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ATTORNEY GENERAL OF NEW JERSEY  
Division of Law  
124 Halsey Street - 5<sup>th</sup> Floor  
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Attorney for Plaintiffs

By: Alina Wells  
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SUPERIOR COURT OF NEW JERSEY  
CHANCERY DIVISION  
MERCER COUNTY  
DOCKET NO: \_\_\_\_\_

JEFFREY S. CHIESA, Attorney General of the  
State of New Jersey, and ERIC T. KANEFSKY,  
Acting Director of the New Jersey Division of  
Consumer Affairs,

Plaintiffs,

v.

GLAXOSMITHKLINE LLC,

Defendant.

Civil Action

**COMPLAINT**

1. Plaintiffs Jeffrey S. Chiesa, Attorney General of the State of New Jersey (“Attorney General”), with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, and Eric T. Kanefsky, Acting Director of the New Jersey Division of Consumer Affairs (“Director”), with offices located at 124 Halsey Street, Seventh Floor, Newark, New Jersey (collectively, “Plaintiffs”) bring this action against GlaxoSmithKline LLC (“Defendant”) for violating the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. (“CFA”), as follows:

## JURISDICTION AND VENUE

2. This action is brought for and on behalf of the People of the State of New Jersey, by the Attorney General and Director, pursuant to the provisions of the CFA, N.J.S.A. 56:8-1 et seq.

3. This Court has jurisdiction over the Defendant pursuant to the CFA, N.J.S.A. 56:8-1 et seq., because the Defendant has transacted business within the State of New Jersey (“New Jersey”) at all times relevant to this Complaint.

4. Venue for this action properly lies in Mercer County, pursuant to R. 4:3-2(b), because Defendant transacts business in, or some of the transactions upon which this action is based occurred, in Mercer County.

## PARTIES

5. The Attorney General is charged with enforcing the CFA. The Director is charged with administering the CFA on behalf of the Attorney General. By this action, the Attorney General and Director seek injunctive and other relief for violations of the CFA, pursuant to N.J.S.A. 56:8-8, 8-11, 8-13 and 8-19.

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

## ADVERTISEMENT AND SALE OF MERCHANDISE

7. The CFA, N.J.S.A. 56:8-1(a), defines “advertisement” as:

. . . the attempt directly or indirectly by publication, dissemination, solicitation, indorsement or circulation or in any other way to induce directly or indirectly any person to enter or not enter into any obligation or acquire any title or interest in any merchandise or to increase the consumption thereof . . .

8. The CFA, N.J.S.A. 56:8-1(c), defines “merchandise” as “any objects, wares, goods, commodities, services or anything offered, directly or indirectly to the public for sale.”

9. The CFA, N.J.S.A. 56:8-1(e), defines “sale” as “any sale, rental or distribution, offer for sale, rental or distribution or attempt directly or indirectly to sell, rent or distribute.”

10. The CFA, N.J.S.A. 56:8-1(d) defines "person" as “any natural person or his legal representative, partnership, corporation, company, trust, business entity or association, and any agent, employee, salesman, partner, officer, director, member, stockholder, associate, trustee or *cestuis que trustent* thereof.”

11. Defendant was at all times relative hereto, engaged in the advertisement and sale of merchandise in New Jersey, to wit: selling, promoting and distributing prescription drugs.

**ALLEGATIONS RELATING TO  
DEFENDANT’S MARKETING OF AVANDIA**

**I. BACKGROUND INFORMATION**

**A. The Basic Medicine of Diabetes**

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

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

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

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

16. 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.

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

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

**B. Treatment of Diabetes**

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

20. 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.

21. 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.

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

23. 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.

24. 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.

25. Avandamet tablets combine Avandia with metformin.

26. Avandaryl tablets combine Avandia with a sulfonylurea.

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

## **II. DEFENDANT'S MARKETING OF AVANDIA**

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

29. 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 may increase cardiovascular risks.

### **VIOLATIONS OF LAW**

#### **COUNT I**

#### **VIOLATION OF THE CFA BY DEFENDANT (UNCONSCIONABLE COMMERCIAL PRACTICES AND DECEPTION)**

30. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 29 as if more fully set forth herein.

31. The CFA, N.J.S.A. 56:8-2, prohibits:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing[] concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of merchandise. . .

32. Defendant, in the course of marketing, promoting, selling, and distributing prescription drugs in New Jersey, has engaged in the advertisement or sale of merchandise through unconscionable commercial practices and deception in violation of the CFA, specifically by making written and oral representations about Avandia when Defendant knew the written and oral representations were not true.

## COUNT II

### **VIOLATION OF THE CFA BY DEFENDANT (FALSE PROMISES AND/OR MISREPRESENTATIONS)**

33. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 32 as if more fully set forth herein.

