IN THE COMMON PLEAS COURT OF LUCAS COUNTY, OHIO

CI0201402690

STATE OF OHIO, *ex rel.* ATTORNEY GENERAL MICHAEL DEWINE 30 E. Broad Street, 14th Floor Columbus, Ohio 43215 Plaintiff, v. GLAXOSMITHKLINE LLC, 5 Crescent Drive Philadelphia, PA 19112 Defendant.	)	Case No. Judge Duhart

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COMPLAINT FOR PERMANENT INJUNCTIVE AND OTHER RELIEF

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1. Plaintiff, State of Ohio, in its sovereign capacity, by and through Michael DeWine, Attorney General of the State of Ohio ("Attorney General" or "State") brings this action against Defendant GLAXOSMITHKLINE LLC for violating the Ohio Consumer Sales Protection Act ("CSPA"), R.C. 1345.01 et seq.

2. The Attorney General brings this action pursuant to the CSPA, 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. *See* R.C. 1345.01 et seq. The Attorney General has reason to believe that the above-named Defendant has violated

and/or is continuing to violate the CSPA. The Attorney General also has reason to believe that this action is in the public interest.

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

JURISDICTION AND VENUE

4. This Court has jurisdiction over Defendant pursuant to R.C. 1345.04 because Defendant has transacted business within the State of Ohio at all times relevant to this Complaint.

5. Venue for this action properly lies in Lucas County, Ohio pursuant to Ohio Civ. R. 3(B)(3) because Defendant transacts business in Lucas County, Ohio and/or some of the transactions out of which this action arose occurred in Lucas County, Ohio.

PARTIES

6. Plaintiff, State of Ohio ex rel. Michael DeWine, Attorney General, is charged with enforcing the CSPA, which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce. Pursuant to the CSPA, the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the CSPA and to secure such equitable and other relief as may be appropriate in each case.

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

COMMERCE

8. Defendant is a "supplier" as that term is defined in R.C. 1345.01(C) as the

Defendant was, at all times relative hereto, engaged in the business of effecting consumer transactions in the State of Ohio by developing, manufacturing, promoting, selling, and distributing prescription drugs to consumers for purposes that were primarily for personal, family or household use, within the meaning specified in R.C. 1345.01(A) and (D).

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

I. ADVAIR

A. The Basic Medicine of Asthma

9. 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.

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

11. 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.

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

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

14. 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.

15. 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

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

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

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

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

20. 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 . . . ."

21. 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.

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

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

24. 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 . . . ."

25. 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."

26. 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.

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

28. 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

29. 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.

30. 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.

31. 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

32. 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).

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

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

35. 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

36. 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).

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

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

39. 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.

40. 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: CONSUMER SALES PRACTICES ACT

41. Plaintiff realleges and incorporates by reference herein each and every allegation

contained in the preceding Paragraphs 1 through 40.

42. 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 or deceptive acts or practices, and is therefore unlawful under R.C. 1345.02(A) by making representations about Advair, Paxil, and Wellbutrin when Defendant knew the representations were not true.

43. 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 deceptive practices, and is therefore unlawful under R.C. 1345.02(B)(1), by 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, State of Ohio, respectfully request that this honorable Court enter an order:

A. That pursuant to R.C. 1345.07, this Court permanently enjoins 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 and deceptive acts or practices which violate the CSPA, R.C. 1345.01 et seq;

B. Ordering Defendant to pay civil penalties of up to $25,000.00 for each and every violation of the CSPA, pursuant to R.C. 1345.07(D);

C. Ordering Defendant to pay all costs for the prosecution and investigation of this action; and

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

Respectfully submitted,

MICHAEL DEWINE
Ohio Attorney General

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