company through the eyes of management by providing both a short and long-term analysis of the business of the company…." *See* Management's Discussion and Analysis of Financial Condition and Results of Operation, Securities Act Release No. 6835, 1989 WL 1092885, at *3 (May 18, 1989). Defendants' wrongdoing during the Class Period, as alleged herein, also violated this specific requirement and obligation.

226. Defendants' statements were also false and/or misleading because, as described above, they created an impression of a state of affairs that differed in material ways from the one that actually existed.

227. As more fully alleged *infra* in ¶ 254, the disclosure correcting these misrepresentations and/or omissions of material fact was a substantial proximate cause of the stock drop on May 10 and 11, 2007.

POST-CLASS PERIOD EVENTS

228. On May 10, 2007, Amgen received a subpoena from the New York Attorney General seeking documents related to "promotional activities, sales and marketing activities, medical education, clinical studies, pricing and contracting, license and distribution agreements and corporate communications."

229. On May 15, 2007, Medicare announced a proposal to limit reimbursement for Aranesp to patients with especially severe anemia and deny it entirely to all patients with certain kinds of cancer.

230. On July 30, 2007, the U.S. Centers for Medicare and Medicaid Services announced plans to limit what dosages of the EPO drugs it would reimburse for saying the drugs are only necessary for patients with hemoglobin levels less than 10 grams per deciliter. Amgen shares fell $2.74, or 5.1 percent, to $51.

CLASS ACTION ALLEGATIONS

231. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class consisting of all persons who purchased the securities of Amgen during the period from April 22, 2004 through May 10, 2007, inclusive. Excluded from the Class are Defendants; former Defendants; the affiliates and subsidiaries of the Company, including the Company's employee retirement and benefit plan(s); the officers and directors of the Company and its subsidiaries and affiliates at all relevant times; members of the immediate family of any excluded person; the legal representatives, heirs, successors, and assigns of any excluded person; and any entity in which any excluded person has or had a controlling interest.

232. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Amgen had more than 1.1 billion of shares of common stock outstanding, which were actively traded on the NASDAQ. The average daily trading volume during the Class Period was

more than 9.14 million shares. While the exact number of Class members is unknown to Plaintiff at this time, Plaintiff believes that there are at least thousands of members of the proposed Class. Record owners and other members of the Class may be identified from records maintained by Amgen or its transfer agent and can be notified of the pendency of this action by mail and publication using forms of notice similar to those customarily used in securities class actions.

233. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class were similarly damaged by Defendants' wrongful conduct as complained of herein.

234. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests that conflict with the interests of the Class.

235. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether Defendants' statements and omissions during the Class Period materially misrepresented the safety of Aranesp;

(b) whether Defendants' acts and omissions as alleged herein violated federal securities laws;

(c) whether Defendants participated in the wrongful scheme described herein;

(d) whether Defendants acted with *scienter*; and

(e) whether the members of the Class have sustained damages and the proper measure of damages.

236. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. As the damages suffered by many individual Class members may be small relative to the expense and burden of

individual litigation, it is practically impossible for most members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE

237. At all relevant times, the market for Amgen securities was an efficient market for the following reasons, among others:

(a) Amgen's stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Amgen filed periodic and other public reports with the SEC and the NASDAQ;

(c) Amgen regularly communicated with public investors by means of established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Amgen was followed by numerous securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and customers of their respective brokerage firms. Those reports were publicly available and entered the public marketplace.

238. In their April 2, 2008 Answer and Affirmative Defenses to Plaintiff's October 1, 2007 Complaint (Dkt. No. 149), Defendants admitted allegations identical to those in the preceding paragraph.

239. As a result of the foregoing, the market for Amgen's securities promptly digested current information regarding Amgen from all publicly available sources and reflected such information in Amgen's stock price. Under these circumstances, all purchasers of Amgen's securities during the Class Period suffered similar injury through their purchase of Amgen's securities at artificially

inflated prices, which fell as the truth concerning Aranesp became known, and a presumption of reliance applies.

240. In their April 2, 2008 Answer and Affirmative Defenses to Plaintiff's October 1, 2007 Complaint (Dkt. No. 149), Defendants admitted allegations identical to those in the first sentence of the preceding paragraph.

NO SAFE HARBOR

241. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Amgen who knew that those statements were false when made.

LOSS CAUSATION

242. As detailed herein, throughout the Class Period, the Defendants made material misrepresentations and omissions and engaged in a scheme and course of conduct to deceive the market that resulted in artificially inflated prices for Amgen common stock. As a result, Plaintiff and other members of the Class purchased Amgen common stock at artificially inflated prices. When the Company's prior misrepresentations, omissions and other fraudulent conduct were revealed through a series of partial corrective disclosures, the price of Amgen common stock fell significantly on several occasions (as detailed herein), as portions of the artificial

inflation were removed from the Company's stock price. As a result of its purchases of Amgen common stock during the Class Period, Plaintiff and the other members of the Class therefore suffered economic loss.

