

**STATE OF VERMONT
SUPERIOR COURT
WASHINGTON UNIT**

STATE OF VERMONT

Plaintiff,

vs.

GLAXOSMITHKLINE LLC

Defendant.

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CIVIL DIVISION

Docket No. 784-11-12-WVCU

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

NOW COMES the State of Vermont, through William H. Sorrell, Attorney General of the State of Vermont, and brings this action against Defendant GlaxoSmithKline LLC for violating the Vermont Consumer Protection Act, 9 V.S.A. §§ 2451, *et seq.* as follows:

PARTIES

1. Plaintiff, the State of Vermont, through William H. Sorrell, Attorney General, is charged, *inter alia*, with the enforcement of the Vermont Consumer Protection Act, 9 V.S.A § 2451 *et seq.*

2. Defendant GlaxoSmithKline LLC (“GSK” or “Defendant”) is a Delaware corporation with a principal place of business at 1 Franklin Plaza, Philadelphia, Pennsylvania 19102. Defendant transacts business in Vermont by promoting, selling, and distributing prescription drugs.

JURISDICTION AND VENUE

3. This action is brought for and on behalf of the State of Vermont, by William H. Sorrell, Attorney General of the State of Vermont, pursuant to the provisions of the Vermont Consumer Protection Act.

4. This Court has subject matter jurisdiction over this matter pursuant to 4 V.S. A. 113. This Court has personal jurisdiction over the Defendant because GSK has transacted business within the State of Vermont at all times relevant to this Complaint.

5. Venue for this action properly lies in Washington County, Vermont, pursuant to 9 V.S.A. § 2458.

ALLEGATIONS RELATING TO DEFENDANT'S MARKETING OF AVANDIA

I. BACKGROUND INFORMATION

A. The Basic Medicine of Diabetes

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

7. Approximately 90-95% of adults diagnosed with diabetes have Type 2 diabetes.

8. Type 2 diabetes results from the body's failure to produce enough insulin and/or the inability to use insulin properly. The relationship of Type 2 diabetes to obesity and inadequate exercise is considered to be strong because those lifestyle habits greatly increase the body's resistance to insulin production.

9. Insulin is a hormone needed to convert sugar and other food into energy.

10. Without insulin, sugar that cannot be used by the cells builds up in the bloodstream. Consequently, the cells are starved for energy and this causes numerous health problems.

11. Diabetes is a major cause of heart disease and stroke, and is the seventh leading cause of death in the United States.

12. Since diabetics already have high cardiovascular risks, it is important that any treatment not increase these risks.

B. Treatment of Diabetes

13. The first line drug treatment for Type 2 diabetes consists of established and inexpensive oral medications, including Metformin and sulfonylureas.

14. 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.

15. Sulfonylureas are a class of popular first line treatment medications. 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.

16. As diabetes progresses, patients typically need additional treatment agents and/or insulin therapy.

17. Rosiglitazone, which GSK sells under the brand name Avandia, is one of a newer generation of diabetes drugs called thiazolidinediones (“TZDs”). Avandia and other TZDs decrease blood sugar levels by sensitizing the cells to use insulin more efficiently and effectively.

18. Avandia is available in three forms, namely Avandia tablets, Avandamet tablets, and Avandaryl tablets. Avandamet tablets combine Avandia with Metformin. Avandaryl tablets

combine Avandia with a sulfonylurea. The three forms of Avandia are collectively referred to below as “Avandia”.

C. FDA Approval of Avandia

19. GSK filed its new drug application for Avandia on November 25, 1998.

20. Timing was a factor in Avandia’s success because one TZD, Rezulin, was already on the market, and another, Actos, was expected to enter the market at about the same time as Avandia. If the Food and Drug Administration (“FDA”), approved Actos before it approved Avandia, GSK would be the third TZD in the market. This was commercially unacceptable to GSK because it would reduce Avandia’s peak year sales by approximately 30%. As a result, GSK wanted to move Avandia through the development and approval phases as swiftly as possible.

