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2 DANIEL A. OLIVAS  
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3 JUDITH FIORENTINI  
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8 *Attorneys for Plaintiff*

9  
10 SUPERIOR COURT OF THE STATE OF CALIFORNIA  
11 FOR THE COUNTY OF SAN DIEGO  
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13

14 **THE PEOPLE OF THE STATE OF**  
15 **CALIFORNIA,**

16 Plaintiff,

17 v.

18 **GLAXOSMITHKLINE LLC,**

19 Defendant.

Case No.

**STIPULATION FOR ENTRY OF FINAL  
JUDGMENT**

20  
21 Plaintiff, the People of the State of California (Plaintiff or the People), through its attorney,  
22 Kamala D. Harris, Attorney General, by Judith Fiorentini, Deputy Attorney General, and  
23 GlaxoSmithKline LLC (GSK or Defendant) by its attorneys, Covington & Burling LLP, by  
24 Matthew J. O'Connor, and Emily Johnson Henn, stipulate as follows:

25 1. The Final Judgment (Judgment), a true and correct copy of which is attached to this  
26 Stipulation for Entry of Final Judgment (Stipulation) as Exhibit 1, may be entered in this matter.  
27  
28

1           2.     Concurrently with the filing of this Stipulation, Plaintiff has filed its Complaint in this  
2 matter alleging that Defendant committed violations of California Business and Professions Code  
3 sections 17200 et seq. and 17500 et seq.

4           3.     Plaintiff, by its counsel, and Defendant, by its counsel, have agreed to the entry of  
5 this Judgment by the Court without trial or adjudication of any issue of fact or law or finding of  
6 wrongdoing or liability of any kind.

7           4.     The Court has jurisdiction over the subject matter of this action, jurisdiction over  
8 Plaintiff and Defendant (Parties) to this action, and venue is proper in this Court.

9           5.     The terms of this Judgment shall be governed by the laws of the State of California.

10          6.     Defendant, at all relevant times, has transacted business in the City and County of San  
11 Diego and elsewhere in the State of California.

12          7.     At the same time that Defendant is stipulating to enter into this Judgment with the  
13 California Attorney General's Office, Defendant is entering into similar Judgments with the  
14 Attorneys General of forty-four states<sup>1</sup> and the District of Columbia (collectively, the Attorneys  
15 General)<sup>2</sup>, each of whom conducted an investigation under their State consumer protection laws  
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18 <sup>1</sup> Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of  
19 Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine,  
20 Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New  
Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon,  
Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia,  
Washington, Wisconsin, and Wyoming.

21 <sup>2</sup> With regard to Georgia, the Administrator of the Fair Business Practices Act, appointed  
22 pursuant to O.C.G.A. § 10-1-395, is statutorily authorized to undertake consumer protection  
23 functions for the State of Georgia. References to the "States," "Parties," or "Attorneys General,"  
24 with respect to Georgia, include the Administrator of the Fair Business Practices Act. Hawaii is  
25 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  
27 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. The Utah Attorney General's Office represents the Utah Division of Consumer  
Protection (Division), the state agency charged with enforcement of the Consumer Sales Practices  
Act, in this action, but is not a party itself. As to Utah, the definition of "Attorneys General"  
means the Utah Attorney General as counsel to the Division.

1 regarding Defendant's Promotional practices, dissemination of information, and remuneration to  
2 HCPs regarding the prescription drugs Advair®, Paxil®, and Wellbutrin® in the United States.

3 8. The Attorneys General conducted an investigation regarding the Covered Conduct as  
4 defined in the Judgment. The Parties have agreed to resolve the concerns related to the Covered  
5 Conduct under the State Consumer Protection Laws, by entering into this Judgment. This  
6 Judgment is entered pursuant to California Business and Professions Code sections 17200 et seq.  
7 and 17500 et seq.

8 9. This Stipulation and the Judgment reflect a negotiated agreement entered into by the  
9 Parties as their own free and voluntary act, and with full knowledge and understanding of the  
10 nature of the proceedings and the obligations and duties imposed by this Stipulation and the  
11 Judgment. GSK is entering into this Stipulation and Judgment solely for the purpose of  
12 settlement, and nothing contained herein or in the Judgment may be taken as or construed to be an  
13 admission or concession of any violation of law or regulation, or of any other matter of fact or  
14 law, or of any liability or wrongdoing, all of which GSK expressly denies. Through this  
15 Stipulation and the Judgment, GSK does not admit any violation of law, and does not admit any  
16 wrongdoing that was or could have been alleged by any of the signatory Attorneys General before  
17 the date of the Judgment. No part of this Stipulation and the Judgment, including their statements  
18 and commitments, shall constitute evidence of any liability, fault, or wrongdoing by GSK. This  
19 Stipulation and the Judgment do not constitute an admission by GSK that the Covered Conduct  
20 violated or could violate the State Consumer Protection Laws. It is the intent of the Parties that  
21 neither this Stipulation nor the Judgment shall be admissible or binding in any other matter,  
22 including, but not limited to, any investigation or litigation, other than in connection with the  
23 enforcement of this Judgment. No part of this Stipulation and the Judgment shall create a private  
24 cause of action or convert any right to any third party for violation of any federal or state statute  
25 or law, except that an Attorney General may file an action, or use other appropriate means, to  
26 enforce the terms of the Judgment. Nothing contained in this Stipulation prevents or prohibits the  
27 use of this Stipulation and/or the Judgment for purposes of enforcement by the California  
28 Attorney General.

