

15CV011237

STATE OF NORTH CAROLINA

IN THE GENERAL COURT OF JUSTICE  
FILED SUPERIOR COURT DIVISION  
FILE NO.

WAKE COUNTY

STATE OF NORTH CAROLINA, *ex rel.* )  
ROY COOPER, ATTORNEY GENERAL, )  
WAKE COUNTY, C.S.C. )

Plaintiff, )

BY )

v. )

COMPLAINT

AMGEN INC. )

Defendant. )

**INTRODUCTION**

Plaintiff State of North Carolina, by and through its Attorney General, Roy Cooper, (“Attorney General” or “State”) brings this action against Defendant AMGEN INC. (“Defendant or Amgen”) pursuant to North Carolina’s Unfair and Deceptive Trade Practices Act, N.C.G.S. §§ 75-1.1, *et seq.* Plaintiff seeks a permanent injunction, statutory civil penalties, costs, and other appropriate relief.

PLAINTIFF COMPLAINS OF DEFENDANT AND ALLEGES AND SAYS AS FOLLOWS:

**PARTIES**

1. Plaintiff is the State of North Carolina acting on relation of its Attorney General, Roy Cooper, who brings this action pursuant to authority found in Chapters 75 and 114 of the North Carolina General Statutes.

2. The State of North Carolina (hereinafter “the State”), by Roy Cooper, Attorney General of the State of North Carolina, is charged, *inter alia*, with the enforcement of North Carolina’s Unfair and Deceptive Trade Practices Act, N.C.G.S. §§ 75-1.1, *et seq.*

3. 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 North Carolina by marketing, selling, and promoting the biologic medications Aranesp® and Enbrel®.

### **COMMERCE**

4. Amgen was at all times relative hereto, engaged in trade or commerce in the State of North Carolina by marketing, selling, and promoting the biologic medications Aranesp® and Enbrel®.

### **ALLEGATIONS: ARANESP**

5. 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.

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

7. 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.

8. 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.

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

10. 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.

11. Patients with AOC have active malignant disease and are not receiving

chemotherapy or radiation.

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

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

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

15. The most common way to obtain reimbursement for an off-label use is to obtain a listing in a CMS recognized drug compendium.

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

17. In 2003, there were two main compendia recognized by CMS: American Hospital Formulary Service (AHS) Drug Information and United States Pharmacopeia (USP) Drug Information.

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

19. 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.

20. 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.

21. 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.

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

23. In January of 2007, Amgen notified the FDA and health care professionals of the results of its pivotal 103 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.

24. 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.”

25. Aranesp’s label also states, “Aranesp has not been shown to improve quality of life, fatigue, or patient well-being.”

#### **ALLEGATIONS: ENBREL**

26. Enbrel® is Amgen’s trade name for etanercept, a tumor necrosis factor (TNF) blocker for treatment of a number of conditions, including plaque psoriasis.

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

28. 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.

29. 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.

30. 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.

31. 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.

32. 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**

33. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 32.

34. Defendant, in the course of engaging in the marketing, promotion, selling, and distributing the biologic medications Aranesp® and Enbrel®, has engaged in a course of trade or

commerce which constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under N.C.G.S. § 75-1.1 by making misrepresentations about Aranesp® and Enbrel®.

35. Defendant, in the course of marketing, promoting, selling, and distributing the biologic medications Aranesp® and Enbrel®, has engaged in a course of trade or commerce which constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under N.C.G.S. § 75-1.1, by representing that Aranesp® and Enbrel® have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, State of North Carolina, respectfully requests that:

A. Pursuant to N.C.G.S. § 75-1.1, permanently enjoin and restrain 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 unfair, deceptive or misleading conduct, acts, or practices in the promotion and marketing of its biologic medications Aranesp® and Enbrel®;

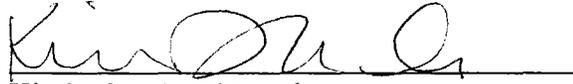
B. That the Court fashion equitable relief to cure Defendant’s deceptive practices;

C. Pursuant to N.C.G.S. § 75-16.1, the Court order Defendant to pay costs and reasonable attorneys’ fees incurred by the State in connection with the investigation and litigation of this matter; and

D. That the Court grant such further relief as the Court deems necessary or appropriate to remedy the effects of Defendant’s unlawful trade practices.

This the 18<sup>th</sup> day of August, 2015.

ROY COOPER  
Attorney General

A handwritten signature in black ink, appearing to read "Kimberley A. D'Arruda", is written over a horizontal line.

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