STATE OF INDIANA )
) SS:
COUNTY OF MARION )

IN THE MARION SUPERIOR COURT

CAUSE NO. _____

STATE OF INDIANA,

Plaintiff,

v.

AMGEN INC.,

Defendant.

49D07 15 08 PL 027483

FILED

175 AUG 18 2015

Myla A. Eldridge
CLERK OF THE MARION CIRCUIT COURT

**APPEARANCE BY ATTORNEY IN CIVIL CASE**

**Party Classification:** Initiating

1. The undersigned attorneys now appear in this case for the following party: State of Indiana

2. Applicable attorney information for service as required by Trial Rule 5(B)(2) and for case information as required by Trial Rules 3.1 and 77(B) is as follows:

| | | |
|---|---|---|
| Name: | Richard M. Bramer | Atty. No.: 15989-77 |
| Address: | Office of the Attorney General<br>Indiana Government Center South<br>302 West Washington Street, 5th Floor<br>Indianapolis, Indiana 46204 | Phone: (317) 232-1008<br>Richard.Bramer@atg.in.gov |

3. There are other party members: Yes _____ No __X__

4. *If first initiating party filing this*, the Clerk is requested to assign this case the following Case Type under Administrative Rule 8(b)(3): PL

5. I will accept service by FAX at the above noted number: Yes _____ No __X__

6. This case involves support issues: Yes_____ No __X__

7. There are related cases: Yes _____ No __X__

8. This form has been served on all other parties. Certificate of service appears below: Yes: _____ No: __X__

9. Additional information required by local rule: ____N/A_____

Respectfully submitted,

FOR THE STATE OF INDIANA

**GREGORY F. ZOELLER**
Attorney General of Indiana
Attorney No. 1958-98

By: Richard M. Bramer
Richard M. Bramer
Director and Chief Counsel, Consumer Protection Division
Atty. No. 15989-77
Office of the Attorney General
Indiana Government Center South, 5th Floor
302 West Washington Street
Indianapolis, IN 46204

| | | |
|---|---|---|
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| STATE OF INDIANA, | ) | 49D07 15 08 PL 027483 |
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| v. | ) | (175) AUG 18 2015 |
| AMGEN INC., | ) | Myla A. Eldridge |
| Defendant. | ) | CLERK OF THE MARION CIRCUIT COURT |

**COMPLAINT FOR PERMANENT INJUNCTIVE AND OTHER RELIEF**

Plaintiff, the State of Indiana, by Indiana Attorney General Gregory F. Zoeller and Deputy Attorney General Richard M. Bramer, brings this action against Defendant AMGEN INC. for violating the Indiana Deceptive Consumer Sales Act, Indiana Code § 24-5-0.5-0.1 *et seq.*("DCSA").

1. Plaintiff, the State of Indiana, in its sovereign capacity, by Indiana Attorney General Gregory F. Zoeller and Deputy Attorney General Richard M. Bramer, ("Attorney General" or "State") brings this action against Defendant AMGEN INC. ("Defendant or Amgen") for violating the DCSA.

2. The Attorney General brings this action pursuant to the Ind. Code § 24-5-0.5-4, in the public interest, to protect the public's health, safety and welfare and pursuant to his general statutory and common law authority powers and duties. The Attorney General has reason to believe that the above-named Defendant has violated and/or is continuing to violate the DCSA. The Attorney General also has reason to believe that this action is in the public interest.

3. Upon interest and belief, the State of Indiana alleges as follows:

**JURISDICTION AND VENUE**

4. This Court has jurisdiction over Amgen pursuant to the DCSA because Amgen has

transacted business within the State of Indiana at all times relevant to this Complaint.

5. Venue for this action properly lies in Marion County, Indiana, pursuant to the Indiana Trial Rule 75(A) because Amgen transacts business in the State of Indiana and at all relevant times, it engaged in consumer transactions, within the meaning of the DCSA, in the State of Indiana including, but not limited to Marion County.

## PARTIES

6. Plaintiff, the State of Indiana, by and through Gregory F. Zoeller, Attorney General, is charged with enforcing the DCSA, which prohibits unfair or deceptive acts or practices affecting consumer transactions. Pursuant to the DCSA, the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the DCSA 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 the State of Indiana by marketing, selling, and promoting the biologic medications Aranesp® and Enbrel®.

## COMMERCE

8. The DCSA defines consumer transactions as: "a sale, lease, assignment, award by chance, or other disposition of an item of personal property, real property, a service, or an intangible, . . . to a person for purposes that are primarily personal, familial, charitable, agricultural, or household, or a solicitation to supply any of these things." Ind. Code § 24-5-0.5-2(a)(1).

9. Amgen was, at all times relative hereto, engaged in consumer transactions in the State of Indiana by marketing, selling, and promoting the biologic medications Aranesp® and Enbrel®.

## ALLEGATIONS

### ARANESP

10. 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.

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

12. 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.

13. 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.

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

15. 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.

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

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

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

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

20. The most common way to obtain reimbursement for an off-label use is to obtain a listing

in one of the Centers for Medicare and Medicaid Services (CMS) recognized drug compendia.

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

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

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

24. 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.

25. 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.

26. 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.

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

28. 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.

29. 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."

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

ENBREL

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

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

33. 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.

34. 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.

35. 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.

36. 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.

37. 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: Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-3.**

38. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 37.

39. Defendant, in the course of engaging in the marketing, promotion, selling, and distributing the biologic medications Aranesp® and Enbrel®, has engaged in consumer transactions which constitutes unfair, deceptive, or misleading practices, and are therefore unlawful under the DCSA, Ind. Code § 24-5-0.5-3 by making misrepresentations about Aranesp® and Enbrel®.

40. Defendant, in the course of marketing, promoting, selling, and distributing the biologic medications Aranesp® and Enbrel®, has engaged in consumer transactions which constitutes unfair, deceptive, or misleading practices, and are therefore unlawful under the DCSA, Ind. Code § 24-5-0.5-3, by representing that Aranesp® and Enbrel® have sponsorship, approval,

performance, characteristics, accessories, uses, benefits, quantities, or qualities that they do not have.

41. Defendant, in the course of marketing, promoting, selling, and distributing the biologic medications Aranesp® and Enbrel®, has engaged in consumer transactions which constitutes unfair, deceptive, or misleading practices, and are therefore unlawful under the DCSA, Ind. Code § 24-5-0.5-3, by making representations about Aranesp® and Enbrel® when Defendant knew the representations were not true.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, State of Indiana, respectfully request that this Court:

A. 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, abusive, or deceptive acts, omissions or practices which violate the DCSA in the promotion and marketing of its biologic medications Aranesp® and Enbrel®, pursuant to Ind. Code § 24-5-0.5-4(c)(1);

B. Order Defendant to pay civil penalties of up to the amount of five hundred dollars ($500) per violation for Defendant's intentional violation of the DCSA, payable to the State of Indiana, pursuant to Ind. Code § 24-5-0.5-8;

C. Order Defendant to pay civil penalties of up to the amount of five thousand dollars ($5,000) per violation for Defendant's knowing violation of the DCSA, payable to the State of Indiana, pursuant to Ind. Code § 24-5-0.5-4(g);

D. Order Defendant to pay all costs for the prosecution and investigation of this action, pursuant to Ind. Code § 24-5-0.5-4(c)(4); and

E. Grant Plaintiff such other and further relief as the Court deems equitable and proper.

Respectfully submitted,

FOR THE STATE OF INDIANA

**GREGORY F. ZOELLER**
Attorney General of Indiana
Attorney No. 1958-98

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