1           10. Neither this Stipulation nor the Judgment creates a waiver or limits GSK's legal  
2 rights, remedies, or defenses in any other action by the California Attorney General, and does not  
3 waive or limit GSK'S right to defend itself from, or make arguments in, any other matter, claim,  
4 or suit, including, but not limited to, any investigation or litigation relating to the existence,  
5 subject matter, or terms of this Stipulation and/or the Judgment. Nothing in this Stipulation and  
6 the Judgment shall waive, release, or otherwise affect any claims, defenses, or other positions  
7 GSK may assert in connection with any investigations, claims, or other matters the Attorneys  
8 General are not releasing hereunder. Notwithstanding the foregoing, the California Attorney  
9 General may file an action, or use other appropriate means, to enforce the terms of the Judgment.

10           11. Neither this Stipulation nor the Judgment constitutes an approval by the Attorneys  
11 General of GSK's business practices, and GSK shall make no representation or claim to the  
12 contrary.

13           12. This Stipulation and the Judgment set forth the entire agreement between the Parties  
14 and supersedes all prior agreements or understandings, whether written or oral, between the  
15 Parties and/or their respective counsel, with respect to the Covered Conduct.

16           13. The Parties acknowledge that they are each the proper Party to this Stipulation and  
17 Judgment and further warrant and represent that the individual signing this Stipulation on behalf  
18 of each Party is doing so in his or her official capacity and is fully authorized by each Party to  
19 enter into this Stipulation and Judgment and to legally bind each Party to all of the terms and  
20 conditions of the Stipulation and Judgment.

21           14. The Judgment may be entered by any judge of the San Diego Superior Court.  
22 Counsel for Plaintiff may submit the Judgment to any judge of the Superior Court for approval  
23 and signature, during the Court's ex parte calendar or on any other ex parte basis. Defendant  
24 waives the right to any personal notice of any such ex parte submission of the Judgment to the  
25 Court. Defendant will accept notice of entry of judgment entered in this action by delivery of  
26 such notice to its counsel of record, and Defendant agrees that such service of notice of entry of  
27 judgment will be deemed personal service upon it for all purposes.

1           15. This Stipulation may be executed in counterparts, each of which shall be deemed to  
2 constitute an original counterpart of this Stipulation, and all of which shall together constitute one  
3 and the same Stipulation. One or more counterparts of this Stipulation may be delivered by  
4 facsimile or electronic transmission with the intent that it, or they, shall constitute an original  
5 counterpart of this Stipulation.

6  
7 Dated: June 4, 2014

Respectfully Submitted,

8 KAMALA D. HARRIS  
9 Attorney General of California  
10 DANIEL A. OLIVAS  
11 Acting Senior Assistant Attorney General  
12 JUDITH FIORENTINI  
13 Deputy Attorney General



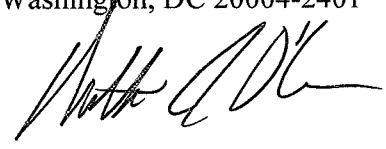
14 JUDITH FIORENTINI  
15 Deputy Attorney General  
16 *Attorneys for Plaintiff*

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23 *(Additional signatures on next page)*  
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May 30  
Dated: June \_\_, 2014

Matthew J. O'Connor  
Covington & Burling LLP  
1201 Pennsylvania Avenue, NW  
Washington, DC 20004-2401

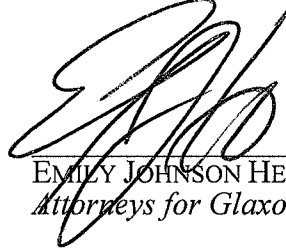


MATTHEW J. O'CONNOR  
*Attorneys for GlaxoSmithKline LLC*

*(Additional signatures on next page)*

1 Dated: May 28, 2014  
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Emily Johnson Henn  
California Bar No. 269482  
Covington & Burling LLP  
333 Twin Dolphin Drive  
Suite 700  
Redwood Shores, CA 94065-1418