34. Defendant, in the course of engaging in the promotion, sales, and distribution of prescription drugs in New Jersey, has engaged in the advertisement and/or sale of merchandise through false promises and/or misrepresentations in violation of the CFA, specifically by representing that Avandia had the benefit of reducing cardiovascular risks when, in fact, it does not and may instead increase cardiovascular risks.

### REMEDIES

35. N.J.S.A. 56:8-8, provides, in relevant part:

Whenever it shall appear to the Attorney General that a person has engaged in, is engaging in or is about to engage in any practice declared to be unlawful by this act he may seek and obtain in a summary action in the Superior Court an injunction prohibiting such person from continuing such practices or engaging therein or doing any acts in furtherance thereof or an order appointing a receiver, or both. [...] The court may make such orders or judgments as may be necessary to prevent the use or employment by a person of any prohibited practices, or which may be necessary to restore to any person in interest any moneys or property, real or personal which may have been acquired by means of any practice herein declared to be unlawful.

36. N.J.S.A. 56:8-13 provides, in pertinent part:

Any person who violates any of the provisions of the act to which this act is a supplement shall, in addition to any other penalty provided by law, be liable to a penalty of not more than \$10,000 for the first offense and not more than \$20,000 for the second and each subsequent offense.

37. N.J.S.A. 56:8-11 provides that “[i]n any action or proceeding brought under the

provisions of this act, the Attorney General shall be entitled to recover costs for the use of the State.”

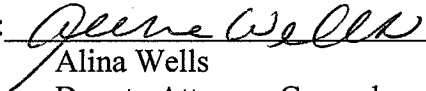
38. N.J.S.A. 56:8-19 further provides that “[i]n all actions under this section, including those brought by the Attorney General, the court shall also award reasonable attorneys’ fees, filing fees and reasonable costs of suit.”

### **PRAYER FOR RELIEF**

WHEREFORE, based upon the following allegations, Plaintiffs respectfully request that the Court enter judgment against Defendant:

- (a) Finding that the acts and omissions of Defendant constitute unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 et seq.;
- (b) Permanently enjoining and restraining 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 deceptive practices in the promotion and marketing of its pharmaceutical products in violation of the CFA, N.J.S.A. 56:8-1 et seq., including, but not limited to, the acts and practices alleged in this Complaint;
- (c) Directing the assessment of restitution amounts against Defendant to restore to any affected person, whether or not named in this Complaint, any money or real or personal property acquired by means of any alleged practice herein to be unlawful and found to be unlawful, as authorized by the CFA, N.J.S.A. 56:8-8;
- (d) Assessing the maximum statutory civil penalties against Defendant for each and every violation of the CFA, in accordance with the CFA, N.J.S.A. 56:8-13;
- (e) Directing the assessment of costs and fees, including attorneys’ fees, against Defendant for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56:8-11 and N.J.S.A. 56:8-19; and
- (f) Granting such other relief as the interests of justice may require.

JEFFREY S. CHIESA  
ATTORNEY GENERAL OF NEW JERSEY  
Attorney for Plaintiffs

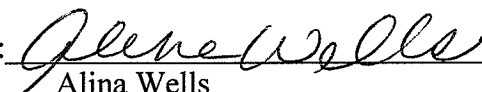
By:   
Alina Wells  
Deputy Attorney General  
Consumer Fraud Prosecution Section

Dated: November 15, 2012  
Newark, New Jersey

**RULE 4:5-1 CERTIFICATION**

I certify, to the best of my information and belief, that the matter in this action involving the aforementioned violations of the CFA, N.J.S.A. 56:8-1 et seq., is not the subject of any other action pending in any other court of this State. I am aware that private actions have been brought against the Defendant, but have no direct information that any such actions involve consumer fraud allegations. I further certify that the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated. I certify that there is no other party who should be joined in this action at this time.

JEFFREY S. CHIESA  
ATTORNEY GENERAL OF NEW JERSEY  
Attorney for Plaintiffs

By:   
Alina Wells  
Deputy Attorney General  
Consumer Fraud Prosecution Section

Dated: November 15, 2012  
Newark, New Jersey



**RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE**

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with Rule 1:38-7(b).

JEFFREY S. CHIESA  
ATTORNEY GENERAL OF NEW JERSEY  
Attorney for Plaintiffs

By: *Alina Wells*  
Alina Wells  
Deputy Attorney General  
Consumer Fraud Prosecution Section

Dated: November 15, 2012  
Newark, New Jersey

**DESIGNATION OF TRIAL COUNSEL**

Pursuant to R. 4:25-4, Deputy Attorney General Alina Wells is hereby designated as trial counsel for the Plaintiffs in this action.

JEFFREY S. CHIESA  
ATTORNEY GENERAL OF NEW JERSEY  
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By: *Alina Wells*  
Alina Wells  
Deputy Attorney General  
Consumer Fraud Prosecution Section

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