IN THE IOWA DISTRICT COURT FOR POLK COUNTY

THE STATE OF IOWA, ex rel. THOMAS J. MILLER, ATTORNEY GENERAL 99AG25112	)	
Plaintiff,	)	Equity No. CE 73033
v.	)	
GLAXOSMITHKLINE LLC,	)	**CONSENT JUDGMENT**
Defendant.	)	

FILED
POLK COUNTY, IA.
12 NOV 15 AM 8:46
CLERK DISTRICT COURT

Plaintiff, the State of Iowa ex rel. Attorney General Thomas J. Miller, has filed a Petition for a permanent injunction and other relief in this matter pursuant to the Iowa Consumer Fraud Act, Iowa Code § 714.16 alleging that Defendant GlaxoSmithKline LLC (hereinafter "GlaxoSmithKline") committed violations of the aforementioned Act. Plaintiff, by its counsel, Special Assistant Attorney General William L. Brauch, and GlaxoSmithKline, by its counsel, have agreed to the entry of this Consent Judgment ("Consent Judgment") by the Court without trial or adjudication of any issue of fact or law, and without finding or admission of wrongdoing or liability of any kind.

IT IS HEREBY ORDERED THAT:

I. FINDINGS

A. This Court has jurisdiction over the subject matter of this lawsuit and over all Parties.

B. The terms of this Consent Judgment shall be governed by the laws of the State of Iowa.

C. Entry of this Consent Judgment is in the public interest and reflects a negotiated

agreement among the Parties.

D. GlaxoSmithKline, at all times relevant hereto, engaged in the advertisement and sale of merchandise, within the meaning of the Iowa Consumer Fraud Act, in the State of Iowa including, but not limited to, Polk County.

E. The Attorneys General conducted an investigation regarding the Covered Conduct. The Parties have agreed to resolve all issues raised by and concerns related to the Covered Conduct under the Iowa Consumer Fraud Act by entering into this Consent Judgment.

F. This Consent Judgment reflects a negotiated agreement entered into by the Parties as their own free and voluntary act, and with full knowledge and understanding of the nature of the proceedings and the obligations and duties imposed by this Consent Judgment. Defendant is entering into this Consent Judgment solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Defendant expressly denies. Through this Consent Judgment, Defendant does not admit any violation of law, and does not admit any wrongdoing that was or could have been alleged by any of the signatory Attorneys General before the date of the Consent Judgment. No part of this Consent Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Defendant. This Consent Judgment does not constitute an admission by Defendant that the Covered Conduct violated or could violate the State Consumer Protection Laws. It is the intent of the Parties that this Consent Judgment shall not be admissible or binding in any other matter, including, but not limited to, any investigation or litigation, other than in connection with the enforcement of this Consent Judgment. No part of this Consent Judgment shall create a private cause of action or convert any right to any third party for

violation of any federal or state statute or law, except that the Attorney General may file an action to enforce the terms of this Consent Judgment. Nothing contained herein prevents or prohibits the use of this Consent Judgment for purposes of enforcement by the Iowa Attorney General.

G. This Consent Judgment does not create a waiver or limit Defendant's legal rights, remedies, or defenses in any other action by the Iowa Attorney General, and does not waive or limit Defendant's right to defend itself from, or make arguments in, any other matter, claim, or suit, including, but not limited to, any investigation or litigation relating to the existence, subject matter, or terms of this Consent Judgment. Nothing in this Consent Judgment shall waive, release, or otherwise affect any claims, defenses, or other positions Defendant may assert in connection with any investigations, claims, or other matters the Attorneys General are not releasing hereunder. Notwithstanding the foregoing, the Iowa Attorney General may file an action to enforce the terms of this Consent Judgment.

H. This Consent Judgment does not constitute an approval by the Attorneys General of Defendant's business practices, and Defendant shall make no representation or claim to the contrary.

I. This Consent Judgment sets forth the entire agreement between the Parties hereto and supersedes all prior agreements or understandings, whether written or oral, between the Parties and/or their respective counsel, with respect to the Covered Conduct.