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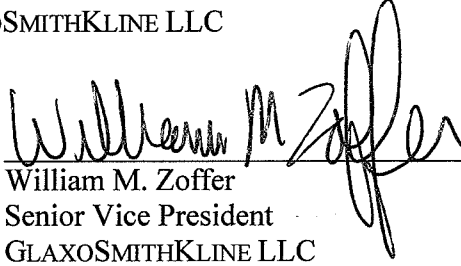
EMILY JOHNSON HENN  
*Attorneys for GlaxoSmithKline LLC*

*(Additional signatures on next page)*

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GLAXOSMITHKLINE LLC

By:

  
\_\_\_\_\_  
William M. Zoffer  
Senior Vice President  
GLAXOSMITHKLINE LLC

Date: 27 May 2014



## **Exhibit 1**

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SUPERIOR COURT OF THE STATE OF CALIFORNIA  
FOR THE COUNTY OF SAN DIEGO

**THE PEOPLE OF THE STATE OF  
CALIFORNIA,**

Plaintiff,

v.

**GLAXOSMITHKLINE LLC,**

Defendant.

Case No.

**FINAL JUDGMENT**

Plaintiff, the People of the State of California (Plaintiff or the People), having filed its Complaint and appearing through its attorney, Kamala D. Harris, Attorney General of the State of California, by Judith Fiorentini, Deputy Attorney General, and GlaxoSmithKline LLC (GSK or Defendant), by its attorney, Covington & Burling LLP, by Matthew J. O'Connor and Emily Johnson Henn, having stipulated as follows to the entry of this Final Judgment (Judgment) by the Court without trial or adjudication of any issue of fact or law, and without admission of wrongdoing or liability of any kind as follows:

This Judgment may be signed by any judge of the San Diego Superior Court; and,

1 Plaintiff has filed its Complaint in this matter pursuant to California Business and  
2 Professions Code sections 17200 et seq. and 17500 et seq.; and,

3 Defendant denies the allegations of the Complaint and denies any alleged violations; and,

4 This Judgment is made without trial or adjudication of any issue of fact or law or finding  
5 of wrongdoing or liability of any kind; and,

6 Defendants does not admit any violation of law or any wrongdoing and that no part of this  
7 Judgment, including its statements and commitments, shall constitute evidence of any liability,  
8 fault or wrongdoing by Defendant; and,

9 The Court having considered the pleadings and the Stipulation for Entry of Final  
10 Judgment (Stipulation) executed by the Plaintiff and Defendant filed herewith, and good cause  
11 appearing,

12 IT IS HEREBY ORDERED, ADJUDGED AND DECREED as follows:

13 **I. PARTIES AND JURISDICTION**

14 1. The People of the State of California is the Plaintiff in this case.

15 2. GlaxoSmithKline LLC is the Defendant in this case.

16 3. The Court has jurisdiction over the subject matter of this action, jurisdiction over  
17 the parties to this action, and venue is proper in this Court.

18 4. Defendant, at all relevant times, has transacted business in the State of California,  
19 including, but not limited to, San Diego County.

20 5. This Judgment is entered pursuant to and subject to California Business and  
21 Professions Code sections 17200 and 17500 et seq.

22 **II. DEFINITIONS**

23  
24 The following definitions shall be used in construing this Judgment:

25 6. "Applicable Clinical Trials" shall mean those clinical trials required by the Food  
26 and Drug Administration (FDA) Amendments Act of 2007 (Public Law No. 110-85).

27 7. "Attorneys General" shall mean the Attorneys General of the Multistate Working  
28 Group.

1           8.       “Clinically Relevant Information” shall mean information that reasonably prudent  
2 clinicians would consider relevant when making prescribing decisions regarding a GSK Product.

3           9.       “Clinical Response” shall mean a non-Promotional, scientific communication to  
4 address Unsolicited Requests for medical information.

5           10.      “Covered Conduct” shall mean GSK’s Promotional practices, dissemination of  
6 information, and remuneration to HCPs regarding the prescription drugs Advair®, Paxil®, and  
7 Wellbutrin® in the United States.

8           11.      “Effective Date” shall mean the date on which a copy of this Judgment, duly  
9 executed by GSK and by the signatory Attorney General, is approved by, and becomes a  
10 Judgment, of the Court.

11          12.      “GlaxoSmithKline LLC,” “GlaxoSmithKline,” or “GSK” shall mean  
12 GlaxoSmithKline LLC, including all of its predecessors, subsidiaries, successors, and assigns.

13          13.      “GSK Law Department” shall mean personnel of the GSK Law Department or its  
14 designee providing legal advice to GSK.

15          14.      “GSK Marketing” shall mean GSK personnel responsible for marketing GSK  
16 Products.

