



**Rob McKenna**  
**ATTORNEY GENERAL OF WASHINGTON**  
Consumer Protection Division  
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(206) 464-7745

**Consumer Protection Division Background**

The Consumer Protection Division of the Washington State Attorney General's Office (AGO) enforces the state Consumer Protection Act in order to provide a marketplace free from unfair and deceptive practices. Our work is accomplished by educating our constituency, providing informal complaint resolution between businesses and consumers, working for changes through the legislative process, and taking legal action against those that violate the Consumer Protection Act.

The resolution of lawsuits brought by the AGO often will result in the payment of restitution funds to compensate injured consumers. Although we first try to get the money back to consumers directly, at times it is impossible or impractical to do so. In those instances, the court may allow us to indirectly compensate injured consumers by proposing a "next best use" for the money. These funds, called "cy pres" funds, may be used for programs that benefit the class of individual or business consumers who were harmed by the unlawful acts. For example, recoveries from a settlement with a defendant that preyed on senior citizens may be used to benefit the affected class of consumers by supporting a consumer education program specifically targeted to helping senior citizens who live in the geographic area where the unlawful conduct occurred avoid becoming victims of similar scams. A court might also permit a broader use of the funds, such as helping senior citizens generally. The AGO and any beneficiaries of cy pres funds must comply with any restrictions placed on the funds by the court.

**Current Request for Proposals:**

REQUEST FOR APPLICATIONS TO FUND PROJECTS THAT  
BENEFIT WASHINGTON RESIDENTS WHO SUFFER FROM TYPE 2 DIABETES

The specific fund availability and controlling court order language is:

**"Funds shall be distributed for the benefit of Washington residents who have type 2 diabetes...."**

**Deadline:** All applications must be e-mailed or physically received no later than **January 23, 2013, 5:00 p.m. (PDT)**.

**Total Amount:** The total amount available for grants in this process is \$2,177,201.80 which was obtained in a consumer protection case brought by our office, State of Washington v. GlaxoSmithKline LLC. For your information, the court resolution document is attached as **Addendum A**.

## **Funding Focus**

The AGO has resolved many cases in which the court has approved using funds recovered for consumers in a cy pres manner. In the GSK settlement, the court has restricted funds for uses that benefit Washington residents who have type 2 diabetes. Projects should be strengths-based and applications should detail those strengths and your strategies to achieve your project goals. Applications also should describe approaches and methods tailored specifically to the needs of targeted constituents in your service areas.

Although the AGO's selection criteria are dependent upon a number of fluid factors, the most competitive proposals typically will meet a combination of the following criteria: provide direct benefits to constituents, such as goods or services, reach the population of consumers who were harmed by the unfair or deceptive practice, reach underserved populations, offer the greatest public benefit potential per dollar spent, or provide a unique or necessary service to the state.

Proposals can be made for any amount up to the total funding available. Organizations may submit multiple proposals for the available funds. Proposals must be within the funding focus and proposals must be complete as stated in the application form below.

## **Project Period**

Projects should be operational within 12 months of the grant approval date and have established results within 24 months. Organizations receiving funding from the AGO are required to provide the AGO with regular status reports throughout the project period as well as a final report at the conclusion of the project according to the reporting schedule stated in the agreement. See sample agreement attached as **Addendum B**.

## **Projected Proposal Review Period**

The proposal review and selection period will depend on the total number of proposals received for consideration. The estimated approval date for proposals submitted in response to the GSK Request is February 21, 2013.

## **Notice of Proposals Selected for Funding**

The Attorney General's Office will notify applicants in writing of those proposals selected for funding as well as those proposals that were not selected for funding. The notice will be sent to the contact person listed on the proposal form.

## **Grant Uses and Limitations**

This grant cannot provide funding to replace or supplant current funding for operating costs, salaries, benefits for staff, or overhead of your organization. Administrative costs must be limited to 10 percent of your project budget. Large capital investments not directly related to provision of services are considered inappropriate expenses and should not be acquired using grant funds. For state agencies, any receipt of funds is subject to the Budget, Accounting and Reporting Act and we advise any recipients to consult with OFM concerning any budget or reporting requirements.

## **Geographic Reach**

The Office of the Attorney General is interested in receiving proposals that will be executed within Washington state. Where appropriate, applicants are encouraged to seek out collaborators and partnerships around the state to include different agencies or institutions, commitments from other sources of matching funding, supplemental funding, and/or other resources for the purpose of funding projects that achieve statewide scope and reach as many geographic or population areas in Washington state as possible.

### Who Should Apply

501(c)(3) private non-profit organizations, tribal organizations, public or private schools, or local, county or state government entities serving Washington state residents may apply. Organizations previously awarded Consumer Protection Division Cy Pres Grants are eligible to apply for this Grant if they are current with the reporting requirements of their existing Grant Agreement. Organizations must have the capacity to implement their proposed project within the project period stated above.

### How to Apply

Submit the completed GSK Project Proposal Application Form, attached, including all required attachments via email or mail to the addresses stated below. Applications should be no longer than 12 (8.5 x 11inch) pages, not including attachments, and in 12-point font. Additional information may be requested of applicants if determined necessary by the Committee. The Committee reserves the right to reject any and all proposals or to award less than the amount applied for. All decisions of the Attorney General are final.