The February 16, 2007 Drop

243. On February 16, 2007, *The Cancer Letter* published an article concerning the mid-October 2006 halting and December 2006 termination of the DAHANCA 10 Trial. Defendants did not inform investors of these developments, and Amgen hastily arranged an analyst call on the same afternoon the article was published because, according to Defendant Perlmutter, "enough people had called us." *The Cancer Letter* stated that "even informed observers have been largely unaware that the Danish study was temporarily stopped on Oct. 18, 2006, and that the decision not to resume the study was made on Dec. 1, 2006, and posted on the Web by the principal investigator, Jens Overgaard" and that the DAHANCA 10 Trial result had been "eagerly awaited by physicians, investors, regulators, and payers around the world." (*See* ¶¶ 100-103 above.) As a direct and proximate result of this disclosure, which partially corrected Amgen's omission of material fact as set forth in Section C.3, Amgen's share price declined $1.55 per share, or 2.3%, to $66.73 on trading volume that was approximately 280% greater than the average daily trading volume for Amgen common stock over the prior 30 day period.

The March 9, 2007 Drop

244. On March 9, 2007, the FDA announced that it would mandate what is commonly referred to as a "black box" warning or "boxed warning" on the label for ESAs, including Aranesp and Epogen. The FDA imposed the black box warning on ESAs as a result of negative results in several "off-label" clinical trials including the DAHANCA 10 Trial and the 103 Study. The boxed warning had the economic effect of curtailing Amgen's off-label marketing of Aranesp, as recognized in the Criminal Information to which Amgen pleaded guilty in

December 2012 (*see* ¶¶ 113, 165-169 above). As a direct and proximate result of the March 9, 2007 disclosure of the FDA Health Advisory and boxed warning, which partially corrected the misrepresentations and omissions of material fact set forth in Sections C.3 and C.7, the Company's share price declined $1.31 per share, or 2.1%, to $60.86 on trading volume that was approximately 150% greater than the average daily trading volume for Amgen common stock over the prior 30 day period.

The May 10 and 11, 2007 Drops

245. At the 2007 ODAC Meeting on May 10, 2007, both Amgen and the FDA made presentations concerning the evidence, or in the FDA's case, the lack of evidence of the safety of ESAs when used in accordance with FDA labeling guidelines.

246. Statements by the FDA and by ODAC panel members confirmed the lack of evidence of ESA safety. The FDA's presenter at the meeting was unequivocal: "With the 2004 recommendations in mind, we ask the question, have any ongoing or proposed trials presented at ODAC 2004 or since ODAC 2004 fully met the Committee's recommendations? The answer, unfortunately, is no."

247. The FDA had noted in its briefing book that "there is no evidence that ESAs improve quality of life or cancer outcomes," and "data continue to accumulate regarding the increased risk of mortality and of possible tumor promotion from the use of ESAs." Dr. Richard Pazdur, Director of the FDA's Office of Oncology Drug Products stated at the 2007 ODAC Meeting itself that "[o]bviously, if we had data at the recommended hemoglobin and there was a therapy-associated death rate associated with it, we wouldn't having this discussion."

248. The FDA also found that the 145 Study was not generalizable. The FDA further stated that "no completed or ongoing trial has addressed safety issues

of ESAs in cancer patients with chemotherapy-associated anemia using currently approved dosing regimens in a generalizable tumor type."

249. With respect to the evidence that was available, the FDA explained as follows:

> In examining the collective evidence of the use of ESAs in cancer patients, six studies have demonstrated inferior overall survival, locoregional progression-free survival, or local regional control for an ESA-containing arm.
>
> . . . .
>
> Based on the six studies that showed decreased survival or increased tumor promotion, FDA believes there should be a reconsideration of the risk-to-benefit ratio of ESAs in cancer patients.

250. Three of the six studies to which the FDA referred had all been concluded by, and discussed at, the 2004 ODAC Meeting, i.e., BEST, ENHANCE, and a J&J study known as EPO-CAN-20 involving 70 patients that had been terminated in 2003 due to increased thrombovascular events and decreased survival in the epoetin alfa arm of the study. The other three clinical trials on which the FDA's belief that "there should be a reconsideration of the risk-to-benefit ratio of ESAs in cancer patients" was based were the Aranesp trials that Defendants had sought to minimize or conceal entirely from public scrutiny—the 161 Study, the 103 Study, and the DAHANCA 10 Trial.

