JOHN C. ALBERT
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STATE OF WISCONSIN CIRCUIT COURT DANE COUNTY
BRANCH ___ 2014 JUN -4 AM 11:05

CIRCUIT COURT
DANE COUNTY, WI

STATE OF WISCONSIN
17 West Main Street
Post Office Box 7857
Madison, Wisconsin 53707-7857,

Plaintiff,

v.

Case No. 14-CX- 26

Complex Forfeiture: 30109

GLAXOSMITHKLINE LLC
5 Crescent Drive
Philadelphia, Pennsylvania 19112,

Defendant.

THIS IS AN AUTHENTICATED COPY OF THE ORIGINAL DOCUMENT FILED WITH THE DANE COUNTY CLERK OF CIRCUIT COURT.

SUMMONS

CARLO ESQUEDA
CLERK OF CIRCUIT COURT

THE STATE OF WISCONSIN,

To each person named above as a Defendant:

You are hereby notified that the Plaintiff named above has filed a lawsuit or other legal action against you. The complaint, which is attached, states the nature and basis of the legal action.

Within twenty (20) days of receiving this summons, you must respond with a written answer, as that term is used in Chapter 802 of the Wisconsin Statutes, to the complaint. The court may reject or disregard an answer that does not follow the requirements of the statutes. The answer must be sent or delivered to the court, whose address is Dane County Courthouse, 215 South Hamilton St., Room 1000, Madison, WI 53703, and to Phillip D. Ferris, Assistant Attorney General, Plaintiff's attorney, whose address is Wisconsin Department of

Justice, 17 West Main Street, Post Office Box 7857, Madison, Wisconsin 53707-7857. You may have an attorney help or represent you.

If you do not provide a proper answer within twenty (20) days, the court may grant judgment against you for the award of money or other legal action requested in the complaint, and you may lose your right to object to anything that is or may be incorrect in the complaint. A judgment may be enforced as provided by law. A judgment awarding money may become a lien against any real estate you own now or in the future, and may also be enforced by garnishment or seizure of property.

Dated this 4th day of June, 2014.

J.B. VAN HOLLEN
Attorney General

PHILLIP D. FERRIS
Assistant Attorney General
State Bar No.: 1000138
Attorneys for State of Wisconsin

Wisconsin Department of Justice
17 West Main Street
Post Office Box 7857
Madison, Wisconsin 53707-7857
(608) 266-7971, Fax: (608) 267-2778

STATE OF WISCONSIN CIRCUIT COURT BRANCH ____ 2014 JUN -4 AM 11:05 DANE COUNTY

CIRCUIT COURT
DANE COUNTY, WI

STATE OF WISCOSIN
17 West Main Street
Post Office Box 7857
Madison, Wisconsin 53707-7857,

Plaintiff,

Case No. 14-CX- 20

v.

Complex Forfeiture: 30109

GLAXOSMITHKLINE LLC
5 Crescent Drive
Philadelphia, Pennsylvania 19112,

Defendant.

COMPLAINT FOR PERMANENT INJUNCTIVE AND OTHER RELIEF

The State of Wisconsin (hereinafter the "State" or "Plaintiff"), by its attorneys, J.B. Van Hollen, Attorney General, and Phillip D. Ferris, Assistant Attorney General, on behalf of the Wisconsin Department of Agriculture, Trade and Consumer Protection, brings this action against Defendant GlaxoSmithKline LLC for violating Wis. Stat. §§ 100.182(2) and (3), and alleges as follows:

JURISDICTION AND VENUE

1. This action is brought pursuant to Wis. Stat. § 100.182(5)(a) to enjoin and restrain violations of Wis. Stat. §§ 100.182(2) and (3); and pursuant to Wis. Stat. § 100.26(4), to recover civil forfeitures for each violation of Wis. Stat. §§ 100.182(2) or (3).