### **Incomplete or untimely applications will not be considered.**

Applications should be addressed to:

Name	Attorney General's Office Consumer Protection Division Grant Review Committee
Mailing Address	800 5 <sup>th</sup> Avenue, Ste. 2000
City, State, Zip Code	Seattle, WA 98104-3188
E-Mail Address	<a href="mailto:CPGrants@atg.wa.gov">CPGrants@atg.wa.gov</a>
Phone contact	Cynthia Lockridge (206) 464-7786

Attached is a FAQ for your reference. If you have questions after reviewing the FAQ, please direct your questions to Cynthia Lockridge. Consideration of grant applications is a fair and competitive process and as such we can only provide general answers about the application process and/or clarify questions or requests for information required to complete the application. We are not able to assess the merits or competitiveness of individual projects or determine whether or not applicants should submit specific project applications for consideration. All applicants are encouraged to submit complete applications that support the stated funding focus and controlling court order language.

# GSK Project Proposal Application

## Applicant Information

Organization Name

Primary Contact Person

Phone and email

Secondary Contact Person

Phone and email

Mailing Address

City, State, Zip Code

County

Phone

Fax

## Organization Type

- 501 c3 Private Non-Profit  
 Tribal Organization  
 Local, County, or State Government Agency

## Business Information

Tax Identification Number (TIN):

Uniform Business Identifier (UBI):

Does your organization currently receive funding from the AGO or any other state or federal government agency?

Yes  No If yes, list the contracts by project title, contract number, and funding amount:

Is the organization solely owned/operated by a current state employee?

Yes  No If yes, complete the Ethics Certification process at [www.ethics.wa.gov](http://www.ethics.wa.gov).

## How did you hear about available funds?

- AGO Staff. If so, who and when: \_\_\_\_\_  
 Request for Proposal Notice  
 Other: \_\_\_\_\_

## **Project Proposal**

### **Project Title**

**Project Description.** Describe your (a) planning process, (b) outreach strategies, (c) curriculum or approach, (d) activities or services, and (e) staffing levels and experience.

**Describe the relevance of your project to the objectives of the AGO.** Include supporting data

**Describe how your project benefits Washington residents who have type 2 diabetes.**

**Describe the demographics of the consumers you serve.** Please include any relevant statistics and specify regional areas of jurisdiction or service

### **Is the population:**

- Urban
- Suburban
- Rural
- Remote
- Statewide
- Regional (identify region) \_\_\_\_\_

**What is the total number of constituents you expect to serve during this grant cycle?**

### **Is this a:**

- New project
- Expansion of existing project (Eligibility considered on a case by case basis)
- Enhancement of a current project (Eligibility considered on a case by case basis)
- Other: (describe)

## **Project Date**

**What are the *start* and *completion* dates for the project or event during which funds will be used?**

## **Project Budget**

**Provide the following information for your proposed project budget and submit your proposed detailed budget in Excel format. Attach all supporting documents and materials.**

You may request any amount you deem necessary to complete the project, but the actual amount awarded will be determined at the sole discretion of the Attorney General. Your budget should be consistent with the Grant Uses and Limitations provision above. The Committee reserves the right to request a more detailed budget prior to selection as well as the right to restrict any grant award to preclude funding current staff or benefits.

**Salaries:**

**Goods and Services** (i.e., printing, production, consulting, etc.):

**Advertising/Outreach** (directly related to the project):

**Administrative Overhead** (limited to 10% of project total):

**Travel:**

**Total AGO Funding Request:**

**What percentage of your total project budget does your AGO funding request represent?**

**List type and amount of other funding sources for this project (e.g., ABC Foundation, \$2500).**

**Does your organization plan to sustain this project upon completion of this contract? If so, please explain.**

## **Organizational Structure**

**Identify who within your organization will be *directly responsible* for each of the following project components: (a) administration, (b) fiscal, (c) service delivery. Please provide contact information for each person identified.** Additionally, please attach the current resume for the agency/organization director, the lead project staff person, and a current agency/organization/project organizational chart.

**Administration:**

**Fiscal and Budget:**

**Service Delivery:**

## **Community Collaboration**

**Describe how you plan to partner with organizations or agencies in your community on this project.** Attach a letter of support from each organization. Each letter must specify the partnership agreement, and how the partner will support the project.

## **Project Evaluation**

**List two goals you expect to achieve as a result of this project.**

**List two outcomes you expect to see as a result of achieving those goals.**

**Describe how you plan to measure and evaluate the success of your project.** (Include sample of evaluation tools.)

**Have you applied for an similar grant in the past, and if so, to which entity, when, and how much funding did you apply for?**

## Application Submission Checklist

Incomplete applications will **not** be considered. Complete applications must address each question and include the following back-up documentation:

- Completed, signed and dated application.**
- (2) Letters of Support from collaborating organizations**
- Current organizational chart**
- Evidence of tax status**
- Resume for agency director and for lead project staff person**
- Budget detail in Excel**

I certify that I have the authority to submit this proposal, and that the information in this proposal is true and accurate. If my organization is faith-based, I understand that federal and state law prohibit the use of public funds for religious worship, exercise, instruction or support of any religious establishment.

