IN THE CIRCUIT COURT FOR THE CITY OF RICHMOND

COMMONWEALTH OF VIRGINIA *ex rel.* MARK R. HERRING, ATTORNEY GENERAL Plaintiff, v. AMGEN INC., a Delaware corporation, Defendant.	)	Case No._____

COMPLAINT

1. Plaintiff, the Commonwealth of Virginia (the "Commonwealth") in its sovereign capacity, by and through Attorney General Mark R. Herring ("Attorney General") brings this action against Defendant AMGEN INC. ("Defendant or Amgen") for violating the Virginia Consumer Protection Act, ("VCPA"), Virginia Code §§ 59.1-196 through 59.1-207.

2. The Commonwealth prays that this Court grant the relief requested in this Complaint and states the following in support thereof:

JURISDICTION AND VENUE

3. The Circuit Court of the City of Richmond has authority to entertain this action and to grant the relief requested herein pursuant to Virginia Code §§ 8.01-620, 17.1-513, and 59.1-203.

4. Venue is preferred in this Court pursuant to Virginia Code § 8.01-261(15)(c) because some or all of the acts to be enjoined are, or were, being done in the City of Richmond. Venue is permissible in this Court pursuant to § 8.01-262(3) and (4) because Defendant regularly conducts substantial business activity within the City of Richmond and the cause of action arose, in part,

in the City of Richmond.

5. Prior to the commencement of this action, the Plaintiff gave the Defendant written notice, through communications by a multi-state group of Attorneys General, that these proceedings were contemplated and a reasonable opportunity to appear before the Office of the Attorney General to demonstrate that no violations of the VCPA had occurred, or to execute an appropriate Assurance of Voluntary Compliance, pursuant to Virginia Code § 59.1-203(B). The Defendant has not established that no violation of the VCPA occurred and has agreed to execute an acceptable Consent Judgment in lieu of an Assurance of Voluntary Compliance.

PARTIES

6. Plaintiff, the Commonwealth of Virginia ex rel. Mark R. Herring, Attorney General, is charged with enforcing the Virginia Consumer Protection Act, which prohibits fraudulent acts or practices committed by a supplier in connection with a consumer transaction. Pursuant to the VCPA, the Attorney General may initiate civil law enforcement proceedings in the name of the Commonwealth to enjoin violations of the VCPA and to secure such equitable and other relief as may be appropriate in each case.

7. Defendant AMGEN INC. is a Delaware corporation with its principal place of business at 1 Amgen Center Drive in Thousand Oaks, California 91320. At all relevant times, Amgen did business in Virginia by marketing, selling, and promoting the biologic medications Aranesp® and Enbrel®.

FACTS

I. ARANESP

8. Aranesp ® (darbepoetin alfa) is a biologic medication used to treat certain types of anemia by stimulating bone marrow to produce red blood cells. It belongs to a class of drugs

called erythropoiesis-stimulating agents or ESAs.

9. Aranesp is FDA approved to treat anemia caused by chronic renal failure ("CRF") and chemotherapy-induced anemia ("CIA") at a specified dose and frequency.

10. Aranesp's main competitor is Procrit, an ESA produced by Johnson & Johnson. Procrit has a shorter half-life and is dosed more frequently than Aranesp.

11. To better compete against Procrit, Amgen promoted Aranesp to treat anemia caused by CRF and CIA at dosing frequencies longer than the FDA-approved label.

12. At the time Amgen promoted extended dosing frequencies, it lacked competent and reliable scientific evidence to substantiate the extended dosing frequencies.

13. Aranesp has never been FDA approved to treat anemia caused by cancer ("Anemia of Cancer" or "AOC"), which is distinct from anemia caused by chemotherapy.

14. Patients with AOC have active malignant disease and are not receiving chemotherapy or radiation.

15. Amgen promoted Aranesp to treat AOC even though it lacked competent and reliable scientific evidence to substantiate such use.

16. In 2001, when Amgen came on the market, Procrit was being used to treat AOC.

17. In order to compete with Procrit in the AOC market, Aranesp had to be reimbursable by insurance companies and federal programs.

18. The most common way to obtain reimbursement for an off-label use is to obtain a listing in a drug compendium recognized by the Centers for Medicare and Medicaid Services ("CMS").

19. A drug compendium is typically a non-profit reference book listing drug strengths, quality, and ingredients.

20. In 2003, there were two main compendia recognized by CMS: American Hospital

Formulary Service Drug Information ("AHS") and United States Pharmacopeia Drug Information ("USP").

21. AHS would not consider Phase 2 trial data, abstracts, open label studies, or special supplements, but USP would.

22. In October of 2003, after considerable lobbying by Amgen, USP accepted an AOC indication for Aranesp. To promote Aranesp off-label to treat AOC, Amgen distributed the USP monograph (a document which describes USP's approval of the off-label use), as well as various studies that encouraged off-label use of Aranesp to treat AOC.

23. In August and October of 2003, two large randomized controlled trials found increased death and possible tumor stimulation in cancer patients receiving ESAs that were not approved in the United States.

24. In May of 2004, the FDA's Oncologic Drugs Advisory Committee met to discuss safety concerns of increased thrombotic events, tumor progression, and decreased survival seen in the 2003 studies as they applied to Aranesp and Procrit. The committee recommended large, randomized, controlled clinical trials with primary endpoints, including survival and transfusion rates to address the safety concerns.