17          15.      “GSK Medical Affairs” shall mean the organization within GSK consisting of  
18 highly trained experts with specialized scientific and medical knowledge, usually with an  
19 advanced scientific degree (e.g., an MD, PhD, or PharmD), whose role is limited to the provision  
20 of specialized, medical or scientific information, scientific analysis and/or scientific information  
21 to HCPs but excludes anyone performing sales, marketing, Promotional ride alongs, or other  
22 primarily commercial roles.

23          16.      “GSK Product” or “GSK Products” shall mean: (1) Advair®; (2) Paxil®; (3)  
24 Wellbutrin®; (4) any pharmaceutical or biological product approved by the FDA for the  
25 treatment of major depressive disorder; (5) any selective serotonin reuptake inhibitor (SSRI); and  
26 (6) any norepinephrine dopamine reuptake inhibitor (NDRI), that GSK Promotes or for which it  
27 directs Promotion.  
28

1           17.     “GSK Sales” shall mean the GSK sales force responsible for selling GSK  
2 Products.

3           18.     “GSK Scientifically Trained Personnel” shall mean GSK personnel who are highly  
4 trained experts with specialized scientific and medical knowledge, usually with an advanced  
5 scientific degree (e.g., an MD, PhD, or PharmD), whose roles involve the provision of  
6 specialized, medical or scientific information, scientific analysis and/or scientific information to  
7 HCPs but excludes anyone performing sales, marketing, Promotional ride alongs, or other  
8 primarily commercial roles.

9           19.     “Health Care Professional” or “HCP” shall mean any physician or other health  
10 care practitioner who is licensed to provide health care services or to prescribe pharmaceutical  
11 products.

12          20.     “Meta-analyses” shall mean formal analyses combining evidence from  
13 independent studies using appropriate statistical methods, but shall not include any such analyses  
14 conducted in connection with the preparation or submission of an Investigational New Drug  
15 Application (IND), New Drug Application (NDA), Supplemental New Drug Application (sNDA),  
16 Abbreviated New Drug Application, (ANDA), nor shall it include any such analyses conducted in  
17 connection with any other regulatory report required under the Food, Drug and Cosmetic Act, 21  
18 U.S.C. § 301 et seq. (FDCA), or by the U.S. Food and Drug Administration (FDA) or other  
19 regulatory body, to the extent the content or submission of which is treated as non-public or  
20 confidential by the relevant agency.

21          21.     “Multistate Executive Committee” shall mean the Attorneys General and their  
22 staff representing Arizona, Florida, Illinois, Maryland, Oregon, Pennsylvania, Tennessee, and  
23 Texas.

24          22.     “Multistate Working Group” shall mean the Attorneys General and their staff  
25 representing Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the  
26 District of Columbia, Florida, Georgia<sup>1</sup>, Hawaii<sup>2</sup>, Idaho, Illinois, Indiana, Iowa, Kansas,

27                 <sup>1</sup>     With regard to Georgia, the Administrator of the Fair Business Practices Act,  
28 appointed pursuant to O.C.G.A. § 10-1-395, is statutorily authorized to undertake consumer  
(continued...)

1 Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska,  
2 Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma,  
3 Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah<sup>3</sup>, Vermont, Virginia,  
4 Washington, Wisconsin, and Wyoming.

5 23. "Off-Label" shall mean a non-FDA approved use.

6 24. "Parties" shall mean the STATE Attorney General and GSK.

7 25. "Promotional," "Promoting," or "Promote" shall mean representations about a  
8 GSK Product intended to influence sales of that product, including attempts to influence  
9 prescribing practices and utilization of a GSK Product, that would be deemed Promotional  
10 labeling or advertising under the FDCA or any regulation promulgated thereunder, or by the  
11 FDA, under the most current draft or final standard promulgated by the FDA or the most current  
12 draft or final FDA Guidance for Industry.

13 26. "Promotional Materials" shall mean any item used to Promote any GSK Product.

14 27. "Relevant State Consumer Protection Statutes" shall mean the consumer protection  
15 laws under which the Attorneys General have conducted the investigation.<sup>4</sup>

16 28. "Reprints Containing Off-Label Information" shall mean articles or reprints from a  
17 Scientific or Medical Journal, as defined in 21 C.F.R. 99.3(j), or Reference Publication, as  
18 defined in 21 C.F.R. 99.3(i), describing an Off-Label use of a GSK Product.

19  
20  
21 (...continued)

22 protection functions for the State of Georgia. References to the "States," "Parties," or "Attorneys  
23 General," with respect to Georgia, include the Administrator of the Fair Business Practices Act.

24 <sup>2</sup> Hawaii is being represented on this matter by its Office of Consumer Protection,  
25 an agency which is not part of the state Attorney General's Office, but which is statutorily  
26 authorized to undertake consumer protection functions, including legal representation of the State  
27 of Hawaii. For simplicity, the entire group will be referred to as the "Attorneys General," and  
28 such designation, as it includes Hawaii, refers to the Executive Director of the State of Hawaii  
Office of Consumer Protection.