[http://www.acf.hhs.gov/programs/ccb/law/state\\_faith\\_based.htm](http://www.acf.hhs.gov/programs/ccb/law/state_faith_based.htm)

<http://www.leg.wa.gov/LawsAndAgencyRules/constitution.htm>

I understand that my organization will not receive reimbursement for any costs incurred in preparing this proposal. If awarded funding, I understand that our proposal will be incorporated into the final contract.

<b>Printed Name and Title</b>	
<b>Signature (by entering name here, form is electronically signed):</b>	
<b>Date</b>	

1  
2 **RECEIVED**  
3 in King County Superior Court Clerks Office

4 NOV 15 2012

5 Cashier Section  
6 Superior Court Clerk

7  
8 **STATE OF WASHINGTON  
KING COUNTY SUPERIOR COURT**

9 STATE OF WASHINGTON,

NO. 12-2-37029-0

10 Plaintiff,

CONSENT DECREE

11 v.

12 GLAXOSMITHKLINE LLC,

13 Defendant.

14  
15 **JUDGMENT SUMMARY**

16 1.1 Judgment Creditor: State of Washington  
17 1.2 Judgment Debtor: GlaxoSmithKline LLC  
18 1.3 Principal Judgment Amount: \$ 2,199,736.31  
19 1.4 Total Judgment: \$ 2,199,736.31  
20 1.5 Attorney for Judgment Creditor: Elizabeth J. Erwin  
Assistant Attorney General  
21 1.6 Attorney for Judgment Debtor: John W. Phillips  
Phillips Law Group, PLLC

22  
23 **FINAL CONSENT DECREE**

24 Plaintiff, Attorney General of the State of Washington, by and through its Consumer  
25 Protection Division, has filed a Complaint for a permanent injunction and other relief in this  
26 matter pursuant to the Washington State Consumer Protection Act, RCW 19.86 alleging that

1 Defendant GlaxoSmithKline LLC (hereinafter "GlaxoSmithKline") committed violations of  
2 the aforementioned Act. Plaintiff, by its counsel, and GlaxoSmithKline, by its counsel, have  
3 agreed to the entry of this Final Consent Decree ("Consent Decree") by the Court without trial  
4 or adjudication of any issue of fact or law, and without finding or admission of wrongdoing or  
5 liability of any kind.

6 **IT IS HEREBY ORDERED THAT:**

7 **I. FINDINGS**

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

10 B. The terms of this Consent Decree shall be governed by the laws of the State of  
11 Washington.

12 C. Entry of this Consent Decree is in the public interest and reflects a negotiated  
13 agreement among the Parties.

14 D. GlaxoSmithKline, at all times relevant hereto, engaged in trade and commerce  
15 affecting consumers, within the meaning of RCW 19.86.010, in the State of Washington,  
16 including, but not limited to, King County.

17 E. The Attorneys General conducted an investigation regarding the Covered  
18 Conduct. The Parties have agreed to resolve all issues raised by and concerns related to the  
19 Covered Conduct under the Washington State Consumer Protection Act, RCW 19.86 by  
20 entering into this Consent Decree.  
21

22 F. This Consent Decree reflects a negotiated agreement entered into by the Parties  
23 as their own free and voluntary act, and with full knowledge and understanding of the nature of  
24 the proceedings and the obligations and duties imposed by this Consent Decree. Defendant is  
25 entering into this Consent Decree solely for the purpose of settlement, and nothing contained  
26 herein may be taken as or construed to be an admission or concession of any violation of law

1 or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of  
2 which Defendant expressly denies. Through this Consent Decree, Defendant does not admit  
3 any violation of law, and does not admit any wrongdoing that was or could have been alleged  
4 by any of the signatory Attorneys General before the date of the Consent Decree. No part of  
5 this Consent Decree, including its statements and commitments, shall constitute evidence of  
6 any liability, fault, or wrongdoing by Defendant. This Consent Decree does not constitute an  
7 admission by Defendant that the Covered Conduct violated or could violate the Washington  
8 State Consumer Protection Act. It is the intent of the Parties that this Consent Decree shall not  
9 be admissible or binding in any other matter, including, but not limited to, any investigation or  
10 litigation, other than in connection with the enforcement of this Consent Decree. No part of  
11 this Consent Decree shall create a private cause of action or convert any right to any third party  
12 for violation of any federal or state statute or law except that an Attorney General may file an  
13 action to enforce the terms of this Consent Decree. Nothing contained herein prevents or  
14 prohibits the use of this Consent Decree for purposes of enforcement by the Washington  
15 Attorney General.

18 G. This Consent Decree does not create a waiver or limit Defendant's legal rights,  
19 remedies, or defenses in any other action by the Washington Attorney General, and does not  
20 waive or limit Defendant's right to defend itself from, or make arguments in, any other matter,  
21 claim, or suit, including, but not limited to, any investigation or litigation relating to the  
22 existence, subject matter, or terms of this Consent Decree. Nothing in this Consent Decree  
23 shall waive, release, or otherwise affect any claims, defenses, or other positions Defendant may  
24 assert in connection with any investigations, claims, or other matters the Attorneys General are  
25  
26

1 not releasing hereunder. Notwithstanding the foregoing, the Washington Attorney General  
2 may file an action to enforce the terms of this Consent Decree.

