KAMALA D. HARRIS
Attorney General of California
DANIEL A. OLIVAS
Supervising Deputy Attorney General
JUDITH FIORENTINI
Deputy Attorney General
State Bar No. 201747
110 West A Street, Suite 1100
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 645-2207
Fax: (619) 645-2062
E-mail: judith.fiorentini@doj.ca.gov
Attorneys for Plaintiff

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SAN DIEGO

THE PEOPLE OF THE STATE OF CALIFORNIA, Plaintiff, v. **GLAXOSMITHKLINE LLC,** Defendant.	Case No. **COMPLAINT FOR INJUNCTION, CIVIL PENALTIES AND OTHER EQUITABLE RELIEF**

Plaintiff, the People of the State of California (Plaintiff or the People), by its attorney, Kamala D. Harris, Attorney General of the State of California, by Judith Fiorentini, Deputy Attorney General, is informed and believes and thereupon alleges as follows:

JURISDICTION AND VENUE

1. The People brings this action, by Kamala D. Harris, Attorney General of the State of California, pursuant to the provisions of California Business and Professions Code sections 17200 et seq. and 17500 et seq.

2. Defendant GLAXOSMITHKLINE LLC (Defendant), at all relevant times, has transacted business in the City and County of San Diego and elsewhere in the State of California. The violations of law alleged in this complaint have been and are being carried out within the City and County of San Diego and elsewhere in the State of California. This Court has jurisdiction over Defendant and venue for this action properly lies in San Diego, California, because Defendant transacts business in San Diego, California.

PARTIES

3. Plaintiff is the People of the State of California.

4. Defendant GLAXOSMITHKLINE LLC (GSK) is a Delaware corporation with a principal place of business at 5 Crescent Drive, Philadelphia, Pennsylvania 19112. GSK transacts business in San Diego and elsewhere in California by developing, manufacturing, promoting, selling, and distributing prescription drugs.

ALLEGATIONS RELATING TO DEFENDANT'S MARKETING OF ADVAIR, PAXIL, AND WELLBUTRIN

ADVAIR

The Basic Medicine of Asthma

5. The National Institute of Health (NIH) published consensus guidelines for the diagnosis and treatment of asthma, which categorize patients into those with mild, moderate, and severe asthma.

6. Patients with occasional symptoms are categorized as mild "intermittent."

7. The NIH recommended treatment for mild intermittent asthma is a short-acting beta agonists (SABA), such as albuterol, on an as-needed basis in response to symptoms.

8. Patients with regular asthma symptoms are categorized as persistent.

9. For persistent asthma, the NIH guidelines recommend using a "controller" in addition to a SABA.

10. For mild persistent asthma, the NIH Guidelines recommend an inhaled corticosteroid (ICS) used to treat inflammation in the airways as a "first line" treatment as a controller along with a SABA on an as needed basis as "rescue medicine" to open up airways during acute asthma attacks. In the asthma context, "first line" use refers to the first controller medication a patient is prescribed.

11. For moderate asthma, the NIH Guidelines recommend adding a second controller medication, such as a long-acting beta agonist (LABA), used to keep airways open and intended for chronic use, to the ICS along with as needed use of a SABA for acute episodes.

Advair's Label

12. The ADVAIR DISKUS® (Advair) is GSK's trade name for an inhaled combination drug for treatment of a number of respiratory conditions, including asthma.

13. Advair is a combination of two other GSK drugs: Flovent® (fluticasone propionate), an ICS, and Serevent® (salmeterol xinafoate), a LABA.

14. Advair is sold in three strengths: Advair Diskus 100/50, Advair Diskus 250/50, and Advair Diskus 500/50.

15. On August 24, 2000, the FDA approved Advair for sale in the United States.

16. At the time of FDA approval in August 2000, the Advair label's Indications section stated that it was "indicated for the long term, twice-daily, and maintenance treatment of asthma." However, the Dosage and Administration section of the label provided that Advair was for "patients who are not currently on an inhaled corticosteroid, whose disease severity warrants treatment with 2 maintenance therapies. . . ."

17. In 2001, GSK submitted a supplemental New Drug Application (sNDA) for Advair that sought a broader first-line dosing instruction by providing additional clinical data and by removing "whose disease severity warrants treatment with 2 maintenance therapies" from the Dosage and Administration section of the label.

18. The FDA did not approve the sNDA and in 2002, GSK withdrew the application.

19. In early 2003, GSK halted a clinical trial relating to salmeterol (one of Advair's component drugs).

20. In August 2003, the FDA required the addition of a black box warning to Advair's label that stated "data from a large placebo-controlled US study that compared the safety of salmeterol (SEREVENT® Inhalation Aerosol) or placebo added to usual asthma therapy showed a small but significant increase in asthma-related deaths in patients. . . ."

21. In March 2006, the Indications section of the Advair label was modified to state that Advair was not indicated for patients with asthma controlled on ICS and SABAs alone. The Dosage and Administration section of the Advair label was also changed to state that "physicians should only prescribe ADVAIR DISKUS® for patients not adequately controlled on the other asthma-controller medications . . . or whose disease severity clearly warrants initiation of treatment with 2 maintenance therapies."

22. In June 2010, the black box warning on the Advair label was revised to state that the currently available data were inadequate to determine if drugs like Advair provide a level of control that mitigates the increased risk of death from LABA, and that LABA increases the risk of asthma-related hospitalization in pediatric and adolescent patients.

