IN THE COURT OF COMMON PLEAS
FRANKLIN COUNTY, OHIO

STATE OF OHIO, *ex rel.* MICHAEL DEWINE, ATTORNEY GENERAL 30 East Broad Street State Office Tower – 14th Floor Columbus, Ohio 43215	)	CASE NO.
	)	JUDGE
Plaintiff,	)	**COMPLAINT FOR DECLARATORY JUDGMENT, INJUNCTIVE RELIEF, CIVIL PENALTIES AND COSTS**
v.	)	
AMGEN INC. One Amgen Center Drive Thousand Oaks, California 91320-1799	)	
Defendant.	)	

I. JURISDICTION

1. Plaintiff, State of Ohio, by and through the Attorney General of Ohio, Michael DeWine, having reasonable cause to believe that violations of Ohio's consumer laws have occurred, brings this action in the public interest and on behalf of the State of Ohio under the authority vested in him pursuant to R.C. 1345.07 of the Consumer Sales Practices Act.

2. Defendant Amgen Inc. ("Defendant" or "Amgen") is a Delaware corporation with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Defendant transacted business in the state of Ohio and nationwide by marketing, promoting, and selling the prescription drugs Aranesp® and Enbrel®.

3. The actions of Defendant, hereinafter described, have occurred in the State of Ohio, County of Franklin and various other counties, and as set forth below, are in violation of the Consumer Sales Practices Act, R.C. 1345.01 *et seq*.

4. Defendant is a "supplier" as that term is defined in R.C. 1345.01(C) as Defendant was, at all times relevant herein, engaged in the business of effecting "consumer transactions" by marketing, promoting, and selling prescription drugs, including Aranesp® and Enbrel®, to consumers in the State of Ohio for purposes that were primarily for personal, family or household use within the meaning specified in R.C. 1345.01(A) and (D).

5. Jurisdiction over the subject matter of this action lies with this Court pursuant to R.C. 1345.04 of the Consumer Sales Practices Act.

6. This Court has venue to hear this case pursuant to Ohio Civ. R. 3(B)(3), in that some of the transactions complained of herein and out of which this action arose, occurred in Franklin County.

II. ALLEGATIONS

ARANESP®

7. 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.

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

9. 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.

10. 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.

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

12. 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.

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

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

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

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

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

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

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

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

21. 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.

22. 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.

23. 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.

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

25. 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.

26. 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."

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

ENBREL

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

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

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

III. CAUSES OF ACTION

UNFAIR OR DECEPTIVE ACTS OR PRACTICES

COUNT ONE

35. Plaintiff adopts, incorporates herein and re-alleges paragraphs 1 through 34 as if fully set forth below.

36. Defendant, in the course of engaging in the development, manufacture, promotion, sales, and distribution of the prescription drugs Aranesp® and Enbrel®, has engaged in a course of trade or commerce which constitutes unfair or deceptive acts or practices, and is therefore unlawful under R.C. 1345.02 by making misrepresentations about Aranesp® and Enbrel®.

37. Defendant committed unfair or deceptive acts or practices in violation of the Consumer Sales Practices Act, R.C. 1345.02(B)(1) and 1345.02(B)(2) by misrepresenting that Aranesp® and Enbrel® have sponsorship, approval, performance characteristics, accessories, uses, or benefits that they do not have.

38. Defendant committed unfair or deceptive acts or practices in violation of the Consumer Sales Practices Act, R.C. 1345.02(B)(2) by misrepresenting that Aranesp® and Enbrel® are of a particular quality when they are not.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

1. Adjudge and decree that Defendant engaged in acts or practices in violation of the Consumer Sales Practices Act., R. C. 1345.01 *et seq.,* as previously set forth.

2. Permanently enjoin and restrain the Defendant from engaging in deceptive and unfair practices set forth herein and from violating the Consumer Sales Practices Act.

3. Adjudge and decree that the Defendant is liable to the State for the reasonable costs and expenses of the investigation and prosecution of the Defendant's actions.

5. Assess, fine and impose upon Defendant a civil penalty pursuant to R. C. 1345.07(D) of Twenty-Five Thousand Dollars ($25,000.00) for each unfair or deceptive act or practice alleged herein.

6. Order that all costs in this cause be taxed against Defendant.

7. Grant Plaintiff such other and further relief as this Court deems just, equitable and appropriate.

Respectfully Submitted,

MICHAEL DeWINE
Attorney General

/s/ Michael S. Ziegler
MICHAEL S. ZIEGLER
Ohio Sup. Ct. Atty. No. 0042206
Assistant Attorney General
Consumer Protection Section
30 East Broad Street, 14th Floor
Columbus, Ohio 43215-3428
614/466-3980
866/404-4121 (facsimile)
michael.ziegler@ohioattorneygeneral.gov

Counsel for Plaintiff