2. Venue for this action properly lies in Dane County, Wisconsin, pursuant to Wis. Stat. §§ 801.50(2)(c) and (a).

PARTIES

3. Plaintiff, State of Wisconsin, represented by Attorney General J.B. Van Hollen, is a sovereign State of the United States of American, with its principal office located at the State Capital in Madison, Wisconsin. This action is brought in the name of the State, on behalf of the Wisconsin Department of Agriculture, Trade and Consumer Protection, pursuant to the authority granted under Wis. Stat. § 100.182(5)(a).

4. Defendant GlaxoSmithKline LLC ("GSK" or "Defendant") is a Delaware limited liability company with a principal place of business at 5 Crescent Drive, Philadelphia, Pennsylvania 19112. GSK transacts business in Wisconsin by promoting, selling, and distributing prescription drugs.

5. Defendant was, at all times relative hereto, engaged in trade or commerce in the State of Wisconsin by advertising, marketing, promoting, representing, selling, and distributing prescription drugs, within the meaning of Wis. Stat. §§ 100.182(2) and (3).

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

I. ADVAIR

A. The Basic Medicine of Asthma

6. 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.

7. Patients with occasional symptoms are categorized as mild intermittent.

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

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

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

11. 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.

12. 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

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

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

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

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

17. 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 . . . ."

18. 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.

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

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

21. 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 . . . ."

22. 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."

23. 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.

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

25. 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

26. 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.

27. 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.

28. 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 to health care professionals that the FDA rejected that evidence as insufficient.

II. PAXIL

29. 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).

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

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

32. 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

33. 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).

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

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

36. 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.

37. 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 use; 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

WIS. STAT. § 100.182

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

39. Wisconsin Stat. § 100.182(2) provides:

> No person may advertise the availability of any drug or publish or circulate such an advertisement with the intent of selling, increasing the consumption of or generating interest in the drug if the advertisement contains any untrue, deceptive or misleading representations material to the effects of the drug.

40. Wisconsin Stat. § 100.182(3) provides, in pertinent part:

> No person may expressly or impliedly represent that a substance may be used to obtain physical or psychological effects associated with the use of a drug in order to promote the sale of the substance unless it is lawfully marketed for human consumption under the United States food, drug and cosmetic act under 21 USC 301 to 392.

41. In the course of marketing, promoting, selling, and distributing prescription drugs in Wisconsin, Defendant GSK has violated Wis. Stat. § 100.182(2), by making advertising representations about Advair, Paxil, and Wellbutrin with the intent of selling, increasing the consumption of or generating interest in those respective drugs, which representations were untrue, deceptive or misleading as to the effects of those respective drugs.

42. Further, in the course of marketing, promoting, selling, and distributing prescription drugs in Wisconsin, with the intent of selling, increasing the consumption of or generating interest in the prescription drugs Advair, Paxil, and Wellbutrin, Defendant GSK has violated Wis. Stat. § 100.182(2), by making advertising representations that Advair, Paxil, and Wellbutrin have characteristics, uses, benefits, or qualities that they do not have.

43. Further, in the course of marketing, promoting, selling, and distributing the

prescription drug Wellbutrin in Wisconsin, Defendant GSK has violated Wis. Stat. § 100.182(3), by promoting Wellbutrin for uses not approved by the Food and Drug Administration.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, State of Wisconsin, respectfully requests that this Court enter an Order:

1. Permanently enjoining Defendant GSK, 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 deceptive or misleading conduct, acts, or practices which violate Wis. Stat. §§ 100.182(2) and (3);

2. Ordering Defendant to pay civil forfeitures of not less than $50.00 and not more than $200.00 for each and every violation of Wis. Stat. §§ 100.182(2) and (3), pursuant to Wis. Stat. § 100.26(4);

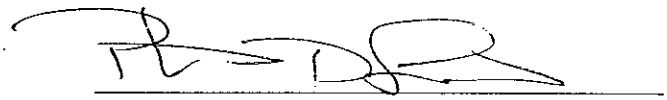
3. Ordering Defendant to pay the Wisconsin Department of Justice all of its reasonable and necessary expenses of prosecution and investigation of this action, including attorneys fees, pursuant to Wis. Stat. § 100.263; and

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

Dated this 4th day of June, 2014.

Respectfully submitted,

J.B. VAN HOLLEN
Attorney General



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