

CAUSE NO. _____

**THE STATE OF TEXAS,
Plaintiff,**

VS.

**AMGEN INC.
Defendant.**

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IN THE DISTRICT COURT OF

DALLAS COUNTY, TEXAS,

___ JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, THE STATE OF TEXAS, acting by and through Attorney General KEN PAXTON ("State"), filing Plaintiff's Original Petition complaining of and against AMGEN INC. ("Defendant") and would respectfully show the court the following:

AUTHORITY

1. This action is brought by Attorney General Ken Paxton, through his Consumer Protection Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by § 17.47 of the Texas Deceptive Trade Practices – Consumer Protection Act, Tex. Bus. & Com. Code Ann. § 17.41 et seq. ("DTPA"), upon the grounds that Defendant has engaged in false, misleading or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by §§ 17.46(a) and (b) of the DTPA.

PARTY DEFENDANT

2. Defendant Amgen Inc. is a Delaware corporation with a principal place of business at 1 Amgen Center Drive in Thousand Oaks, California 91320. At all relevant

times, Amgen did business in Texas by marketing, selling, and promoting the biologic medications Aranesp® and Enbrel®.

VENUE

3. Venue for this action properly lies in Dallas County on the basis of § 17.47(b) of the DTPA because Defendants' acts and practices that violate these statutes occurred throughout Texas, including Dallas County, Texas.

PUBLIC INTEREST

4. Because Plaintiff STATE OF TEXAS has reason to believe that Defendant has engaged in, and will continue to engage in, the unlawful practices set forth below, Plaintiff STATE OF TEXAS has reason to believe that Defendant has caused and will cause adverse effects to legitimate business enterprises which conduct their trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the STATE OF TEXAS believes and is of the opinion that these proceedings are in the public interest.

ACTS OF AGENTS

5. Whenever in this petition it is alleged Defendant did any act or thing, it is meant that Defendant performed or participated in such act or thing or that such act was performed by agents or employees of Defendant and in each instance, the agents or employees of Defendant were then authorized to and did in fact act on behalf of Defendant or otherwise acted under the guidance and direction of Defendant.

TRADE AND COMMERCE

6. Defendant has, at all times described below, engaged in conduct which constitutes "trade" and "commerce" as those terms are defined by § 17.45(6) of the

DTPA.

NOTICE BEFORE SUIT

7. Plaintiff informed Defendant herein at least seven (7) days before instituting this action of the alleged unlawful conduct of which complaint is now made.

ALLEGATIONS

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.

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 CMS recognized drug compendium.

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 (AHS) Drug Information and United States Pharmacopeia (USP) Drug Information.

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

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 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.

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."

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.

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.

VIOLATIONS OF DTPA

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

37. Defendant in the course of engaging in the marketing, promotion, selling, and distributing the biologic medications Aranesp® and Enbrel®, has engaged in the course and conduct of trade and commerce, had directly and indirectly engaged in false, misleading, and deceptive acts and practices declared unlawful by § 17.46 (a) and (b) of the Texas Deceptive Trade Practices-Consumer Protection Act, and violating of § 17.46 (b)(5) of the DTPA by making misrepresentations about Aranesp® and Enbrel®.

38. 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 false, misleading, or deceptive acts or practices, and is declared unlawful by §17.46 (b) (5) of the DTPA, by representing that Aranesp® and Enbrel® have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have.

CONTINUING VIOLATIONS

39. Defendant has violated and could continue to violate the laws as hereinabove alleged. Defendant, unless restrained by this Honorable Court, could continue to violate the laws of the State of Texas. Defendant has violated and could continue to violate the Deceptive Trade Practices-Consumer Protection Act.

PRAYER

40. WHEREFORE, PREMISES CONSIDERED, the STATE OF TEXAS prays that Defendant be cited according to law to appear and answer herein and that upon final hearing a PERMANENT INJUNCTION be issued restraining and enjoining Defendant and its agents, servants, employees, representatives, subsidiaries, divisions, successors, and assigns from engaging in false, misleading, or deceptive practices.

30. The STATE OF TEXAS further prays, that upon final hearing, this Court order Defendant to pay civil penalties of not more than \$20,000.00 per violation, as provided in § 17.47(c)(1) of the DTPA.

31. The STATE OF TEXAS further prays that the Office of the Attorney General be awarded their investigative costs, court costs, reasonable attorneys' fees, expenses, and witness fees pursuant to the laws of the State of Texas including the Tex. Gov't Code Ann. § 402.006(c).

32. The STATE OF TEXAS further prays that upon final hearing that this Court grants all other relief to which the State may be justly entitled.

Respectfully submitted,

Plaintiff State of Texas

Respectfully submitted,

Plaintiff State of Texas

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