

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

THE STATE OF IOWA, ex rel.)
THOMAS J. MILLER, ATTORNEY GENERAL)
99AG25112)
Plaintiff,)
v.)
GLAXOSMITHKINE LLC,)
Defendant.)

EQUITY NO. CE 73033

PETITION

FILED
POLK COUNTY, IA.
12 NOV 15 AM 8:28
CLERK DISTRICT COURT

Plaintiff, the State of Iowa ex rel. Attorney General Thomas J. Miller, by Special Assistant Attorney General William L. Brauch, brings this action against Defendant GlaxoSmithKline, LLC, for violating the Iowa Consumer Fraud Act, Iowa Code section 714.16, as follows:

JURISDICTION AND VENUE

1. This action is brought by the State of Iowa ex rel. Attorney General Thomas J. Miller, pursuant to the provisions of the Iowa Consumer Fraud Act, Iowa Code section 714.16.
2. This Court has jurisdiction over the Defendant pursuant to Iowa Code section 714.16, because the Defendant transacted business within the State of Iowa at all times relevant to this Petition.
3. Venue for this action properly lies in Polk County, Iowa, pursuant to Iowa Code section 714.16 (10), because the Defendant transacts business in Polk County, Iowa and/or some of the transactions out of which this action arose occurred in Polk County, Iowa.

PARTIES

4. Plaintiff is the State of Iowa ex rel. Attorney General Thomas J. Miller.
5. The Attorney General of Iowa is charged, inter alia, with the enforcement of the Consumer Fraud Act, Iowa Code section 714.16(7).
6. Defendant GlaxoSmithKline LLC, ("GSK") is a Delaware corporation with its principal place of business at 1 Franklin Plaza, Philadelphia, Pennsylvania.
7. Defendant GSK transacts business in the State of Iowa and nationwide by developing, manufacturing, promoting, selling, and distributing prescription drugs.

ADVERTISING AND SELLING MERCHANDISE IN IOWA

8. Iowa Code § 714.16(2)(a) applies to the sale, lease or advertisement of merchandise in the State of Iowa. Defendant was at all times relevant hereto, engaged in the advertisement and sale of merchandise in the State of Iowa to wit: advertising, soliciting, offering for sale and selling prescription drugs, including but not limited to the prescription drug Avandia.

ALLEGATIONS RELATING TO DEFENDANT'S MARKETING OF AVANDIA

BACKGROUND INFORMATION

The Basic Medicine of Diabetes

9. Approximately 18.8 million people in the United States are diagnosed with diabetes.
10. Approximately 90-95% of adults diagnosed with diabetes have type 2 diabetes.
11. Type 2 diabetes results from the body's failure to produce enough insulin and/or the inability to use insulin properly.
12. Insulin is a hormone needed to convert sugar and other food into energy.

13. Without insulin, sugar builds up in the bloodstream and cells are starved for energy. This can cause tissue breakdown, which can lead to numerous health dangers.

14. Diabetes is the seventh leading cause of death in the United States.

15. Diabetes is a major cause of heart disease and stroke.

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

Treatment of Diabetes

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

18. 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.

19. 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.

20. As diabetes progresses, patients will need additional agents and/or insulin therapy.

21. 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 body to use insulin more efficiently and effectively.

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

23. Avandamet tablets combine Avandia with metformin.

24. Avandaryl tablets combine Avandia with a sulfonylurea.

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

GSK'S Marketing of Avandia

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

27. GSK misrepresented that Avandia had a positive cholesterol profile when in fact GSK did not possess competent and reliable scientific evidence to substantiate the claim. GSK misrepresented that Avandia had cardiovascular benefits when in fact, it does not, and it may increase cardiovascular risks.