<sup>3</sup> The Utah Attorney General's Office represents the Utah Division of Consumer  
Protection (Division), the state agency charged with enforcement of the Consumer Sales Practices  
Act, in this action, but is not a party itself. As to Utah, the definition of "Attorneys General"  
means the Utah Attorney General as counsel to the Division.

<sup>4</sup> In California, the relevant state consumer protection statutes are California  
Business and Professions Code sections 17200 et seq. and 17500 et seq.

29. "Unsolicited Request" shall mean a request for information regarding a GSK Product communicated to an agent of GSK that has not been prompted by GSK.

### III. COMPLIANCE PROVISIONS

30. In accordance with sections 17203 and 17535 of the California Business and Professions Code:

#### **Promotional Activities**

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

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

C. GSK's policies and procedures shall address compensation (including through salaries, bonuses, or other means) for GSK Sales and GSK Marketing. These policies and procedures shall: (1) be designed to ensure that financial incentives do not inappropriately motivate GSK Sales or GSK Marketing to engage in improper sales Promotion, sales and marketing of GSK Products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate Off-Label Promotion of GSK Products. GSK shall make reasonable efforts in good faith to seek contractual language with any third-party contractor of prescriber-facing sales personnel requiring that any such personnel contracted to Promote GSK Products will not be compensated based on territory/individual level sales goals. GSK represents that, prior to the Effective Date, it implemented a program in the United States to eliminate incentive compensation based on territory/individual level sales goals for prescriber-facing sales personnel (e.g., sales representatives) and their direct managers (Patient First Program). The Patient First Program is described in more detail in Attachment A. GSK shall continue its Patient First Program or a substantially equivalent program through March 1, 2019.

The following paragraphs D through F shall be effective for a period of eight years from the Effective Date of this Judgment.

D. GSK shall not make in a Promotional context a representation or suggestion, not

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

9 E. GSK shall not Promote any GSK Product by use of Promotional Materials that:

- 10 1. contain a drug comparison that represents or suggests that a drug is safer or  
11 more effective than another drug in some particular when it has not been  
12 demonstrated to be safer or more effective in such particular by substantial  
13 evidence or substantial clinical experience;
- 14 2. contain a representation or suggestion that a drug is safer than it has been  
15 demonstrated to be by substantial evidence or substantial clinical experience, by  
16 selective presentation of information from published articles or other references  
17 that report no side effects or minimal side effects with the drug or otherwise  
18 selects information from any source in a way that makes a drug appear to be safer  
19 than has been demonstrated;
- 20 3. present information from a study in a way that implies that the study  
21 represents larger or more general experience with the drug than it actually does; or
- 22 4. use statistics on numbers of patients or counts of favorable results or side  
23 effects, derived from pooling data from various insignificant or dissimilar studies  
24 in a way that suggests either that such statistics are valid if they are not or that they  
25 are derived from large or significant studies supporting favorable conclusions  
26 when such is not the case.

27 F. When presenting information about a clinical study regarding GSK Products in  
28 any Promotional Materials, GSK shall not do any of the following for information that



1 may be material to an HCP prescribing decision:

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

#### 12 **Clinical Research**

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

15 G. GSK shall report research in an accurate, objective, and balanced manner as  
16 follows and as required by applicable law. To the extent permitted by the National  
17 Library of Medicine and as required by the FDA Amendments Act of 2007 (Public Law  
18 No. 110-85), GSK shall register GSK-sponsored Applicable Clinical Trials beginning  
19 after the Effective Date with the applicable registry and submit results of GSK-sponsored  
20 Applicable Clinical Trials completed after the Effective Date to the registry and results  
21 data bank as required by the FDA Amendments Act and any accompanying regulations  
22 that may be promulgated pursuant to that Act.

23 H. When submitting a manuscript on the results of a clinical study regarding any GSK  
24 Product for publication, GSK shall:

- 25 1. adhere to the International Committee of Medical Journal Editors' Uniform
- 26 Requirements for Manuscripts Submitted to Biomedical Journals: Writing and
- 27 Editing for Biomedical Publications, including authorship criteria, unless the
- 28 applicable journal or congress to which the publication is submitted has more

1 stringent requirements, in which case the journal or congress criteria for authorship  
2 will be followed;

3 2. acknowledge GSK's role as a funding source of the study which is the  
4 subject of the manuscript; and

5 3. disclose any change to the plan for the statistical analysis for that clinical  
6 study if such change is inconsistent with GSK's standard operating procedure for  
7 Development, Review and Approval of Reporting and Analysis Plans. GSK's  
8 standard operating procedure for Development, Review and Approval of  
9 Reporting and Analysis Plans shall include requirements that such plans shall be  
10 consistent with the study protocol and shall be finalized before the date of final  
11 database release or interim database release (for an unblinded interim analysis).

