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LUCAS COUNTY

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COMMON PLEAS COURT  
BERNIE QUILTER  
CLERK OF COURTS

**IN THE COURT OF COMMON PLEAS OF LUCAS COUNTY, OHIO**

STATE OF OHIO, *ex rel.*  
MICHAEL DEWINE,  
ATTORNEY GENERAL

Plaintiff,

v.

GLAXOSMITHKLINE LLC,

Defendant.

CASE NO.: CI0201206326

JUDGE: *Mentros*

**AGREED ENTRY AND  
FINAL JUDGMENT ORDER**

Plaintiff, State of Ohio, acting by and through Attorney General Michael DeWine, has brought this action against GlaxoSmithKline LLC (Defendant) pursuant to the various provisions of Ohio's Consumer Sales Practices Act, R.C. 1345.01 *et seq.* The Parties have consented to the entry of this Agreed Entry and Final Judgment Order (or "Order") for the purposes of settlement only, without any admission by Defendant of wrongdoing or liability, and without trial of any issue of fact or law.

**NOW THEREFORE, IT IS HEREBY ORDERED, ADJUDGED AND DECREED  
AS FOLLOWS:**

**I. FINDINGS**

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

RECEIVED  
ATTORNEY GENERAL OF OHIO

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CONSUMER PROTECTION SECTION  
PUBLIC INSPECTION FILE

B. The terms of this Order shall be governed by the laws of the State of Ohio.

C. Entry of this Order is in the public interest and reflects a negotiated agreement among the Parties.

D. GlaxoSmithKline, at all times relevant hereto, engaged in consumer transactions for purposes that were primarily personal, family or household in nature, within the meanings of R.C. 1345.01(A) and (D), in the State of Ohio, including, but not limited to, Lucas 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 Ohio Consumer Sales Practices Act, R.C. 1345.01 *et seq.*, by entering into this Order.

F. This Order 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 Order. Defendant is entering into this Order 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 Order, 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 Order. No part of this Order, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Defendant. This Order 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 Order 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 Order. No part of this Order 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 an Attorney General may file an action to enforce the terms of this Order. Nothing contained herein prevents or prohibits the use of this Order for purposes of enforcement by the Ohio Attorney General.

G. This Order does not create a waiver or limit Defendant's legal rights, remedies, or defenses in any other action by the Ohio 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 Order. Nothing in this Order 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 Ohio Attorney General may file an action to enforce the terms of this Order.

H. This Order 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 Order 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 Order and the Parties hereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as may be necessary and appropriate.

K. This Order 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 Order. One or more counterparts of this Order may be delivered by facsimile or electronic transmission with the intent that it, or they, shall constitute an original counterpart hereof.

L. This Order 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 Order:

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 Order, 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,<sup>1</sup> 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 Ohio 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.

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<sup>1</sup> 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](http://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 Order, 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. Said payment shall be used by the Attorneys General for attorneys' fees and other costs of investigation and litigation, and/or to be placed in, or applied to, the Consumer Protection Enforcement Fund, consumer education fund, litigation fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted 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. Ohio's designated payment amount under this Order shall be \$3,011,168.96.

## V. REPRESENTATIONS AND WARRANTIES

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

The Attorney General, through his duly authorized representative, warrants and represents that he is signing this Order in his official capacity, and that he is fully authorized by his State to enter into this Judgment, including, but not limited to, the authority to grant the release contained in Section VI of this Order, and to legally bind his State to all of the terms and conditions of this Order.

## VI. RELEASE

A. By execution of this Order, the State of Ohio 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, 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 Ohio Consumer Sales Practices Act, R.C. 1345.01 *et seq.*, 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 Order (collectively, the "Released Claims").

B. Notwithstanding any term of this Order, 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 Ohio;

2. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Ohio, 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 Ohio’s Medicaid program;
- d. State false claims violations; and
- e. Claims to enforce the terms and conditions of this Order.

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

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

## **VII. CONFLICTS**

A. If, subsequent to the Effective Date of this Order, 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 Order that creates a conflict with any provision of the Order 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, he shall consent to a modification of such provision of the Order 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 Order 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 Order, shall not be deemed to create a conflict with a provision of this Order unless Defendant cannot reasonably comply with both such law or regulation and the applicable provision of this Order.

### **VIII. DISPUTE RESOLUTION**

A. For the purposes of resolving disputes with respect to compliance with this Order, should any of the signatory Attorneys General have a reason to believe that Defendant has violated a provision of this Order 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 Order 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 Order 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 Order shall be interpreted to limit Ohio's Civil Investigative Demand or investigative subpoena authority.

F. The Attorney General may assert any claim that Defendant has violated this Order in a separate civil action to enforce compliance with this Order, 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 Order, nothing in this Order 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 Order is intended to modify the Order, effective June 23, 2011, between the State of Ohio and GlaxoSmithKline LLC and SB Pharmco Puerto Rico, Inc.

B. Nothing in this Order is intended to modify the Settlement Agreement, effective June 14, 2012, between the State of Ohio 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 Order. The Attorney General shall not unreasonably withhold his consent to the request for additional time.

D. All notices under this Order 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 State of Ohio:  
Megan E. McNulty, AAG  
Michael S. Ziegler, AAG  
Office of the Ohio Attorney General  
One Government Center, Suite 1340  
Toledo, OH 43604



IT IS SO ORDERED, ADJUDGED AND DECREED.

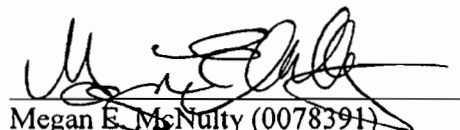
  
JUDGE

**JOINTLY APPROVED AND  
SUBMITTED FOR ENTRY:**

**FOR PLAINTIFF, STATE OF OHIO**

**Michael DeWine  
Attorney General of the State of Ohio**

By:



Megan E. McNulty (0078391)  
Michael S. Ziegler (0042206)  
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Counsel for Plaintiff

Date:

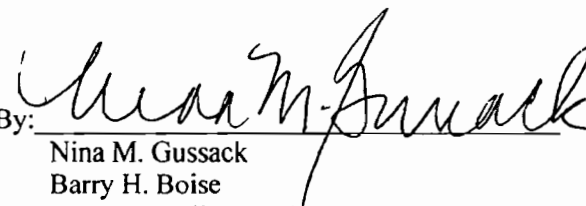
11/14/2012

**DEFENDANT**

**FOR GLAXOSMITHKLINE LLC**

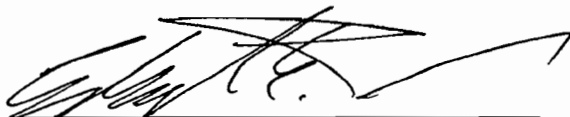
By:  Date: 11/8/2012  
 William J. Mosher  
 Company Secretary  
 GlaxoSmithKline LLC

**FOR DEFENDANT GLAXOSMITHKLINE LLC**

By:  Date: 11/12/12  
 Nina M. Gussack  
 Barry H. Boise  
 Pepper Hamilton LLP  
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Counsel for Defendant

Approved as to form:

By:  Date: 11/6/12

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