J. This Court retains jurisdiction over this Consent Judgment and the Parties hereto for the purpose of enforcing and modifying this Consent Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

K. This Consent Judgment may be executed in counterparts, each of which shall be deemed to constitute an original counterpart hereof, and all of which shall together constitute one and the same Consent Judgment. One or more counterparts of this Consent Judgment may be delivered by facsimile or electronic transmission with the intent that it, or they, shall constitute an original counterpart hereof.

L. This Consent Judgment relates solely to the Covered Conduct.

M. This Judgment (or any portion thereof) shall in no way be construed to prohibit Defendant from making representations with respect to any GSK Diabetes Product that are permitted under Federal law or labeling for the drug under the most current draft or final standard promulgated by the FDA or the most current draft or final FDA Guidance for Industry, or permitted or required under any Investigational New Drug Application, New Drug Application, Supplemental New Drug Application, or Abbreviated New Drug Application approved by FDA, so long as the representation, taken in its entirety, is not false, misleading or deceptive.

N. Nothing in this Judgment shall require Defendant to:

(a) take any action that is prohibited by the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA") or any regulation promulgated thereunder, or by FDA; or

(b) fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA;

or shall preclude Defendant from providing Health Care Economic Information to a formulary committee or similar entity or its members in the course of the committee or entity carrying out its responsibilities for the selection of drugs for managed care or other similar organization pursuant to the standards of FDAMA Section 114, if the information directly relates to an

approved indication of a GSK Diabetes Product, and if based on competent and reliable scientific evidence.

II. DEFINITIONS

The following definitions shall be used in construing this Consent Judgment:

A. "Applicable Clinical Trials" shall mean those clinical trials required by the FDA Amendments Act of 2007 (Public Law No. 110-85).

B. "Attorneys General" shall mean the Attorneys General of the Multistate Working Group.

C. "Avandia" shall mean and include all formulations of rosiglitazone, a diabetes drug in the class of thiazolidinediones ("TZDs"), that GSK sells or sold under the brand name Avandia, Avandamet, and Avandaryl.

D. "Covered Conduct" shall mean Promotional practices and dissemination of information by GSK regarding Avandia in the United States.

E. "Defendant" shall mean GlaxoSmithKline LLC.

F. "Effective Date" shall mean the date on which a copy of this Consent Judgment, duly executed by Defendant and by the signatory Attorney General, is approved by and becomes a Judgment of the Court.

G. "GlaxoSmithKline LLC" or "GSK" shall mean GlaxoSmithKline LLC, all of its officers, directors, employees, subsidiaries, divisions, predecessors, successors, assignees, and transferees.

H. "GSK Diabetes Product" shall mean any pharmaceutical product approved by the Food and Drug Administration for the improvement of glycemic control for patients with Type 2 diabetes and that GSK Promotes, or for which it directs the Promotion.

I. "Health Care Economic Information" shall mean data and other information relating to the inputs and outcomes of health care therapies and services, including, but not limited to, the price, cost-effectiveness, and quality of life implications of any GSK Diabetes Product.

J. "Multistate Working Group" shall mean the Attorneys General and their staff representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Hawaii,[1] Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Jersey, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, and Wisconsin.

K. "Multistate Executive Committee" shall mean the Attorneys General and their staff representing Arizona, Florida, Illinois, Maryland, Oregon, Pennsylvania, Tennessee, and Texas.

L. "Parties" shall mean the Iowa Attorney General and Defendant.

M. "Promotional," "Promoting" or "Promote" shall mean representations about a GSK Diabetes Product intended to influence sales of that product, including attempts to influence prescribing practices and utilization of a GSK Diabetes Product.

N. "Promotional Materials" shall mean any item used to Promote any GSK Diabetes Product.

[1] Hawaii is being represented on this matter by its Office of Consumer Protection, an agency which is not part of the state Attorney General's Office, but which is statutorily authorized to undertake consumer protection functions, including legal representation of the State of Hawaii. For simplicity, the entire group will be referred to as the "Attorneys General," and such designation, as it includes Hawaii, refers to the Executive Director of the State of Hawaii Office of Consumer Protection.

III. COMPLIANCE PROVISIONS

Promotional Activities

A. Defendant shall not make, or cause to be made, any written or oral claim that is false, misleading, or deceptive about any GSK Diabetes Product.