25. Despite the growing concerns, Amgen promoted Aranesp to treat AOC.

26. In January of 2007, Amgen notified the FDA and health care professionals of the results of its pivotal study in which patients receiving Aranesp for the treatment of AOC had a 28.5% increase in death and no significant reductions in transfusions or improvement in quality of life.

27. Shortly thereafter, the FDA required a black box warning on all ESAs that includes the warning "ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck,

lymphoid, and cervical cancers." It also explicitly states to "Discontinue following the completion of a chemotherapy course."

28. Aranesp's label also states, "Aranesp has not been shown to improve quality of life, fatigue, or patient well-being."

II. ENBREL

29. Enbrel® is Amgen's trade name for etanercept, a tumor necrosis factor blocker used to treat a number of conditions, including plaque psoriasis.

30. On November 2, 1998, the FDA approved Enbrel for its first indication, the treatment of moderately to severely active rheumatoid arthritis.

31. On April 30, 2004, the FDA approved Enbrel for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

32. On February 18, 2005, the FDA sent a Warning Letter to Amgen stating that Amgen's direct-to-consumer television advertisement entitled "Freedom" overstated the effectiveness of Enbrel, failed to communicate the limitations of Enbrel's indication (thereby broadening the indication), and minimized the risks associated with Enbrel.

33. In March 2008, the FDA required a black box warning to be added to Enbrel's labeling. This warning informed prescribers and patients that infections, including serious infections that led to hospitalization or death, were observed in patients treated with Enbrel. These infections included cases of bacterial sepsis and tuberculosis.

34. In August 2009, the FDA required that Enbrel's black box warning be expanded to inform prescribers and patients that invasive fungal infections, as well as bacterial, viral, and other infections due to opportunistic pathogens were reported with the use of Enbrel.

Additionally, the black box now warns that lymphoma and other malignancies, some fatal, have been observed in children and adolescent patients taking Enbrel.

35. Despite the black box warnings, the 2005 FDA Warning Letter, and Enbrel's limited approval for use in chronic moderate to severe plaque psoriasis, Amgen promoted Enbrel off-label for patients with mild plaque psoriasis from 2004 to 2011 and overstated Enbrel's efficacy in the treatment of plaque psoriasis.

CAUSE OF ACTION

Count I – Violation of the Virginia Consumer Protection Act, Virginia Code §§ 59.1-200(A)(5) and 59.1-200(A)(14)

36. Plaintiff re-alleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 35.

37. Defendant is a "supplier" and engaged in "consumer transactions," as these terms are defined by Virginia Code § 59.1-198.

38. Virginia Code § 59.1-200(A)(5) prohibits a supplier from misrepresenting that goods or services have certain quantities, characteristics, ingredients, uses, or benefits in connection with a consumer transaction.

39. Defendant, in the course of marketing, promoting, selling, and distributing the biologic medications Aranesp® and Enbrel®, has violated Virginia Code § 59.1-200(A)(5) by representing that Aranesp® and Enbrel® have quantities, characteristics, ingredients, uses, or benefits that they do not have.

40. Virginia Code § 59.1-200(A)(14) prohibits a supplier from using any deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction.

41. Defendant, in the course of marketing, promoting, selling, and distributing the biologic

medications Aranesp® and Enbrel®, has violated Virginia Code § 59.1-200(A)(14) by using deception, fraud, false pretense, false promise, or misrepresentation in connection with Aranesp® and Enbrel®.

42. Defendant willfully committed the violations of §§ 59.1-200(A)(5) and 59.1-200(A)(14) described above.

43. Individual consumers suffered monetary damages and other losses as a result of the aforesaid violations by Defendant.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the Commonwealth of Virginia, prays that this Court:

A. Pursuant to Virginia Code § 59.1-203(A), permanently enjoin Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in deceptive or misleading conduct which violates the VCPA;

B. Pursuant to Virginia Code § 59.1-206(A), order the Defendant to pay civil penalties of up to $2,500 for each and every willful violation of the VCPA;

C. Pursuant to Virginia Code § 59.1-206(C), order the Defendant to pay the costs incurred by the Commonwealth in investigating and preparing the case not to exceed $1,000 per violation and reasonable attorneys' fees; and

D. Grant such other and further relief as the Court deems proper.

Respectfully submitted,

COMMONWEALTH OF VIRGINIA,
EX REL. MARK R. HERRING,
ATTORNEY GENERAL

By: _____
Joelle E. Gotwals

Mark R. Herring
Attorney General

Cynthia E. Hudson
Chief Deputy Attorney General

Rhodes B. Ritenour
Deputy Attorney General

David B. Irvin (VSB # 23927)
Senior Assistant Attorney General

Joelle E. Gotwals (VSB # 76779)
Assistant Attorney General

Office of the Attorney General of Virginia
Consumer Protection Section
900 East Main Street
Richmond, Virginia 23219
Telephone: (804) 371-2084
Fax: (804) 786-0122

CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of August, 2015, a true copy of the foregoing Complaint was mailed, postage prepaid, to H. Scott Johnson, Jr., PCT Law Group, PLLC, 330 John Carlyle Street, Suite 300, Alexandria, Virginia 22314, counsel for Amgen, Inc.

Joelle E. Gotwals, Esq.