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

6  
7 I. This Consent Decree sets forth the entire agreement between the Parties hereto  
8 and supersedes all prior agreements or understandings, whether written or oral, between the  
9 Parties and/or their respective counsel, with respect to the Covered Conduct.

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

13  
14 K. This Consent Decree may be executed in counterparts, each of which shall be  
15 deemed to constitute an original counterpart hereof, and all of which shall together constitute  
16 one and the same Consent Decree. One or more counterparts of this Consent Decree may be  
17 delivered by facsimile or electronic transmission with the intent that it, or they, shall constitute  
18 an original counterpart hereof.

19 L. This Consent Decree relates solely to the Covered Conduct.

20  
21 M. This Judgment (or any portion thereof) shall in no way be construed to prohibit  
22 Defendant from making representations with respect to any GSK Diabetes Product that are  
23 permitted under Federal law or labeling for the drug under the most current draft or final  
24 standard promulgated by the FDA or the most current draft or final FDA Guidance for  
25 Industry, or permitted or required under any Investigational New Drug Application, New Drug  
26 Application, Supplemental New Drug Application, or Abbreviated New Drug Application

1 approved by FDA, so long as the representation, taken in its entirety, is not false, misleading or  
2 deceptive.

3 N. Nothing in this Judgment shall require Defendant to:

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

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

9 or shall preclude Defendant from providing Health Care Economic Information to a formulary  
10 committee or similar entity or its members in the course of the committee or entity carrying out  
11 its responsibilities for the selection of drugs for managed care or other similar organization  
12 pursuant to the standards of FDAMA Section 114, if the information directly relates to an  
13 approved indication of a GSK Diabetes Product, and if based on competent and reliable  
14 scientific evidence.

## 15 II. DEFINITIONS

16 The following definitions shall be used in construing this Consent Decree:

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

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

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

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

26 E. "Defendant" shall mean GlaxoSmithKline LLC.

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

4 G. "GlaxoSmithKline LLC" or "GSK" shall mean GlaxoSmithKline LLC, all of its  
5 officers, directors, employees, subsidiaries, divisions, predecessors, successors, assignees, and  
6 transferees.  
7

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

11 I. "Health Care Economic Information" shall mean data and other information  
12 relating to the inputs and outcomes of health care therapies and services, including, but not  
13 limited to, the price, cost-effectiveness, and quality of life implications of any GSK Diabetes  
14 Product.  
15

16 J. "Multistate Working Group" shall mean the Attorneys General and their staff  
17 representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut,  
18 Delaware, the District of Columbia, Florida, Hawaii,<sup>1</sup> Idaho, Illinois, Iowa, Kansas, Maine,  
19 Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New  
20 Jersey, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island,  
21 South Dakota, Tennessee, Texas, Vermont, Washington, and Wisconsin.  
22  
23

24 \_\_\_\_\_  
25 <sup>1</sup> Hawaii is being represented on this matter by its Office of Consumer Protection, an agency which is not  
26 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.

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

4  
5 L. "Parties" shall mean the Washington Attorney General and Defendant.

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

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

### 11 III. COMPLIANCE PROVISIONS

#### 12 Promotional Activities

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

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

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

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

23 D. Defendant shall not represent in a promotional context that an investigational  
24 new GSK Diabetes Product is safe or effective for the purposes for which it is under  
25 investigation or otherwise promote the drug. This provision is not intended to restrict the full  
26 exchange of scientific information in non-promotional settings concerning the drug, including

1 dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict  
2 promotional claims of safety or effectiveness of the drug for a use for which it is under  
3 investigation and to preclude commercialization of the drug before it is approved for  
4 commercial distribution.

5 E. Defendant shall not make in a promotional context a representation or  
6 suggestion, not approved or permitted for use in the labeling or under the FDCA, that a GSK  
7 Diabetes Product is better, more effective, useful in a broader range of conditions or patients,  
8 safer, has fewer, or less incidence of, or less serious side effects or contraindications than has  
9 been demonstrated by substantial evidence, or substantial clinical experience (as described in  
10 paragraphs (e)(4)(ii)(b) and (c) of 21 C.F.R. § 202.1), whether or not such representations are  
11 made by comparison with other drugs or treatments, and whether or not such a representation  
12 or suggestion is made directly or through use of published or unpublished literature,  
13 quotations, or other references.