251. The FDA talked in detail about the 161 Study in its presentation, making it abundantly clear that based on "updated primary data [] submitted to FDA" in April 2007—just weeks before the 2007 ODAC Meeting, "there was worsened overall survival in the ESA arm" and reiterating later that the 161 Study data "showed decreased survival in patients" who had taken Aranesp. Of the six

trials identified by the FDA, only the 161 Study and BEST were trials in CIA patients.

252. The FDA presenter also discussed the 103 Study, pointing out that, unlike the studies in Amgen's Pharmacovigilance Program, the 103 Study was designed to address the on-label concerns raised at the 2004 ODAC Meeting.

253. At the 2007 ODAC Meeting, the ODAC panel voted on a series of questions posed by the FDA. The first vote addressed the question "Should further marketing authorization [for the use of ESAs with cancer patients] be contingent upon: further restrictions and product labeling." The panel vote was 15 in favor, and only 2 opposed. The second vote addressed the question "should further marketing authorization [for the use of ESAs with cancer patients] be contingent upon additional trials?" The panel vote was 17 in favor, and 0 opposed. These two votes were the most material votes to investors.

254. On May 10, 2007, the FDA's Oncologic Drugs Advisory Committee heard testimony, deliberated, and voted at a public hearing in favor of adding new restrictions on the use of ESAs and requiring the drug makers to conduct new clinical trials. As a direct and proximate result of the final disclosures made during the May 10, 2007 ODAC Meeting, including by the results of the panel's voting, which corrected the misrepresentations and omissions of material fact set forth in Sections C.1-C.2 and C.4-C.8, Amgen's share price declined $5.77 per share, or 9.1%, to $57.33 on trading volume that was approximately 270% greater than the average daily trading volume for Amgen common stock over the prior 30 day period, and on May 11, 2007, Amgen's share price continued to fall, from a close of $57.33 on May 10, 2007, to a close of $56.30 on May 11, 2007, on trading volume that was approximately 13% greater than the May 10 trading volume.

255. In sum, as investors learned the truth about the safety, marketing and market demand of Amgen's ESAs between February 16, 2007 and May 10, 2007,

the Company's common stock price fell more than 16%, wiping out more than $12.75 billion in market capitalization.

256. Each of the declines in the Company's stock price described above was caused by the disclosure of previously concealed information or the materialization of foreseeable events or conditions relating to the material misstatements and omissions alleged herein.

257. Had Plaintiff and the Class known of the material adverse information alleged herein, they would not have purchased Amgen securities at artificially inflated prices and they would not have proximately suffered losses as the previously-withheld information to Defendants became revealed to the market.

FIRST CLAIM FOR RELIEF

(For Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants)

258. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

259. During the Class Period, Defendants carried out a common plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Amgen securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

260. Defendants (i) employed devices, schemes and artifices to defraud; (ii) made untrue statements of material facts and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Amgen's securities in violation of Section 10(b) of the Exchange

Act and SEC Rule 10b-5. All Defendants are liable either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

261. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Amgen's financial well-being, business and prospects, as specified herein.

262. These Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Amgen's financial condition and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Amgen and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as alleged more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Amgen securities during the Class Period.

263. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these Defendants, by virtue of his responsibilities and activities as a senior officer and/or director of the Company was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these Defendants enjoyed significant personal contact and familiarity with the other Defendants and was advised of, and had access to,

other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these Defendants was aware of the Company's dissemination of information to the investing public which they knew or were reckless in disregarding was materially false and misleading.

264. The Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with deliberate reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly with severe recklessness and for the purpose and effect of concealing Amgen's financial well-being, business relationships, and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements of the Company's business prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were deliberately reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

265. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Amgen's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Amgen's securities were artificially inflated, and relying, directly or indirectly, on the false and misleading statements made by Defendants, or upon the integrity of the market in which Amgen's securities trade, and/or in the absence of material adverse information that was known to or deliberately recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other

members of the Class acquired Amgen securities during the Class Period at artificially high prices and were damaged thereby.

266. At the time of said misrepresentations and omissions, Plaintiff and the other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Amgen was experiencing, which were not disclosed by Defendants, Plaintiff and the other members of the Class would not have purchased or otherwise acquired their Amgen securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

267. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder.

268. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM FOR RELIEF

(For Violation of Section 20(a) of the Exchange Act Against the Individual Defendants)

269. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

270. The Individual Defendants were controlling persons of Amgen within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of

the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or to shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

271. In particular, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

272. As set forth above, Amgen and the Individual Defendants each violated Section 10 (b) and SEC Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20 (a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment on behalf of itself and the Class, as follows:

(a) Determining that this action is a proper class action and certifying Plaintiff as class representative under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a jury trial as to all issues so triable.

Dated: April 22, 2014

Respectfully submitted,

By: _____

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