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IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF PIMA

STATE OF ARIZONA, *ex rel.* THOMAS C. HORNE, Attorney General, Plaintiff vs. GLAXOSMITHKLINE LLC, Defendant.	No. C20143053 **COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF** JAMES MARNER

1. The State of Arizona brings this action pursuant to the Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*, to obtain restitution, declaratory and injunctive relief, civil penalties, attorneys' fees and costs, investigative expenses and other relief to prevent the unlawful acts and practices alleged in this Complaint.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and GLAXOSMITHKLINE LLC enter appropriate orders, both prior to and following a determination of liability pursuant to A.R.S. § 44-1528.

3. Venue is proper in Pima County, Arizona.

PARTIES

4. Plaintiff is the State of Arizona, *ex rel.* Thomas C. Horne, the Attorney General of Arizona ("the State") who is authorized to bring this action under the Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*, ("the Act").

5. Defendant GLAXOSMITHKLINE LLC ("GSK") is a Delaware corporation with a principal place of business at 5 Crescent Dr, Philadelphia, Pennsylvania 19112. GSK transacts business in Arizona by developing, manufacturing, promoting, selling, and distributing prescription drugs.

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

I. ADVAIR

A. The Basic Medicine of Asthma

1. 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.

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

3. 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.

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

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

6. 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.

7. 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.

B. Advair's Label

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

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

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

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

12. 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 . . . ."

13. 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.

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

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

16. 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 . . . ."

17. 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."

18. 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.

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

20. 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."

C. GSK'S Marketing of Advair

21. 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.

22. 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.

23. 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.

II. PAXIL

24. 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).

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

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

27. 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.

III. WELLBUTRIN

28. 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).

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

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

31. 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.

32. 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.

VIOLATIONS OF LAW

The Consumer Fraud Act at A.R.S. § 44-1522 (A) states the following:

> (A) The act, use, or employment by any person of any deception, deceptive act or practice, fraud, false pretense, false promise, misrepresentation, or 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 any merchandise whether or not any person has in fact been misled, deceived, or damaged thereby, is declared to be an unlawful practice.

Defendant's actions violated the Arizona Consumer Fraud Act. Defendant, in the course of engaging in the development, manufacture, promotion, sales, and interstate distribution of prescription drugs, has engaged in false, deceptive, and misleading practices, in violation of A.R.S. § 44-1522 (A).

33. The State of Arizona realleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 32.

34. Defendant, in the course of engaging in the development, manufacture, promotion, sales, and interstate distribution of prescription drugs, has engaged in a

course of trade or commerce which constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under the Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*, by making representations about Advair, Paxil, and Wellbutrin when Defendant knew the representations were not true.

35. Defendant, in the course of marketing, promoting, selling, and distributing the prescription drugs Advair, Paxil, and Wellbutrin, has engaged in a course of trade or commerce which constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under the Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*, by representing that Advair, Paxil, and Wellbutrin have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, State of Arizona, respectfully request that this honorable Court enter an order:

That pursuant to A.R.S. § 44-1521 *et seq.,* this Court permanently enjoin 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 the aforementioned unfair, deceptive or misleading conduct acts or practices which violate the Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*;

A. Ordering Defendant to pay civil penalties of up to $10,000 for each and every violation of A.R.S. § 44-1531;

B. Ordering Defendant to pay all costs for the prosecution and investigation of this action, as provided by A.R.S. § 44-1534; and

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C. Granting Plaintiff such other and further relief as the Court deems equitable and proper.

DATED this 4th day of June, 2014.

THOMAS C. HORNE
ATTORNEY GENERAL

By: _____
NOREEN R. MATTS
Assistant Attorney General

By: _____
STEPHEN EMEDI
Assistant Attorney General