

FILED
LUCAS COUNTY

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COMMON PLEAS COURT
BERNIE QUILTER
CLERK OF COURTS

IN THE COURT OF COMMON PLEAS OF LUCAS COUNTY, OHIO

STATE OF OHIO *ex rel.*)
MICHAEL DEWINE)
ATTORNEY GENERAL)
30 E. Broad Street, 14th Floor)
Columbus, Ohio 43215)

Plaintiff,)

v.)

GLAXOSMITHKLINE LLC)
1 Franklin Plaza)
Philadelphia, Pennsylvania 19102)

Defendant.)

CASE NO. **CI0201206326**

JUDGE **Mandros**

**COMPLAINT FOR DECLARATORY
JUDGMENT, INJUNCTIVE RELIEF,
AND CIVIL PENALTY**

JURISDICTION AND VENUE

1. Michael DeWine, Attorney General of Ohio, having reasonable cause to believe that violations of Ohio’s consumer protection laws have occurred, brings this action in the public interest and on behalf of the State of Ohio under the authority vested in him by R.C. 1345.01 *et seq.* (the Ohio Consumer Sales Practices Act).

2. The actions of the Defendant GlaxoSmithKline LLC (“GSK” or “Defendant”) hereinafter described, have occurred in the State of Ohio, in Lucas County and other counties in Ohio and, as set forth below, are in violation of the Consumer Sales Practices Act, R.C. 1345.01 *et seq.*

3. Jurisdiction over the subject matter of this action lies within this Court pursuant to R.C.

1345.04 of the Consumer Sales Practices Act.

4. This Court has venue to hear this case pursuant to Ohio Civ. R. 3(B)(3) in that some of the transactions complained of herein, and out of which this action arose, occurred in Lucas County.

5. The Ohio Attorney General is the proper party to commence these proceedings under the authority provided him under R.C. 1345.07.

DEFENDANT

6. Defendant GSK is a Delaware corporation with a principal place of business at 1 Franklin Plaza, Philadelphia, Pennsylvania 19102. Defendant GSK transacts business in Lucas County, Ohio and other counties in Ohio by promoting, selling, and distributing prescription drugs, including Avandia.

7. Defendant GSK is a “supplier” as that term is defined in R.C. 1345.01(C) as GSK was, at all times relevant herein, engaged in the business of effecting consumer transactions by promoting, selling, and distributing prescription drugs, including Avandia, in Lucas County and other counties in the State of Ohio for purposes that were primarily personal, family or household within the meaning specified in R.C. 1345.01(A) and (D).

ALLEGATIONS RELATING TO DEFENDANT’S MARKETING OF AVANDIA

I. BACKGROUND INFORMATION

A. The Basic Medicine of Diabetes

8. Approximately 18.8 million people in the United States are diagnosed with diabetes.

9. Approximately 90-95% of adults diagnosed with diabetes have type 2 diabetes.

10. Type 2 diabetes results from the body’s failure to produce enough insulin and/or the

inability to use insulin properly.

11. Insulin is a hormone needed to convert sugar and other food into energy.
12. Without insulin, sugar builds up in the bloodstream that cannot be used by the cells; consequently, the cells are starved for energy causing numerous health problems.
13. Diabetes is a major cause of heart disease and stroke and is the seventh leading cause of death in the United States.
14. Since diabetics already have high cardiovascular risks, it is important that any treatment not increase these risks.

B. Treatment of Diabetes

15. The first line drug treatment for type 2 diabetes consists of established and inexpensive oral medications, including metformin and sulfonylureas.
16. Metformin is recognized as the “gold standard” in type 2 diabetes treatment. It reduces the amount of sugar released by the liver between meals, promotes weight loss, and reduces cholesterol and triglycerides levels. Metformin’s side effects, which include nausea and upset stomach, are minimal.
17. Sulfonylureas are another popular first line treatment. They stimulate the pancreas to produce more insulin. Sulfonylureas combine well with other diabetes drugs for maximum effect on blood sugar. Their side effects include hypoglycemia (low blood sugar) and weight gain.
18. As diabetes progresses, patients typically need additional treatment agents and/or insulin therapy.
19. Rosiglitazone, which is sold under the brand name Avandia, is one of a newer generation of diabetes drugs called thiazolidinediones (“TZDs”). Avandia and other TZDs lower blood

sugar levels by sensitizing the cells to use insulin more efficiently and effectively.

20. Avandia is available in three forms: Avandia tablets, Avandamet tablets, and Avandaryl tablets, which will all collectively be referred to as Avandia throughout this Complaint.

21. Avandamet tablets combine Avandia with metformin.

22. Avandaryl tablets combine Avandia with a sulfonylurea.

23. On May 25, 1999, the FDA approved Avandia for sale in the United States.

II. DEFENDANT'S MARKETING OF AVANDIA

24. Defendant promoted Avandia to physicians and other health care providers with false and misleading representations about Avandia's safety profile.

25. Defendant misrepresented that Avandia had a positive cholesterol profile, when in fact Defendant did not possess competent and reliable scientific evidence to substantiate the claim.

Defendant misrepresented that Avandia had cardiovascular benefits when in fact, it does not, and may increase cardiovascular risks.

APPLICABLE STATUTES

26. R.C. 1345.02(A) of the Consumer Sales Practices Act states as follows:

No supplier shall commit an unfair or deceptive act or practice in connection with a consumer transaction. Such an unfair or deceptive act or practice by a supplier violates this section whether it occurs before, during or after the transaction.

27. R.C. 1345.02(B)(1) of the Consumer Sales Practices Act states as follows:

(B) Without limiting the scope of division (A) of this section, the act or practice of a supplier in representing any of the following is deceptive:

(1) That the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits that it does not have;

COUNT I
UNFAIR OR DECEPTIVE ACTS OR PRACTICES

28. Plaintiff incorporates by reference, as if completely rewritten herein, the allegations set forth in Paragraphs 1 through 27.

29. Defendant, in the course of engaging in the promotion, sales, and distribution of prescription drugs in Lucas County and other counties in Ohio, misrepresented that Avandia had sponsorship, approval, performance characteristics, accessories, uses, or benefits that it did not have. Such representations are deceptive acts or practices in violation of R.C. 1345.02(A) and R.C. 1345.02(B)(1) of the Consumer Sales Practices Act.

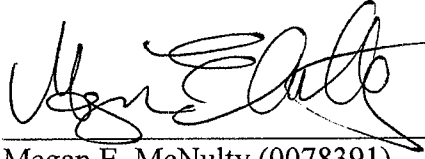
PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

- A. Adjudge and decree that Defendant has engaged in acts or practices in violation of the Consumer Sales Practices Act, R.C. 1345.01 *et seq.*, as previously set forth.
- B. Permanently enjoin and restrain the Defendant from engaging in deceptive practices set forth herein and from violating the Consumer Sales Practices Act.
- C. Adjudge and decree that the Defendant is liable to the State for the reasonable costs and expense of the investigation and prosecution of the Defendant's actions.
- D. Assess, fine and impose upon Defendant a civil penalty pursuant to R.C. 1345.07(D) of Twenty-Five Thousand Dollars (\$25,000.00) for the deceptive act or practice alleged herein.
- E. Order that all costs in this cause be taxed against Defendant.
- F. Grant Plaintiff such other and further relief as the Court deems just, equitable and appropriate.

Respectfully submitted,

MICHAEL DEWINE
Attorney General of Ohio

A handwritten signature in black ink, appearing to read "Megan E. McNulty", written over a horizontal line.

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