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

- 16 1. contain a drug comparison that represents or suggests that a drug is safer or  
17 more effective than another drug in some particular when it has not been  
18 demonstrated to be safer or more effective in such particular by substantial  
19 evidence or substantial clinical experience;
- 20 2. contain favorable information or opinions about a drug previously regarded as  
21 valid but which have been rendered invalid by contrary and more credible  
22 recent information, or contain literature references or quotations that are  
23 significantly more favorable to the drug than has been demonstrated by  
24 substantial evidence or substantial clinical experience;
- 25 3. contain a representation or suggestion that a drug is safer than it has been  
26 demonstrated to be by substantial evidence or substantial clinical experience, by

- 1 selective presentation of information from published articles or other references  
2 that report no side effects or minimal side effects with the drug or otherwise  
3 selects information from any source in a way that makes a drug appear to be  
4 safer than has been demonstrated;
- 5 4. contain favorable data or conclusions from nonclinical studies of a drug, such as  
6 in laboratory animals or in vitro, in a way that suggests they have clinical  
7 significance when in fact no such clinical significance has been demonstrated;
- 8 5. use erroneously a statistical finding of “no significant difference” to claim  
9 clinical equivalence or to deny or conceal the potential existence of a real  
10 clinical difference;
- 11 6. present required information relating to side effects or contraindications by  
12 means of a general term for a group in place of disclosing each specific side  
13 effect and contraindication unless the use of such general term conforms to the  
14 provisions of paragraph (e)(3)(iii) of 21 C.F.R. § 202.1;
- 15 7. present information from a study in a way that implies that the study represents  
16 larger or more general experience with the drug than it actually does; or
- 17 8. use statistics on numbers of patients or counts of favorable results or side  
18 effects, derived from pooling data from various insignificant or dissimilar  
19 studies in a way that suggests either that such statistics are valid if they are not  
20 or that they are derived from large or significant studies supporting favorable  
21 conclusions when such is not the case.
- 22 G. When presenting information about a clinical study regarding GSK Diabetes  
23 Products in any Promotional Materials, Defendant shall not do any of the following for  
24 information that may be material to a health care provider prescribing decision:
- 25 1. present favorable information or conclusions from a study that is inadequate in  
26 design, scope, or conduct to furnish significant support for such information or

1 conclusions;

- 2 2. use the concept of statistical significance to support a claim that has not been  
3 demonstrated to have clinical significance or validity, or fails to reveal the range  
4 of variations around the quoted average results; or  
5 3. use statistical analyses and techniques on a retrospective basis to discover and  
6 cite findings not soundly supported by the study, or to suggest scientific validity  
7 and rigor for data from studies the design or protocol of which are not amenable  
8 to formal statistical evaluations.

9 **Clinical Research**

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

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

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

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

- 23 1. Adhere to the ICMJE Uniform Requirements for Manuscripts Submitted to  
24 Biomedical Journals: Writing and Editing for Biomedical Publications,  
25 including authorship criteria, unless the applicable journal or congress to which  
26 the publication is submitted has more stringent requirements, in which case the

1 journal or congress criteria for authorship will be followed; and

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

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

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

13 **IV. DISBURSEMENT OF PAYMENTS: PAYMENT TO THE STATES**

14 Within 30 days of the Effective Date of this Consent Decree, Defendant shall pay \$90  
15 million to be divided and paid by Defendant directly to each Attorney General of the Multistate  
16 Working Group in an amount to be designated by and in the sole discretion of the Multistate  
17 Executive Committee.<sup>2</sup> The payment received by the Attorney General of the State of  
18 Washington shall be used by the Attorney General for (1) attorneys' fees and other costs of  
19 investigating and litigating this matter; (2) enforcement of this Consent Decree and for  
20 administering the grant process; and (3) remaining funds shall be distributed for the benefit of  
21 Washington residents who have type 2 diabetes. All disbursements shall be at the sole  
22 discretion of the Attorney General. For disbursements in (3), this will occur at the sole  
23 discretion of the Attorney General through an open and competitive grant process. The Parties  
24 acknowledge that the payment described herein is not a fine, penalty, or payment in lieu  
25 thereof.

26 <sup>2</sup> The State of Washington's share is \$2,199,736.31.



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

- 4 1. Any criminal liability that any person or entity, including Released Parties, has  
5 or may have to the State of Washington;
- 6 2. Any civil or administrative liability that any person or entity, including  
7 Released Parties, has or may have to the State of Washington, under any statute,  
8 regulation, or rule not expressly covered by the release in Section VI.A  
9 including, but not limited to, any and all of the following claims:
  - 10 a. State or federal antitrust violations;
  - 11 b. Reporting practices, including "best price," "average wholesale price" or  
12 "wholesale acquisition cost";
  - 13 c. Medicaid violations, including, but not limited to, federal Medicaid drug  
14 rebate statute violations, Medicaid fraud or abuse, and/or kickback  
15 violations related to Washington's Medicaid program;
  - 16 d. State false claims violations; and
  - 17 e. Claims to enforce the terms and conditions of this Consent Decree.
- 18 3. Actions of state program payors of the State of Washington arising from the  
19 Covered Conduct, except for the release of civil penalties under the State of  
20 Washington's above-cited state consumer protection law.
- 21 4. Any claims individual consumers have or may have under the State of  
22 Washington's Consumer Protection Act against any person or entity, including  
23 Released Parties.