23. The revised black box warning also directs physicians to "step down" patients and discontinue Advair if possible after asthma control is achieved and maintained.

24. This black box revision also added "[d]o not use ADVAIR DISKUS® for patients whose asthma is adequately controlled on low or medium dose inhaled corticosteroids."

GSK'S Marketing of Advair

25. From the time of Advair's launch in 2000 until the 2010 label changes, GSK used false and misleading representations to promote Advair as a first line treatment for all asthma patients, including mild asthma patients who were not on ICS medication and only used SABAs intermittently.

26. GSK also provided financial incentives to GSK sales representatives to promote Advair for mild asthma patients, which encouraged sales representatives to make false and misleading representations to health care professionals.

27. GSK also promoted Advair as a first line treatment for mild asthma patients by distributing clinical trials that had been determined by the FDA to be insufficient evidence for the first line treatment for mild asthma patients to health care professionals, without disclosing health care professionals that the FDA rejected that evidence as insufficient.

PAXIL

28. Paxil® is GSK's trade name for the drug paroxetine hydrochloride, which is one of a class of drugs known as selective serotonin reuptake inhibitors (SSRIs).

29. In 1992, the FDA approved Paxil to treat depression in adults, and it was subsequently approved for other uses in adults.

30. The FDA never approved Paxil for patients under the age of 18.

31. Nonetheless, between 1999 and 2003, GSK deceptively promoted Paxil as safe and effective for children and adolescents, despite lack of FDA approval and three GSK clinical trials that both failed to demonstrate Paxil's effectiveness in children and adolescents and raised concerns that Paxil may be associated with an increased risk of suicide in such patient population.

WELLBUTRIN

32. Wellbutrin® is GSK's trade name for the drug bupropion hydrochloride, which is one of a class of drugs known as norepinephrine-dopamine reuptake inhibitors (NDRIs).

33. In 1985, the FDA approved Wellbutrin to treat major depressive disorder in adults.

34. Between 1999 and 2003, Wellbutrin was not approved for any use other than treating major depressive disorder in adults.

35. Despite this limited indication, between 1999 and 2003, GSK promoted Wellbutrin for various indications for which GSK had never submitted substantial evidence of safety and efficacy to the FDA, including weight loss and the treatment of obesity; treatment of sexual dysfunction; treatment of Attention Deficit Hyperactivity Disorder; treatment of addictions; treatment of anxiety; treatment of bipolar disorder; and treatment of patients under the age of 18.

36. GSK engaged in the off-label promotion of Wellbutrin by encouraging sales representatives to detail health care professionals directly on the off-label uses; through speaker programs that promoted off-label; through continuing medical education programs; by paying

health care professionals to attend lavish meetings in places like Jamaica and Bermuda where GSK provided off-label information about Wellbutrin; and by paying health care professionals to be "consultants" on "advisory boards" where they were presented with information about off-label uses.

FIRST CAUSE OF ACTION
Violations of Business and Professions Code
Section 17500 (Untrue or Misleading Representations)

37. The People realleges and incorporates by reference each and every allegation contained in the preceding paragraphs 1 through 36 as though fully set forth here.

38. Defendant, in the course of engaging in the development, manufacture, promotion, sales, and interstate distribution of prescription drugs, in violation of Business and Professions Code section 17500, with the intent to induce members of the public to purchase Defendant's products, has made representations about Advair, Paxil, and Wellbutrin when Defendant knew the representations were not true.

SECOND CAUSE OF ACTION
Violations of Business and Professions Code
Section 17200 (Acts of Unfair Competition)

39. The People realleges and incorporates by reference each and every allegation contained in the preceding paragraphs 1 through 38 as though fully set forth here.

40. Defendant, in the course of engaging in the development, manufacture, promotion, sales, and interstate distribution of prescription drugs, has engaged in unfair competition as defined in Business and Professions Code section 17200, by:

a. Violating Business and Professions Code section 17500 as alleged in paragraph 38 of the above First Cause of Action and which is incorporated by reference as though fully set forth here.

b. Representing that Advair, Paxil, and Wellbutrin have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that:

1. An injunction be issued pursuant to Business and Professions Code sections 17203 and 17535 restraining and enjoining Defendant and its agents, employees, and all other persons or entities, corporate or otherwise, in active concert or participation with any of them, from violating Business and Professions Code sections 17200 or 17500.

2. Pursuant to Business and Professions Code sections 17206 and 17536, Defendant be assessed a civil penalty of two thousand five hundred ($2,500) for each violation of Business and Professions Code sections 17200 and 17500, as proved at trial.

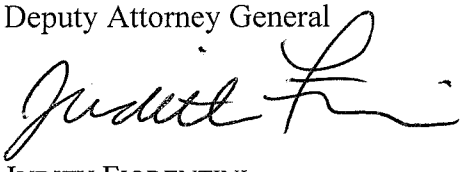
3. The Court order Defendant to pay Plaintiff's attorneys fees and costs.

4. Plaintiff is given such other and further relief as the nature of this case may require and that this Court deems equitable and proper to fully and successfully dissipate the effects of the alleged violations of Business and Professions Code sections 17200 and 17500.

Dated: June 4, 2014

Respectfully Submitted,

KAMALA D. HARRIS
Attorney General of California
DANIEL A. OLIVAS
Supervising Deputy Attorney General
JUDITH FIORENTINI
Deputy Attorney General



JUDITH FIORENTINI
Deputy Attorney General
Attorneys for Plaintiff