B. Defendant shall not represent that any GSK Diabetes Product has any sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

The following subsections shall be effective for a period of the greater of either: eight years from the Effective Date of this Judgment, or five years from approval by the FDA of a GSK Diabetes Product other than Avandia.

C. Defendant shall only Promote GSK Diabetes Products for uses permitted under the FDA-approved labeling or the FDCA.

D. Defendant shall not represent in a promotional context that an investigational new GSK Diabetes Product is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information in non-promotional settings concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

E. Defendant shall not make in a promotional context a representation or suggestion, not approved or permitted for use in the labeling or under the FDCA, that a GSK Diabetes Product is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been

demonstrated by substantial evidence, or substantial clinical experience (as described in paragraphs (e)(4)(ii)(*b*) and (*c*) of 21 C.F.R. § 202.1), whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations, or other references.

F. Defendant shall not Promote any GSK Diabetes Product by use of Promotional Materials that:

1. contain a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience;
2. contain favorable information or opinions about a drug previously regarded as valid but which have been rendered invalid by contrary and more credible recent information, or contain literature references or quotations that are significantly more favorable to the drug than has been demonstrated by substantial evidence or substantial clinical experience;
3. contain a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated;
4. contain favorable data or conclusions from nonclinical studies of a drug, such as

in laboratory animals or in vitro, in a way that suggests they have clinical significance when in fact no such clinical significance has been demonstrated;

5. use erroneously a statistical finding of "no significant difference" to claim clinical equivalence or to deny or conceal the potential existence of a real clinical difference;

6. present required information relating to side effects or contraindications by means of a general term for a group in place of disclosing each specific side effect and contraindication unless the use of such general term conforms to the provisions of paragraph (e)(3)(iii) of 21 C.F.R. § 202.1;

7. present information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does; or

8. use statistics on numbers of patients or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

G. When presenting information about a clinical study regarding GSK Diabetes Products in any Promotional Materials, Defendant shall not do any of the following for information that may be material to a health care provider prescribing decision:

1. present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;

2. use the concept of statistical significance to support a claim that has not been

demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results; or

3. use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations.

Clinical Research

The following subsections shall be effective for eight years from the Effective Date of this Judgment.

H. Defendant shall report research in an accurate, objective and balanced manner as follows and as required by applicable law:

1. To the extent permitted by the National Library of Medicine and as required by the FDA Amendments Act of 2007 (Public Law No. 110-85), Defendant shall register GSK-sponsored Applicable Clinical Trials beginning after the Effective Date with the applicable registry and submit results of GSK-sponsored Applicable Clinical Trials completed after the Effective Date to the registry and results data bank as required by the FDA Amendments Act and any accompanying regulations that may be promulgated pursuant to that Act.

I. When submitting a manuscript on the results of a clinical study regarding any GSK Diabetes Product for publication, Defendant shall:

1. Adhere to the ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications, including authorship criteria, unless the applicable journal or congress to which the

publication is submitted has more stringent requirements, in which case the journal or congress criteria for authorship will be followed; and

2. Acknowledge Defendant's role as a funding source of the study which is the subject of the manuscript.

J. For any GSK Diabetes Product, Defendant shall also post on GSK's clinical study registry any observational studies or meta-analyses conducted by GSK that are designed to inform the effective, safe, and/or appropriate use of any GSK Diabetes Product.

K. Summaries of the results of GSK-sponsored interventional clinical trials of medicinal products that are approved for the improvement of glycemic control in Type 2 diabetics will be posted on a publicly available registry within 8 months of the study primary completion date. Such summaries will be posted on either NIH's register at www.clinicaltrials.gov or on GSK's clinical study register with information fields consistent with the NIH register.

IV. DISBURSEMENT OF PAYMENTS: PAYMENT TO THE STATES

A. Within 30 days of the Effective Date of this Consent Judgment, Defendant shall pay $90 million to be divided and paid by Defendant directly to each Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee.[2] Said payment shall be used by the Attorneys General for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, consumer education or litigation or local consumer aid or revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted

[2] The State of Iowa's share is $1,579,490.72.

by state law, at the sole discretion of each Attorney General. The Parties acknowledge that the payment described herein is not a fine or penalty, or payment in lieu thereof.