## 24 VII. CONFLICTS

25 A. If, subsequent to the Effective Date of this Consent Decree, the federal  
26 government or any state, or any federal or state agency, enacts or promulgates legislation or

1 regulations with respect to matters governed by this Consent Decree that creates a conflict with  
2 any provision of the Consent Decree and Defendant intends to comply with the newly enacted  
3 legislation or regulation, Defendant shall notify the Attorneys General (or the Attorney General  
4 of the affected State) of the same. If the Attorney General agrees, she shall consent to a  
5 modification of such provision of the Consent Decree to the extent necessary to eliminate such  
6 conflict. If the Attorney General disagrees and the Parties are not able to resolve the  
7 disagreement, Defendant shall seek a modification from an appropriate court of any provision  
8 of this Consent Decree that presents a conflict with any such federal or state law or regulation.  
9 Changes in federal or state laws or regulations, with respect to the matters governed by this  
10 Consent Decree, shall not be deemed to create a conflict with a provision of this Consent  
11 Decree unless Defendant cannot reasonably comply with both such law or regulation and the  
12 applicable provision of this Consent Decree.

#### 13 VIII. DISPUTE RESOLUTION

14 A. For the purposes of resolving disputes with respect to compliance with this  
15 Consent Decree, should any of the signatory Attorneys General have a reason to believe that  
16 Defendant has violated a provision of this Consent Decree subsequent to the Effective Date,  
17 then such Attorney General shall notify Defendant in writing of the specific objection, identify  
18 with particularity the provisions of this Consent Decree that the practice appears to violate, and  
19 give Defendant 30 days to respond to the notification.

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

25 C. Except as set forth in Sections VIII.E and F below, the Attorney General may  
26 not take any action during the 30-day response period. Nothing shall prevent the Attorney

1 General from agreeing in writing to provide Defendant with additional time beyond the 30  
2 days to respond to the notice.

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

6 E. Nothing in this Consent Decree shall be interpreted to limit the State's Civil  
7 Investigative Demand or investigative subpoena authority.

8 F. The Attorney General may assert any claim that Defendant has violated this  
9 Consent Decree in a separate civil action to enforce compliance with this Consent Decree, or  
10 may seek any other relief afforded by law, but only after providing Defendant an opportunity  
11 to respond to the notification and to remedy the alleged violation within the 30-day response  
12 period as described above, or within any other period as agreed to by GSK and the Attorney  
13 General; provided, however, that the Attorney General may take any action if the Attorney  
14 General believes that, because of the specific practice, a threat to the health or safety of the  
15 public requires immediate action.

#### 16 IX. COMPLIANCE WITH ALL LAWS

17 A. Except as expressly provided in this Consent Decree, nothing in this Consent  
18 Decree shall be construed as:

- 19 1. Relieving Defendant of its obligation to comply with all applicable state laws,  
20 regulations, or rules, or granting permission to engage in any acts or practices  
21 prohibited by any law, regulation, or rule; or
- 22 2. Limiting or expanding in any way any right any state represented by the  
23 Multistate Working Group may otherwise have to enforce applicable state law  
24 or obtain information, documents, or testimony from Defendant pursuant to any  
25 applicable state law, regulation, or rule, or any right Defendant may otherwise  
26 have to oppose any subpoena, civil investigative demand, motion, or other

1 procedure issued, served, filed, or otherwise employed by the State pursuant to  
2 any such state law, regulation, or rule.

3 **X. GENERAL PROVISIONS**

4 A. Nothing in this Consent Decree is intended to modify the consent decree,  
5 effective June 23, 2011, between the State of Washington and GlaxoSmithKline LLC and SB  
6 Pharmco Puerto Rico, Inc.

7 B. Nothing in this Consent Decree is intended to modify the Settlement  
8 Agreement, effective June 8, 2012, between the State of Washington and GlaxoSmithKline  
9 LLC.

10 C. Nothing will prevent the Attorney General from agreeing in writing to provide  
11 Defendant with additional time to perform any act required by the Consent Decree. The  
12 Attorney General shall not unreasonably withhold consent to the request for additional time.

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

15 For GlaxoSmithKline LLC:

16 Barry H. Boise  
17 Pepper Hamilton LLP  
18 3000 Two Logan Square  
19 Eighteenth and Arch Streets  
20 Philadelphia, PA 19103

21 For Washington State Attorney General:

22 Elizabeth J. Erwin, Senior Counsel  
23 Consumer Protection Division  
24 Attorney General of Washington  
25 800 Fifth Ave., Ste 2000  
26 Seattle, WA 98104

27 **IT IS SO ORDERED, ADJUDGED, AND DECREED.**

28 This the \_\_\_ day of \_\_\_\_\_, 2012.

**CARLOS Y. VELATEGUI**

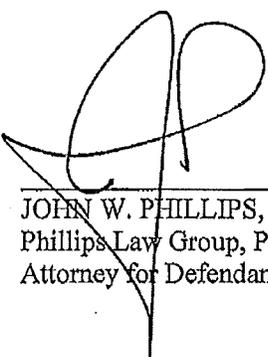
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Presented by:

Approved for Entry, Notice of Presentation  
Waived:

ROBERT M. MCKENNA  
Attorney General

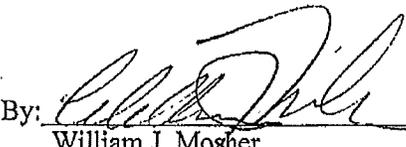


ELIZABETH J. ERWIN, WSBA #16548  
Assistant Attorney General  
Attorneys for Plaintiff  
State of Washington

