

DISTRICT COURT, DENVER CITY AND COUNTY, COLORADO 1437 Bannock Street Denver, Colorado 80202	FILED Document DATE FILED: November 15, 2012 11:48 AM CO Denver County District Court 2nd JD Filing Date: 11/15/2012 10:48:02 MST Filing ID: 47737579 Review Clerk: Paula Lentini <p style="text-align: center;">▲ COURT USE ONLY ▲</p>
STATE OF COLORADO, ex rel. JOHN W. SUTHERS, ATTORNEY GENERAL, Plaintiff, v. GLAXOSMITHKLINE LLC, Defendant.	Case No.:
COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF	

Plaintiff, The State of Colorado, upon relation of John W. Suthers, Attorney General for the State of Colorado through the undersigned counsel states and alleges against Defendant GLAXOSMITHKLINE LLC, as follows, for violation of the Colorado Consumer Protection; Act, §§ 6-1-101 et.seq. C.R.S. (2012) (“CCPA”) as follows:

INTRODUCTION

1. This matter is a civil law enforcement action by the State of Colorado, *ex rel.* John W. Suthers, under the Colorado Consumer Protection Act, §§ 6-1-101 et.seq. C.R.S. (2012) (“CCPA”), to preliminarily and permanently restrain and enjoin Defendants from engaging in deceptive trade practices, to recover statutory civil penalties, to obtain restitution, to disgorge unjust proceeds, and to recover attorney fees and costs.

PARTIES

2. John W. Suthers is the duly elected Attorney General for the State of Colorado and has express authority under § 6-1-103, C.R.S. (2012) to enforce and prosecute violations of the CCPA.

3. Defendant GLAXOSMITHKLINE LLC is a Delaware corporation with a principal place of business at 1 Franklin Plaza, Philadelphia, Pennsylvania 19102. Defendant transacts business in Colorado by promoting, selling, and distributing prescription drugs.

JURISDICTION AND VENUE

4. This Court has jurisdiction to enforce the CCPA under § 6-1-103 and § 6-1-110, C.R.S. (2012), and to enter appropriate orders prior to and following an ultimate determination and liability.

5. Under § 6-1-103 of the CCPA, venue is proper in the City and County of Denver, Colorado because the deceptive trade practice occurred in the City and County of Denver.

APPLICABLE STATUTES

6. The CCPA prohibits deceptive trade practices as set forth in the statute. Colo. Rev. Stat. § 6-1-105 (2012).

7. The CCPA authorizes the Attorney General under C.R.S. § 6-1-110(1) to obtain injunctive relief and orders or judgments as may be necessary to prevent the use or employment by such person of any such deceptive trade practice or which may be necessary to completely compensate or restore to the original position of any person injured by means of any such practice or to prevent any unjust enrichment by any person through the use or employment of any deceptive trade practice.

8. The CCPA authorizes civil penalties under C.R.S. § 6-1-112 for violations for each consumer or transaction involved, and the Court shall award attorney fees and costs under C.R.S. § 6-1-113(4) in all actions where the Attorney General successfully enforces the CCPA.

COMMERCE

9. The CCPA, defines deceptive trade practices as follows:

A person engages in a deceptive trade practice when, in the course of such person's business, vocation, or occupation such person: Knowingly makes a false representation as to the characteristics, ingredients, uses, benefits, alterations,

or quantities of goods, food, services, or property or a false representation as to the sponsorship, approval, status, affiliation, or connection of a person therewith.

§ C.R.S. § 6-1-105(1)(e)

10. Defendant was, at all times relative hereto, engaged in trade or commerce in the State of Colorado by promoting, selling, and distributing prescription drugs.

ALLEGATIONS RELATING TO DEFENDANT'S MARKETING OF AVANDIA

I. BACKGROUND INFORMATION

A. The Basic Medicine of Diabetes

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

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

13. Type 2 diabetes results from the body's failure to produce enough insulin and/or the inability to use insulin properly.

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

15. 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.

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

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

B. Treatment of Diabetes

18. The first line drug treatment for type 2 diabetes consists of established and inexpensive oral medications, including metformin and sulfonylureas.

19. 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.

20. 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.

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

22. 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.

23. 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.

24. Avandamet tablets combine Avandia with metformin.

25. Avandaryl tablets combine Avandia with a sulfonylurea.

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

II. DEFENDANT’S MARKETING OF AVANDIA

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

28. 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

VIOLATIONS OF LAW **COUNT I**

COLORADO CONSUMER PROTECTION ACT

29. The People reallege and incorporate each and every allegation contained in the preceding Paragraphs 1 through 29.

30. Defendant, in the course of engaging in the promotion, sales, and distribution of prescription drugs in Colorado, has engaged in a course of trade or commerce which constitutes unfair, deceptive, or misleading practices, and is therefore

unlawful under C.R.S. § 6-1-105(1)(e) making written and oral representations about Avandia when Defendant knew the written and oral representations were not true.

COUNT II
COLORADO CONSUMER PROTECTION ACT

31. The People reallege and incorporate each and every allegation contained in the preceding Paragraphs 1 through 31.

32. Defendant, in the course of engaging in the promotion, sales, and distribution of prescription drugs in Colorado, has engaged in a course of trade or commerce which constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under § 6-1-105(e) by representing that Avandia had the benefit of reducing cardiovascular risks when, in fact, it does not and may instead increase cardiovascular risks.

REMEDIES

A. Title 6 of the Colorado Consumer Protection Act states in relevant part as follows:

- (1) Whenever the attorney general or a district attorney has cause to believe that a person has engaged in or is engaging in any deceptive trade practice listed in section 6-1-105 or part 7 of this article, the attorney general or district attorney may apply for and obtain, in an appropriate district court of this state, a temporary restraining order or injunction, or both, pursuant to the Colorado rules of civil procedure, prohibiting such person from continuing such practices, or engaging therein, or doing any act in furtherance thereof. The court may make such orders or judgments as may be necessary to prevent the use or employment by such person of any such deceptive trade practice or which may be necessary to completely compensate or restore to the original position of any person injured by means of any such practice or to prevent any unjust enrichment by any person through the use or employment of any deceptive trade practice.

§§ 6-1-110(1)

PRAYER FOR RELIEF

WHEREFORE, THE PEOPLE OF THE STATE OF COLORADO, respectfully request 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, deceptive or misleading conduct;
- B. An Order pursuant to C.R.S. § 6-1-112(1)(a) for civil penalties payable to the

general fund of this state of not more than two thousand dollars for each such violation of any provision of the CCPA with respect to each consumer or transaction involved not to exceed five hundred thousand dollars for any related series of violations;

C. Ordering Defendant to pay all reasonable attorneys fees costs for the prosecution and investigation of this action, as provided by § 6-1-113(4) of the CCPA; and

D. An order pursuant to C.R.S. § 6-1-112(1)(c) for civil penalties payable to the general fund of this state of not more than ten thousand dollars for each violation of any provision of the of the CCPA with respect to each elderly person;

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

DATED: November 15, 2012.

Respectfully submitted,

JOHN W. SUTHERS
Attorney General

/s/ Jay B. Simonson

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