

STATE OF VERMONT  
SUPERIOR COURT  
WASHINGTON COUNTY

2015 AUG 18 P 2:23

STATE OF VERMONT

Plaintiff,

v.

AMGEN INC.

Defendant.

FILED

CIVIL DIVISION

Docket No. 514-8-15 Wncv

**COMPLAINT**

The Vermont Attorney General brings this action for violations of Vermont's Consumer Protection Act, 9 V.S.A. Chapter 63, against Amgen which has made deceptive marketing, advertising, and promotional claims about its Aranesp® and Enbrel® products, for which the Attorney General seeks civil penalties, injunctive relief, restitution, disgorgement, fees and costs, and other appropriate relief.

**I. PARTIES, JURISDICTION AND RELATED MATTERS**

**A. Defendants**

1. 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 Vermont by marketing, promoting, and selling the biologic medications Aranesp® and Enbrel®.

**B. Jurisdiction and Related Matters**

2. The claims described in this Complaint arise from actions by Amgen that occurred in Vermont related to its Aranesp® and Enbrel® products, and from the sales of those

products in Vermont.

3. The Vermont Attorney General is authorized, under the Vermont Consumer Protection Act, 9 V.S.A. § 2458(b), to sue to enforce the Act's prohibitions on unfair and deceptive acts and practices in commerce.

4. The Washington Superior Court has personal jurisdiction over Amgen and is the proper venue for this action, based on Amgen's marketing, promotion and sales of its Aranesp® and Enbrel® products throughout Vermont, including in Washington County.

5. This action is in the public interest.

## **II. STATUTORY FRAMEWORK**

6. The Vermont Consumer Protection Act prohibits unfair and deceptive acts and practices in commerce, 9 V.S.A. § 2453(a).

7. Deceptive marketing and promotion, including the misrepresentation of facts likely to mislead consumers and affect their decisions to purchase products, and making claims that are not substantiated by competent and reliable scientific evidence, violate the Vermont Consumer Protection Act's prohibition against unfair and deceptive acts and practices in commerce.

## **III. ALLEGATIONS**

### **A. 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 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 for Aranesp®.

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, or "anemia of cancer" ("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 insurance reimbursement for an off-label use of a drug is to obtain a listing in a drug compendium recognized by the Centers for Medicare and Medicaid Services ("CMS").

19. Drug compendia are summaries of drug information that are compiled by experts who have reviewed clinical data on drugs and affect coverage and reimbursement decisions. The compendia include summaries of pharmacologic characteristics for each drug such as drug strength, quality, ingredients, and indications. Most insurers, including Medicare, refer to

compendia when they make policy and coverage decisions.

20. In 2003, there were two main compendia recognized by CMS: American Hospital Formulary Service Drug Information (“AFHS”) and United States Pharmacopeia-Drug Information (“USP-DI”).

21. Clinical trials have four phases, each of which is designed to answer different research questions. At that time, AHS did not consider Phase II trial data abstracts, open label studies, or special supplements when it decided whether to include a particular drug in its compendium, but USP did. In Phase II, a drug is given to a larger group of people than the small number who received it for the first time in Phase I. Phase II trials also look at whether the drug is effective, and to further evaluate its safety.

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 conducted outside the U.S. found increased death and possible tumor stimulation in cancer patients receiving ESAs. The drugs that were the subject of those trials were approved in Europe, but not in the United States. The drugs were in the same drug class as Aranesp® and Procrit®.

24. In May of 2004, the FDA’s Oncologic Drugs Advisory Committee met to discuss safety concerns about 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 continued its off-label promotion to doctors of Aranesp® for the treatment of AOC.

26. In January of 2007, Amgen notified the FDA and health care professionals of the results of its pivotal Phase III clinical trial. In a Phase III trial, the drug is given to large groups of people for several reasons which include confirmation of the drug's effectiveness, side effect monitoring, and, the collection of information that will allow it to be used safely. 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 instructs: "Discontinue following the completion of a chemotherapy course."

28. After the Phase III trial, Aranesp's® label was changed to state: "Aranesp® has not been shown to improve quality of life, fatigue, or patient well-being."

**B. Enbrel**

29. Enbrel® is Amgen's trade name for etanercept, a tumor necrosis factor (TNF) blocker for treatment of a number of conditions, including plaque psoriasis, the most common form of the disease.

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® label. The 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, had been reported with the use of Enbrel®. In addition, 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.

#### **VIOLATIONS OF LAW**

36. Plaintiff repeats and re-alleges each and every allegation set forth in the preceding paragraphs as though fully set forth herein.

37. Defendant engaged in unfair and deceptive trade practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by making the above-

described misrepresentations in the course of marketing, promoting, and selling Aranesp® and Enbrel®.

38. Defendants also engaged in unfair and deceptive trade practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), because the above-described misrepresentations were not substantiated by competent and reliable scientific evidence.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff State of Vermont respectfully requests the following relief:

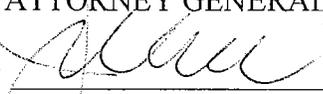
- A. A judgment determining that Defendant has violated the Vermont Consumer Protection Act;
  - B. A permanent injunction prohibiting Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in the marketing, advertising, promotion and sale of Aranesp® and Enbrel®, in violation of the Vermont Consumer Protection Act;
  - C. A judgment requiring Amgen to disgorge all profits obtained as a result of its violations of the Vermont Consumer Protection Act;
  - D. Civil penalties of up to \$ 10,000 for each violation of the Vermont Consumer Protection Act;
  - E. The award of investigative and litigation costs and fees to the State of Vermont;
- and
- F. Such other and further relief as the Court deems equitable and proper.

Dated: August 17, 2015

STATE OF VERMONT

WILLIAM H. SORRELL  
ATTORNEY GENERAL

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