12 I. For any GSK Product, GSK shall also post on GSK's clinical study registry any  
13 observational studies or Meta-analyses conducted by GSK that are designed to inform the  
14 effective, safe, and/or appropriate use of any GSK Product.

### 15 **Product Sampling**

16 The following subsection shall be effective for five years from the Effective Date of this  
17 Judgment.

18 J. GSK shall not provide samples of GSK Products to those HCPs who are not  
19 expected to prescribe the sampled GSK Products for an approved use, but who would be  
20 expected to prescribe the sampled product for an Off-Label use.

21 K. If an HCP who would not be expected to prescribe the GSK Product for an  
22 approved use, but who would be expected to prescribe the product for an unapproved use,  
23 requests samples of that GSK Product, GSK personnel shall refer the HCP to GSK  
24 Medical Affairs where the practitioner can speak directly with a GSK Medical Affairs  
25 representative who will provide answers to the HCP's questions about the GSK Product  
26 and GSK may provide him/her with samples only if appropriate (i.e., if the HCP requests  
27 the samples for an FDA approved ("on-label") use).

### 28 **Reprints**

1 The following subsection shall be effective for five years from the Effective Date of this  
2 Judgment.

3 L. GSK shall not disseminate information describing any Off-Label use of a GSK  
4 Product, unless such information and materials are consistent with applicable FDA  
5 regulations and FDA Guidances for Industry.

6 M. Reprints Containing Off-Label Information regarding a GSK Product:

7 1. shall be accompanied by the FDA-approved labeling for the product, or a  
8 clearly and conspicuously described hyperlink that will provide the reader with  
9 such information;

10 2. shall contain a disclosure that is prominently displayed, which would  
11 include the first page or as a cover page where practicable, indicating that the  
12 article discusses Off-Label information; and

13 3. shall not be referred to or used in a Promotional manner.

14 N. GSK shall not disseminate any Reprint Containing Off-Label Information that  
15 relates to studies submitted to the FDA that were reviewed and specifically rejected by the  
16 FDA.

17 O. Nothing in this Judgment shall preclude GSK from revising its policies and  
18 practices regarding the dissemination of Reprints Containing Off-Label Information to be  
19 consistent with applicable FDA regulations and FDA Guidances for Industry that are  
20 revised or newly issued after the Effective Date of this Judgment.

### 21 **Clinical Responses**

22 The following subsection shall be effective for five years from the Effective Date of this  
23 Judgment.

24 P. GSK, through GSK Scientifically Trained Personnel, shall have ultimate  
25 responsibility for developing and approving all Clinical Responses regarding a GSK  
26 Product, including any that may describe Off-Label information. Additional approvals  
27 may be provided by the GSK Law Department. GSK shall not distribute any such  
28 materials unless:

1. Clinically Relevant Information is included in these materials to provide scientific balance;
2. data in these materials are presented in an unbiased, non-Promotional manner; and
3. these materials are clearly and conspicuously distinguishable from sales aids and other Promotional Materials.

Nothing in this subsection shall prohibit GSK Scientifically Trained Personnel from disseminating materials that are permitted to be distributed under Federal law.

Q. GSK Sales and GSK Marketing personnel shall not develop the medical content of Clinical Responses regarding a GSK Product.

R. Clinical Responses regarding a GSK Product may be disseminated only by GSK Scientifically Trained Personnel to HCPs, and GSK Sales and GSK Marketing personnel shall not disseminate these materials to HCPs except in circumstances implicating public health and safety issues. In such circumstances, GSK Sales and GSK Marketing personnel may disseminate a Clinical Response directly to HCPs when expressly authorized by the Health Care Compliance Officer, the Vice President of Medical/Scientific Affairs responsible for the GSK Product(s) included in the Clinical Response(s), and counsel from the GSK Law Department.

#### **Responses to Unsolicited Requests for Off-Label Information**

The following subsection shall be effective for five years from the Effective Date of this Judgment.

S. In responding to an Unsolicited Request for Off-Label information regarding a GSK Product, including any request for a specific article related to Off-Label uses, GSK shall:

1. advise the requestor that the request concerns an Off-Label use; and
2. inform the requestor of the drug's FDA-approved indication(s), provide labeling information and, where relevant to the Unsolicited Request, provide dosage information.

1 T. If GSK elects to respond to an Unsolicited Request for Off-Label information  
2 regarding a GSK Product, GSK Scientifically Trained Personnel shall provide specific,  
3 accurate, objective, and scientifically-balanced responses. Any such response shall not  
4 Promote a GSK Product for any Off-Label use(s).