V. REPRESENTATIONS AND WARRANTIES

A. GlaxoSmithKline acknowledges that it is a proper party to this Consent Judgment. GlaxoSmithKline further warrants and represents that the individual signing this Consent Judgment on behalf of GlaxoSmithKline is doing so in his or her official capacity and is fully authorized by GlaxoSmithKline to enter into this Consent Judgment and to legally bind GlaxoSmithKline to all of the terms and conditions of the Consent Judgment.

B. The Office of the Iowa Attorney General warrants and represents that it is signing this Consent Judgment in its official capacity, and that it is fully authorized to enter into this Judgment, including, but not limited to, the authority to grant the release contained in Section VI of this Consent Judgment, and to legally bind the State to all of the terms and conditions of this Consent Judgment.

VI. RELEASE

A. By execution of this Consent Judgment, the State of Iowa releases and forever discharges Defendant and all of its past and present officers, directors, shareholders, employees, parents, subsidiaries, divisions, predecessors, successors, assignees, and transferees (collectively, the "Released Parties"), from the following: all civil claims, causes of action, parens patriae claims, damages, restitution, fines, costs, attorneys' fees, remedies and/or penalties that were or could have been asserted against the Released Parties by the Attorney General under the Iowa Consumer Fraud Act or any amendments thereto, or by common law claims other than claims asserted or that could be asserted under VI.B concerning unfair, deceptive, or fraudulent trade

practices resulting from the Covered Conduct, up to and including the Effective Date of this Consent Judgment (collectively, the "Released Claims").

B. Notwithstanding any term of this Consent Judgment, specifically reserved and excluded from the Released Claims as to any entity or person, including Released Parties, are any and all of the following:

1. Any criminal liability that any person or entity, including Released Parties, has or may have to the State of Iowa.

2. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Iowa under any statute, regulation, or rule not expressly covered by the release in Section VI.A including, but not limited to, any and all of the following claims:

   a. State or federal antitrust violations;

   b. Reporting practices, including "best price," "average wholesale price" or "wholesale acquisition cost";

   c. Medicaid violations, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to the State of Iowa's Medicaid program;

   d. State false claims violations; and

   e. Claims to enforce the terms and conditions of this Consent Judgment.

3. Actions of state program payors of the State of Iowa arising from the Covered Conduct, except for the release of civil penalties under the State of Iowa's above-cited state consumer protection law.

4. Any claims individual consumers have or may have under the State of Iowa's consumer protection laws against any person or entity, including Released Parties.

VII. CONFLICTS

A. If, subsequent to the Effective Date of this Consent Judgment, the federal government or any state, or any federal or state agency, enacts or promulgates legislation or regulations with respect to matters governed by this Consent Judgment that creates a conflict with any provision of the Consent Judgment and Defendant intends to comply with the newly enacted legislation or regulation, Defendant shall notify the Attorneys General (or the Attorney General of the affected State) of the same. If the Attorney General agrees, the Attorney General shall consent to a modification of such provision of the Consent Judgment to the extent necessary to eliminate such conflict. If the Attorney General disagrees and the Parties are not able to resolve the disagreement, Defendant shall seek a modification from an appropriate court of any provision of this Consent Judgment that presents a conflict with any such federal or state law or regulation. Changes in federal or state laws or regulations, with respect to the matters governed by this Consent Judgment, shall not be deemed to create a conflict with a provision of this Consent Judgment unless Defendant cannot reasonably comply with both such law or regulation and the applicable provision of this Consent Judgment.

VIII. DISPUTE RESOLUTION

A. For the purposes of resolving disputes with respect to compliance with this Consent Judgment, should any of the signatory Attorneys General have a reason to believe that Defendant has violated a provision of this Consent Judgment subsequent to the Effective Date, then such Attorney General shall notify Defendant in writing of the specific objection, identify

with particularity the provisions of this Consent Judgment that the practice appears to violate, and give Defendant 30 days to respond to the notification.

B. Upon receipt of written notice from any of the Attorneys General, Defendant shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why Defendant believes it is in compliance with the Consent Judgment or a detailed explanation of how the alleged violation occurred and statement explaining how and when Defendant intends to remedy the alleged violation.