APPLICABLE STATUTES

28. Iowa Code section 714.16(2)(a), states in relevant part as follows:

The act, use or employment by a person of an unfair practice, deception, fraud, false pretense, false promise, or misrepresentation, or the concealment, suppression, or omission of a material fact with intent that others rely upon the concealment, suppression, or omission, in connection with the lease, sale, or advertisement of any merchandise or the solicitation of contributions for charitable purposes, whether or not a person has in fact been misled, deceived, or damaged, is an unlawful practice.

29. As used in the Consumer Fraud Act, the term "person" includes:

any natural person or the person's legal representative, partnership, corporation (domestic and foreign), company, trust, business entity or association, and any agent, employee, salesperson, partner, officer, director, member, stockholder, associate, trustee or cestui que trust thereof.

Iowa Code section 714.16(1)(j).

30. Neither all nor any part of the application for injunctive relief herein has been previously been presented to or refused by any court or justice. Iowa R. Civ. P. 1.1504.

31. In an action by the state, no security shall be required of the state. Iowa R. Civ. P. 1.207.

VIOLATIONS OF LAW

IOWA CONSUMER FRAUD ACT

32. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 31.

33. Defendant, in the course of marketing, promoting, selling, and distributing the prescription drug Avandia engaged in unfair, deceptive, or misleading practices in connection with the sale of merchandise, and therefore, engaged in practices that are unlawful under Iowa Code section 714.16(2)(a) by making written and oral representations about Avandia when Defendant knew the written and oral representations were not true.

34. Defendant, in the course of marketing, promoting, selling, and distributing the prescription drug Avandia engaged in unfair, deceptive, or misleading practices in connection with the sale of merchandise, and therefore, engaged in practices that are unlawful under Iowa Code section 714.16(2)(a) by misrepresenting Avandia had the benefit of reducing cardiovascular risks when, in fact, it may increase cardiovascular risks.

REMEDIES

35. Iowa Code section 714.16(7), in relevant part, provides:

If it appears to the attorney general that a person has engaged in, is engaging in, or is about to engage in a practice declared to be unlawful by this section, the attorney general may seek and obtain in an action in a district court a temporary restraining order, preliminary injunction, or permanent injunction prohibiting the person from continuing the practice or engaging in the practice or doing an act in furtherance of the practice. The court may make orders or judgments as necessary to prevent the use or employment by a person of any prohibited practices, or which are necessary to restore to any person in interest any moneys or property, real or personal, which have been acquired by means of a practice declared to be unlawful by this section, including the appointment of a receiver in cases of substantial and willful violation of this section.

. In addition to the remedies otherwise provided for in this subsection, the attorney general may request and the court may impose a civil penalty not to exceed forty thousand dollars per violation against a person found by the court to have engaged in a method, act, or practice declared unlawful under this section; provided, however, a course of conduct shall not be considered to be separate and different violations merely because the conduct is repeated to more than one person. In addition, on the motion of the attorney general or its own motion, the court may impose a civil penalty of not more than five thousand dollars for each day of intentional violation of a temporary restraining order, preliminary injunction, or permanent injunction issued under authority of this section. A penalty imposed pursuant to this subsection is in addition to any penalty imposed pursuant to section 537.6113. Civil penalties ordered pursuant to this subsection shall be paid to the treasurer of state to be deposited in the general fund of the state.

36. Iowa Code section 714.16(10) provides:

In an action brought under this section, the attorney general is entitled to recover costs of the court action and any investigation which may have been conducted, including reasonable attorneys' fees, for the use of this state.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this 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, as provided by Iowa Code section 714.16(7);
- B. Ordering Defendant to pay civil penalties of up to \$40,000 for each violation of the Consumer Fraud Act, as provided by Iowa Code section 714.16(7);
- C. Ordering Defendant to pay all costs, court costs, and attorney fees for the prosecution and investigation of this action, as provided by Iowa Code section 714.16(11); and,
- D. Granting such other and further relief as the Court deems equitable and proper.

Respectfully submitted,

STATE OF IOWA ex rel.
ATTORNEY GENERAL
THOMAS J. MILLER



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