JOHN W. PHILLIPS, WSBA #12185  
Phillips Law Group, PLLC  
Attorney for Defendants

JOINTLY APPROVED AND  
SUBMITTED FOR ENTRY:

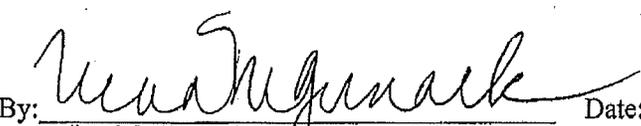
FOR GLAXOSMITHKLINE LLC



By: William J. Mosher  
Company Secretary  
GlaxoSmithKline LLC

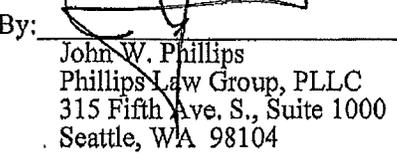
Date: 11/8/2012

FOR DEFENDANT GLAXOSMITHKLINE LLC



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

Date: 11/12/12



By: John W. Phillips  
Phillips Law Group, PLLC  
315 Fifth Ave. S., Suite 1000  
Seattle, WA 98104

Date: 11.06.12

CONSENT DECREE

ATTORNEY GENERAL OF WASHINGTON  
Consumer Protection Division  
800 Fifth Avenue, Suite 2000  
Seattle, WA 98104-3188  
(206) 464-7745

~~17~~  
EGE 17  
To conform with final version.



**Rob McKenna**  
**ATTORNEY GENERAL OF WASHINGTON**

Consumer Protection Division  
800 Fifth Avenue • Suite 2000 • MS TB 14 • Seattle WA 98104-3188  
(206) 464-7745

**AGO Grant Award & Agreement**

November 29, 2012

[Name of Organization]  
[Name of Organization Contact]  
[Street Address]  
[City, State Zip]

**RE: [Name of account/settlement] Grant**

Dear [Contact Name]:

The Washington State Office of the Attorney General (AGO) is pleased to award the [Name of Organization] a grant in the amount of \$dollar amount for the period of [Month day, year] to [Month day, Year]. You shall use the grant only for the purpose described in your grant application and you shall adhere to the details and budget stated in your grant application. The grant application you submitted to the AGO dated [Month day, year], is incorporated into this agreement. The purpose of the grant is to insert Grant purpose and use quotations around titles.

**Tax Status:** You have confirmed that Organization name is currently registered as a [Enter non-profit status] with the [Enter filing agency (IRS?)]. Should there be any change to your organization's status, you must advise us immediately and document any such change as part of the grant reporting process outlined below. If you should lose your non-profit status, the AGO reserves the right to request a full refund of granted funds.

**Use of Grant Funds:** The use of grant funds and earnings thereon is restricted solely to the purposes of the project described in your grant application and may not be expended, borrowed, pledged, or transferred for reasons other than carrying out the project. You must keep careful and detailed accounting of your use of the grant. Any funds remaining at the end of the agreed upon deadline shall be returned to the AGO regardless of project status.

[ADD ADDITIONAL GRANT DETAILS HERE OR DELETE IF NOT NEEDED]

Grant funds may not be used for lobbying or for any political purposes. This grant is not for general operating costs or for planning. This grant may not be used to supplant existing funding

for ongoing projects or programs. It may not be used to supplement general operational or administrative costs, or for salaries, benefits, overhead, or infrastructure, except in the delivery of contracted services that support the development of technology, partnership and program coordination, outreach and education delivery, and/or data recovery and analysis. Capital investments such as computer hardware and audio/visual equipment are considered inappropriate expenses and should be available as part of an organization’s infrastructure.

A detailed and accurate budget must be kept, and any significant increase or decrease to a budget line item must be reported to the AGO.

**Indemnification:**

1) Grantee shall indemnify, defend, and hold harmless the Office of the Attorney General and the State of Washington, its officers, agents, and employees, from and against all claims for harm arising out Grantee’s performance or failure to perform the contract. Grantee’s duty to indemnify and hold harmless shall apply only to the extent the harm/claim is caused, in whole or in part, by the intentional, willful, or negligent acts or omissions of Grantee, its officers, employees, or agents.

Grantee waives its immunity under Title 51 to the extent it is required to indemnify, defend and hold harmless the Office of the Attorney General, the State of Washington, and its agencies, officers, agents or employees.

2) If Grantee will make use of subcontractors, Grantee agrees it shall use due diligence to select only capable subcontractors. Grantee shall require all subcontractor agreements to include an indemnification clause requiring the subcontractor to indemnify the Grantee, the Office of the Attorney General, and the State of Washington, its officers, agents and employees, to the same extent Grantee is required to indemnify the Office of the Attorney General and State of Washington.