C. Except as set forth in Sections VIII.E and F below, the Attorney General may not take any action during the 30-day response period. Nothing shall prevent the Attorney General from agreeing in writing to provide Defendant with additional time beyond the 30 days to respond to the notice.

D. The Attorney General may not take any action during which a modification request is pending before a court pursuant to Section VII.A, except as provided for in Sections VIII.E and F below.

E. Nothing in this Consent Judgment shall be interpreted to limit the Attorney General's Civil Investigative Demand or investigative subpoena authority.

F. The Attorney General may assert any claim that Defendant has violated this Consent Judgment in a separate civil action to enforce compliance with this Consent Judgment, or may seek any other relief afforded by law, but only after providing Defendant an opportunity to respond to the notification and to remedy the alleged violation within the 30-day response period as described above, or within any other period as agreed to by GSK and the Attorney General; provided, however, that the Attorney General may take any action if the Attorney

General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

IX. COMPLIANCE WITH ALL LAWS

A. Except as expressly provided in this Consent Judgment, nothing in this Consent Judgment shall be construed as:

1. Relieving Defendant of its obligation to comply with all applicable state laws, regulations, or rules, or granting permission to engage in any acts or practices prohibited by any law, regulation, or rule; or
2. Limiting or expanding in any way any right any state represented by the Multistate Working Group may otherwise have to enforce applicable state law or obtain information, documents, or testimony from Defendant pursuant to any applicable state law, regulation, or rule, or any right Defendant may otherwise have to oppose any subpoena, civil investigative demand, motion, or other procedure issued, served, filed, or otherwise employed by the State pursuant to any such state law, regulation, or rule.

X. GENERAL PROVISIONS

A. Nothing in this Consent Judgment is intended to modify the Consent Judgment, effective June 23, 2011, between the State of Iowa and GlaxoSmithKline LLC and SB Pharmco Puerto Rico, Inc.

B. Nothing in this Consent Judgment is intended to modify the Settlement Agreement, effective June 19, 2012, between the State of Iowa and GlaxoSmithKline LLC.

C. Nothing will prevent the Attorney General from agreeing in writing to provide Defendant with additional time to perform any act required by the Consent Judgment. The

Attorney General shall not unreasonably withhold the Attorney General's consent to the request for additional time.

D. All notices under this Consent Judgment shall be sent by overnight United States mail. The documents shall be sent to the following addresses:

For GlaxoSmithKline LLC:
Barry H. Boise
Pepper Hamilton LLP
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103

For the Iowa Attorney General:
Director, Consumer Protection Division
1305 E. Walnut Street
Des Moines, IA 50319

E. Defendant shall be responsible for paying all court costs.

IT IS SO ORDERED this 15th day of Nov., 2012.

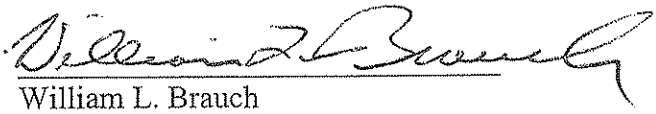
JUDGE, FIFTH JUDICIAL DISTRICT

ELIZA J. OVROM, Judge
Fifth Judicial District of Iowa

Copies served on all parties.
WJB
11-15-12

JOINTLY APPROVED AND
SUBMITTED FOR ENTRY:

FOR PLAINTIFF, STATE OF IOWA ex rel.
ATTORNEY GENERAL THOMAS J. MILLER



William L. Brauch
Special Assistant Attorney General
Director-Consumer Protection Division
1305 E. Walnut Street
Des Moines, IA 50319

FOR GLAXOSMITHKLINE LLC

By: _____ Date: 11/8/2012

William J. Mosher
Company Secretary
GlaxoSmithKline LLC

FOR DEFENDANT GLAXOSMITHKLINE LLC

By: Nina M Gussack Date: 11/12/12

Nina M. Gussack
Barry H. Boise
Pepper Hamilton LLP
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103

Approved as to form:

By: Kerrie M. Murphy Date: Nov. 5, 202

Kerrie M. Murphy
Gonzalez Saggio & Harlan LLP
1501 42nd Street, Suite 465
West Des Moines, IA 50266

Counsel for Defendant GlaxoSmithKline LLC