21. GSK knew that the FDA prohibited pharmaceutical companies from promoting drugs before they received FDA approval. GSK promoted Avandia before receiving FDA approval because GSK knew that early promotion would result in a more profitable launch.

22. On April 28, 1999, before Avandia was approved by the FDA, GSK received a warning letter from the FDA regarding its pre-approval promotion.

23. Avandia was approved by the FDA on May 25, 1999, and GSK immediately resumed its promotion of the drug.

24. GSK viewed Avandia as its most important commercial asset for the company’s financial future. It believed that Avandia had the potential to be a “blockbuster drug”, a term commonly used in the drug industry for a drug that produces over \$1 billion per year in sales.

25. When Avandia entered the market in 1999, GSK had only one blockbuster drug, Augmentin, which was quickly approaching its patent's expiration date.

II. DEFENDANT'S MARKETING OF AVANDIA

26. GSK publicly represented that Avandia was a significant advance in diabetes treatment, despite the fact that it lacked substantiation for that claim.

27. GSK promoted Avandia to physicians and other health care providers and made false and misleading representations about Avandia's safety profile. GSK misrepresented that Avandia has cardiovascular benefits, but it does not. It may actually increase cardiovascular risks.

28. GSK also misrepresented that Avandia had a positive cholesterol profile, but Avandia increases patients' total cholesterol level, an especially dangerous side effect for diabetics who already have increased risk of cardiovascular disease. A diabetic with the same total cholesterol level as a non-diabetic has a higher risk of death from cardiovascular disease than a person who does not have diabetes. GSK did not possess competent and reliable scientific evidence to support the claim that Avandia had a positive cholesterol profile.

29. At the time of Avandia's launch, Metformin was its biggest competitor. GSK's marketing target was to displace Metformin as the preferred first line therapy for Type 2 diabetes. Avandia is, at best, comparable to Metformin in reducing diabetics' blood sugar. Internal 2002 GSK correspondence indicates that it had evidence that Metformin may be superior to Avandia in lowering diabetics' blood sugar.

30. Avandia and Actos are similar in terms of glycemic control, but Avandia has a higher risk of heart attacks and congestive heart failure than Actos. Actos has a lower risk of cardiovascular adverse effect because, among other things, it increases LDL cholesterol ("bad"

cholesterol) less than Avandia, and increases HDL cholesterol (“good” cholesterol) more than Avandia. GSK knew this as early as October 2000 but did not publicly disclose it.

VIOLATIONS OF LAW

31. Paragraphs 1-30 of this complaint are incorporated herein as though set forth in full.

32. 9 V.S.A. § 2458(a) authorizes the Attorney General to bring an action to enjoin a defendant from engaging in a method, act, or practice that is in violation of the Vermont Consumer Protection Act, 9 V.S.A § 2451 *et seq.*

33. In the course of advertising, soliciting, selling, promoting and distributing the prescription drug Avandia, GSK has engaged in a course of trade or commerce that violates the Vermont Consumer Protection Act, 9 V.S.A § 2451 *et seq.* by making written and oral representations regarding Avandia that GSK knew to be untrue.

34. GSK’s actions are unfair or deceptive acts or practices affecting the conduct of trade or commerce in Vermont, in violation of the Vermont Consumer Protection Act, 9 V.S.A § 2451 *et seq.*

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this honorable Court enter an Order:

- A. Issuing a permanent injunction prohibiting 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 unfair or deceptive conduct;
- B. Ordering Defendant to pay all costs for the prosecution and investigation of this action, as provided by 9 V.S.A. § 2458(b)(3);
- C. Ordering Defendant to pay civil penalties of \$10,000.00 pursuant to 9 V.S.A. § 2458(b)(1) for each and every violation of the Vermont Consumer Fraud Act, 9

V.S.A § 2451 *et seq.*; and

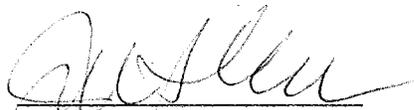
D. Granting such other and further relief as the Court deems equitable and proper.

DATED at Montpelier, Vermont this 15th day of November, 2012.

STATE OF VERMONT

WILLIAM H. SORRELL
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