5 U. Any written response to an Unsolicited Request for Off-Label information  
6 regarding a GSK Product shall include:

- 7 1. an existing Clinical Response prepared in accordance with Section III.P-R  
8 of this Judgment.
- 9 2. a Clinical Response prepared in response to the request in accordance with  
10 Section III.P-R of this Judgment; or
- 11 3. a report containing the results of a reasonable literature search using terms  
12 from the request.

13 V. Only GSK Scientifically Trained Personnel may respond in writing to an  
14 Unsolicited Request for Off-Label information regarding a GSK Product.

15 W. GSK Sales and GSK Marketing personnel may respond orally to an Unsolicited  
16 Request for Off-Label information regarding a GSK Product only by offering to request  
17 on behalf of the requester that a Clinical Response prepared in accordance with Section  
18 III.P-R of this Judgment or other information set forth in the current section above be sent  
19 in follow-up or by offering to put the requester in touch with GSK Medical Affairs. GSK  
20 Non-Scientifically Trained Personnel shall not characterize, describe, identify, name, or  
21 offer any opinions about or summarize any such Off-Label information.

## 22 Grants

23 The following subsection shall be effective for five years from the Effective Date of this  
24 Judgment.

25 X. GSK shall disclose information about medical education grants, including  
26 continuing medical education (CME) grants, regarding a GSK Product as required by  
27 applicable law.

28 Y. GSK Medical Affairs shall manage all requests for funding related to medical

1 education grants relating to a GSK Product. Approval decisions shall be made by GSK  
2 Medical Affairs, and shall be kept separate from the GSK Sales and GSK Marketing  
3 organizations.

4 Z. GSK shall not use medical education grants or any other type of grant to Promote a  
5 GSK Product. This provision includes, but is not limited to, the following prohibitions:

- 6 1. GSK Sales and GSK Marketing personnel shall not initiate, coordinate or  
7 implement grant applications on behalf of any customer or HCP;
- 8 2. GSK Sales and GSK Marketing personnel shall not be involved in  
9 selecting grantees or medical education speakers; and
- 10 3. GSK shall not measure or attempt to track in any way the impact of grants  
11 or speaking fees on participating HCPs' subsequent prescribing habits, practices or  
12 patterns.

13 AA. GSK shall not condition funding of a medical education program grant request  
14 relating to a GSK Product upon the requester's selection or rejection of particular  
15 speakers.

16 BB. GSK shall not suggest, control, or attempt to influence the specific topic, title,  
17 content, speakers or audience for CMEs relating to a GSK Product, consistent with  
18 Accreditation Council for Continuing Medical Education (ACCME) guidelines.

19 CC. GSK Sales and GSK Marketing personnel shall not approve grant requests  
20 regarding a GSK Product, nor attempt to influence the awarding of grants to any  
21 customers or HCPs for their prescribing habits, practices, or patterns.

22 DD. GSK shall contractually require each medical education provider to clearly and  
23 conspicuously disclose to attendees of a medical education program regarding any GSK  
24 Product(s) GSK's financial support of the medical education program and any financial  
25 relationship with faculty and speakers at such medical education program.

26 EE. After initial delivery of a CME program regarding a GSK Product, GSK shall not  
27 knowingly fund the same program, nor shall it provide additional funding for re-  
28 distribution of the same program, if the program's speakers are Promoting a GSK Product

1 for Off-Label use in that program.

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

3  
4 31. Within thirty (30) days of the Effective Date of this Judgment, Defendant shall pay  
5 \$105 million (\$105,000,000) to be divided and paid by Defendant directly to each Attorney  
6 General of the Multistate Working Group in an amount to be designated by and in the sole  
7 discretion of the Multistate Executive Committee.<sup>5</sup> Said payment shall be used by the Attorneys  
8 General for attorneys' fees and other costs of investigation and litigation, or to be placed in, or  
9 applied to, the consumer protection enforcement fund, consumer education or litigation or local  
10 consumer aid or revolving fund, used to defray the costs of the inquiry leading hereto, or for other  
11 uses permitted by state law, at the sole discretion of each Attorney General. The Parties  
12 acknowledge that the payment described herein is not a fine or penalty, or payment in lieu  
13 thereof.

14 **V. RELEASE**

15 32. By execution of this Judgment, the State of California releases and forever discharges  
16 GSK and all of its past and present, assigns, directors, divisions, employees, officers, parents,  
17 predecessors, shareholders, subsidiaries, successors, and transferees (collectively, the Released  
18 Parties), from the following: all civil claims, causes of action, parens patriae claims, damages,  
19 restitution, fines, costs, attorneys' fees, remedies and/or penalties that were or could have been  
20 asserted against the Released Parties by the Attorney General under California Business and  
21 Professions Code sections 17200 et seq. and 17500 et seq. or any amendments thereto, or by  
22 common law claims concerning unfair, deceptive, or fraudulent trade practices resulting from the  
23 Covered Conduct, up to and including the Effective Date of this Judgment (collectively, the  
24 Released Claims).