**Payment of Grant Funds:** The grant shall be disbursed to your organization via check according to the following schedule:

<b>Payment Date</b>	<b>Payment Amount</b>	<b>Contingent Upon</b>	<b>Due Date</b>
m/d/y	\$ enter amount	Return of signed Agreement (or other contingency)	
		Final Interim Narrative and Financial Report on or before	[m/d/y]
		Return of unused funds to the AGO	[m/d/y]

**Grant Reporting:** The AGO requires that you provide our office with written summaries and financial reports detailing your project’s progress in accordance with the schedule above. Although the format of the reports is not a condition of the grant award, reports must include a budget detail of progress to date, narrative about the project including measurables such as

constituents reached, number of new clients, direct contacts made with the community, new partnerships developed, and copies of any collateral material produced in the process of program delivery. Reports shall include all relevant financial attachments. A sample report form that complies with our requirements is attached for reference.

The reports must be signed by an authorized officer of your organization. If there are any changes in your organizational leadership or key personnel during the term of the grant, please inform our office immediately. All reports shall be sent to Michelle Ferazza, Legal Assistant to Shannon Smith, Division Chief, at the Washington State Attorney General's Office, Consumer Protection Division, 800 5<sup>th</sup> Ave., Suite 2000, Seattle, WA 98104-3188.

Any funds that have not been used in the delivery of the agreed upon services must be returned to the AGO no later than Month day, year.

**Record Maintenance and Inspection:** By signing this document, you agree to maintain adequate records to enable the AGO to confirm that your expenditure and stewardship of the grant funds is consistent with this agreement. You agree to retain documentation to support all expenditures made with the grant funds, including receipts and invoices. You also agree to make your books and records available for AGO inspection at reasonable times. You further agree to permit the AGO to monitor and evaluate your operations under this grant, which may include a visit by AGO staff to observe your organization's project, discuss the project with your organization's staff, and review your financial and other records connected with this grant.

**Compliance:** If the AGO deems the progress of your project for which you have received grant funds unsatisfactory, we reserve the right to terminate the grant and request that any unspent grant funds be returned. An unsatisfactory performance may also preclude your organization from qualifying for future grant awards from the AGO.

**Public Records:** Information regarding this grant may be publicly disclosed. If your organization would like to make a public announcement about this award, please provide our office with the opportunity to comment in advance on the proposed media release. Please contact Shannon Smith, Consumer Protection Division Chief, (206) 389-3996, [shannons@atg.wa.gov](mailto:shannons@atg.wa.gov), and she will coordinate the release with the AGO Public Affairs staff.

Thank you for participating in our grant process. If your understanding of the terms of this grant is not accurately described within this document and its attachment, please contact Shannon Smith and we will be happy to address your questions and concerns. We look forward to this new partnership.

On behalf of Attorney General Rob McKenna

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Shannon Smith, Senior Counsel

---

Date

Consumer Protection Division Chief  
Washington State Attorney General's Office

**By signing below, Organization name agrees to all the terms and conditions as set forth above and incorporated herein. The AGO will disburse funds upon receipt of this signed agreement.**

\_\_\_\_\_  
[Organizations Authorized signer, Title]  
[Name of Organization]

\_\_\_\_\_  
Date

Attachment

## Grantee Reporting Guidelines

During the term of the grant, it shall be required of \_\_\_\_\_ to provide both interim and final written reports to the Attorney General's Office. Please refer to your grant agreement for a schedule of your report due dates. The report should include a narrative and all relevant financial attachments. If the grant to your organization supported a particular project, the report should focus specifically on that project. Please submit one hardcopy and one digital copy via email. Other documents may be requested by the grant administrator.

Such periodic reports are necessary not only for proper oversight to ensure accountability, but also serve as a valuable learning tool for both your organization and the Attorney General's Office. The thoughtful and sincere review of your organization's experience is greatly appreciated.

Any questions should be directed to Shannon Smith, Consumer Protection Division Chief, at [shannons@atg.wa.gov](mailto:shannons@atg.wa.gov).

### **Narrative Report Requirements**

1. Please limit answers to each of the questions below to no more than one page.
2. Describe your progress towards the grant outcomes that were outlined in your proposal.
  - a. What has been the actual impact for participants due to your program?
  - b. If the project delivered services, please indicate numbers of clients served.
  - c. Please describe clients' demographic information such as race/ethnicity, age, gender and geography as appropriate.
3. In writing your interim report, please focus on reporting both your progress up until the time of the report as well as on describing how you plan to proceed.
4. Describe your successes and accomplishments as well as the challenges you have encountered.
  - a. How did you respond or how do you plan to respond to the challenges of your project?
5. Give specific examples highlighting any changes in your project plan, timeline, staff or finances that affected the project's outcomes. Include a summary on any adjustments you have had to make on your original proposal.
6. Describe your future goals and plans for the program.

7. In the final report, please inform us of whether the grant was beneficial or ineffective in regards to your project and include an evaluation of your project. In doing so, please describe the method you used to evaluate your project.

### **Financial Report Requirements**

1. Using an excel spreadsheet provide the AGO with a detailed budget report. Please include all actual versus budgeted expenditures. Please include specifically how funding from the Attorney General's Office was expended, including all costs associated with the project, staff and contractor salaries, equipment purchases and travel expenses.
2. Please include and explain any significant variances in your budget from what you proposed prior to the commencement of your project in your narrative report.
3. Include an explanation of any left over grant funds, or funds that were not spent on the approved project.
4. Be prepared to support all expenditures made with AGO monies with receipts and/or invoices.