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SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION, MERCER COUNTY
DOCKET NO._____

JOHN J. HOFFMAN, Acting Attorney General of the State of New Jersey, and STEVE C. LEE, Acting Director of the New Jersey Division of Consumer Affairs, Plaintiffs, v. AMGEN INC., Defendant.	Civil Action **COMPLAINT**

1. Plaintiffs John J. Hoffman, Acting Attorney General of the State of New Jersey ("Attorney General"), with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, and Steve C. Lee, Acting Director of the New Jersey Division of Consumer Affairs ("Director"), with offices located at 124 Halsey Street, Seventh Floor, Newark, New Jersey (collectively, "Plaintiffs") bring this action against Amgen Inc. ("Defendant") for violating the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1et seq. ("CFA").

2. The Plaintiffs allege as follows:

JURISDICTION AND VENUE

3. This Court has jurisdiction over Defendant pursuant to N.J.S.A. 56:8-1et seq. because Defendant has transacted business within the State of New Jersey ("New Jersey") at all times relevant to this Complaint.

4. Venue for this action properly lies in Mercer County, New Jersey, pursuant to R. 4:3-2(b) because Defendant transacts business in Mercer County, New Jersey and/or some of the transactions out of which this action arose occurred in Mercer County, New Jersey.

PARTIES

5. The Attorney General, is charged with enforcing the CFA. The Director is charged with administering the CFA on behalf of the Attorney General. By this action, the Attorney General and Director seek injunctive and other relief for violations of the CFA, pursuant to N.J.S.A. 56:8-8, 8-11, 8-13 and 8-19.

6. Defendant 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 New Jersey by marketing, selling, and promoting the biologic medications Aranesp® and Enbrel®.

ADVVERTISEMENT AND SALE OF MERCHANDISE

7. The CFA, N.J.S.A. 56:8-1, defines "advertisement" as:

> . . . the attempt directly or indirectly by publication, dissemination, solicitation, indorsement or circulation or in any other way to induce directly or indirectly any person to enter or not enter into any obligation or acquire any title or interest in any merchandise or to increase the consumption thereof . . .

8. The CFA, N.J.S.A. 56:8-1, defines "merchandise" as "any objects, wares, goods, commodities, services or anything offered, directly or indirectly to the public for sale."

9. The CFA, N.J.S.A. 56:8-1, defines "sale" as "any sale, rental or distribution, offer for sale, rental or distribution or attempt directly or indirectly to sell, rent or distribute."

10. Defendnat was, at all times relative hereto, engaged in the advertisement and sale of merchandise in New Jersey by marketing, selling, promoting, and distributing the biologic medications Aranesp® and Enbrel®.

ALLEGATIONS

ARANESP

11. 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.

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

13. 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.

14. 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.

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

16. 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.

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

18. Amgen promoted Aranesp to treat AOC even though it lacked competent and

reliable scientific evidence to substantiate such use.

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

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

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

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

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

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

25. 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.

26. 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.

27. 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.

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

29. 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.

30. 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."

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

ENBREL

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

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

34. 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.

35. 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.

36. 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.

37. 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.

38. 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.

COUNT I

VIOLATION OF THE CFA BY DEFENDANTS (UNCONSCIONABLE COMMERCIAL PRACTICES AND DECEPTION)

39. Plaintiffs repeat and reallege the allegations contained in Paragraphs 1 through 38.

40. The CFA, N.J.S.A. 56:8-2, prohibits:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false

> promise, misrepresentation, or the knowing[] concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of merchandise. . .

41. Defendant, in the course of engaging in the marketing, promotion, selling, and distributing the biologic medication Aranesp® has engaged in the advertisement or sale of merchandise through unconscionable commercial practices and deception in violation of the CFA, specifically, it continued to promote Aranesp for AOC despite safety concerns and limited efficacy.

42. Defendant, in the course of engaging in the marketing, promotion, selling, and distributing the biologic medication Enbrel®, has engaged in the advertisement or sale of merchandise through unconscionable commercial practices and deception in violation of the CFA, specifically, 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.

43. Each unconscionable commercial practice and act of deception by Defendant constitutes a separate violation of the CFA, N.J.S.A. 56:8-2.

COUNT II

VIOLATION OF THE CFA BY DEFENDANTS (FALSE PROMISES AND/OR MISREPRESENTATIONS)

44. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 43 as if more fully set forth herein.

45. Defendant, in the course of marketing, promoting, selling, and distributing the biologic medications Aranesp® and Enbrel®, has engaged in the advertisement or sale of

merchandise through false promises and/or misrepresentations in violation of the CFA, specifically by representing that Aranesp® and Enbrel® have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have.

46. Each false promise and/or misrepresentation by Defendants constitutes a separate violation of the CFA, N.J.S.A. 56:8-2.

PRAYER FOR RELIEF

WHEREFORE, based on the foregoing allegations, Plaintiffs respectfully request that the Court enter judgment against Defendant:

(a) Finding that the acts and omissions of Defendant constitute unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 et seq.;

(b) Permanently enjoining and restraining 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 deceptive practices in the promotion and marketing of its pharmaceutical products in violation of the CFA, N.J.S.A. 56:8-1 et seq., including, but not limited to, the acts and practices alleged in this Complaint;

(c) Directing the assessment of restitution amounts against Defendant to restore to any affected person, whether or not named in this Complaint, any money or real or personal property acquired by means of any alleged practice herein to be unlawful and found to be unlawful, as authorized by the CFA, N.J.S.A. 56:8-8;

(d) Assessing the maximum statutory civil penalties against Defendant for each and every violation of the CFA, in accordance with the CFA, N.J.S.A. 56:8-13;

(e) Directing the assessment of costs and fees, including attorneys' fees, against Defendant for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56:8-11 and N.J.S.A. 56:8-19; and

(f) Granting such other relief as the interests of justice may require.

JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General
Consumer Fraud Prosecution Section

Dated: August 18, 2015
Newark, New Jersey

RULE 4:5-1 CERTIFICATION

I certify, to the best of my information and belief, that the matter in this action involving the aforementioned violations of the CFA, N.J.S.A. 56:8-1 et seq., is not the subject of any other action pending in any other court of this State. I am aware that private actions have been brought against the Defendant, but have no direct information that any such actions involve consumer fraud allegations. I further certify that the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated. I certify that there is no other party who should be joined in this action at this time.

JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: Patricia Schiripo
Patricia Schiripo
Deputy Attorney General
Consumer Fraud Prosecution Section

Dated: August 18, 2015
Newark, New Jersey

RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with Rule 1:38-7(b).

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DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Deputy Attorney General Patricia Schiripo is hereby designated as trial counsel for the Plaintiffs in this action.

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