25  
26  
27  
28 <sup>5</sup> The State of California's share is \$7,087,897.93.

33. Notwithstanding any term of this 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:

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

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

1. State or federal antitrust violations;

2. Medicaid violations, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to California's Medicaid program;

3. Claims involving “best price,” “average wholesale price,” or “wholesale acquisition cost”;

4. State false claims violations; and

5. Claims to enforce the terms and conditions of this Judgment.

C. Actions of state program payors of the State of California arising from the Covered Conduct, except for the release of civil penalties under the Relevant State Consumer Protection Laws.

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

## VI. CONFLICTS

34. If, subsequent to the Effective Date of this 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 Judgment that creates a conflict with any provision of the Judgment and GSK intends to comply with the newly enacted legislation or regulation, GSK shall notify the Attorneys General (or the Attorney General of the affected State) of the same. If the Attorney



1 General agrees, she shall consent to a modification of such provision of the Judgment to the  
2 extent necessary to eliminate such conflict. If the Attorney General disagrees and the Parties are  
3 not able to resolve the disagreement, GSK shall seek a modification from an appropriate court of  
4 any provision of this Judgment that presents a conflict with any such federal or state law or  
5 regulation. Changes in federal or state laws or regulations, with respect to the matters governed  
6 by this Judgment, shall not be deemed to create a conflict with a provision of this Judgment  
7 unless GSK cannot reasonably comply with both such law or regulation and the applicable  
8 provision of this Judgment.

## 9 **VII. DISPUTE RESOLUTION**

10 35. For the purposes of resolving disputes with respect to compliance with this Judgment,  
11 should any of the signatory Attorneys General believe that GSK has violated a provision of this  
12 Judgment subsequent to the Effective Date, then such Attorney General shall notify GSK in  
13 writing of the specific objection, identify with particularity the provisions of this Judgment that  
14 the practice appears to violate, and give GSK 30 days to respond to the notification.

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

20 37. Except as set forth in Paragraphs 39 and 40 below, the Attorney General may not take  
21 any action during the 30 day response period. Nothing shall prevent the Attorney General from  
22 agreeing in writing to provide GSK with additional time beyond the 30 days to respond to the  
23 notice.

24 38. The Attorney General may not take any action during which a modification request is  
25 pending before a court pursuant to Paragraph 34, except as provided for in Paragraphs 39 and 40  
26 below.

27 39. Nothing in this Judgment shall be interpreted to limit the State's Civil Investigative  
28 Demand (CID) or investigative subpoena authority.

1        40. The Attorney General may assert any claim that GSK has violated this Judgment in a  
2 separate civil action to enforce compliance with this Judgment, or may seek any other relief  
3 afforded by law, but only after providing GSK an opportunity to respond to the notification as  
4 described above and to remedy the alleged violation within the 30 day response period as  
5 described above, or within any other period as agreed to by GSK and the Attorney General;  
6 provided, however, that the Attorney General may take any action if the Attorney General  
7 believes that, because of the specific practice, a threat to the health or safety of the public requires  
8 immediate action.

9                    **VIII. COMPLIANCE WITH ALL LAWS**

10        41. Except as expressly provided in this Judgment, nothing in this Judgment shall be  
11 construed as:

- 12            A. relieving GSK of its obligation to comply with all applicable state laws, regulations,  
13 or rules, or granting permission to engage in any acts or practices prohibited by any law,  
14 regulation, or rule; or
- 15            B. limiting or expanding in any way any right any state represented by the Multistate  
16 Working Group may otherwise have to enforce applicable state law or obtain information,  
17 documents, or testimony from GSK pursuant to any applicable state law, regulation, or  
18 rule, or any right GSK may otherwise have to oppose any subpoena, civil investigative  
19 demand, motion, or other procedure issued, served, filed, or otherwise employed by the  
20 State pursuant to any such state law, regulation, or rule.

21                    **IX. GENERAL PROVISIONS**

22        42. This Court retains jurisdiction of this Judgment and the Parties hereto for the purpose  
23 of enforcing and modifying this Judgment and for the purpose of granting such additional relief as  
24 may be necessary and appropriate.

25        43. This Judgment relates solely to GSK's business in the United States.

26        44. This Judgment (or any portion thereof) shall in no way be construed to prohibit GSK  
27 from making representations with respect to any GSK Product that are permitted under Federal  
28 law or labeling for the drug under the most current draft or final standard promulgated by the

1 FDA or the most current draft or final FDA Guidance for Industry, or permitted or required under  
2 any IND, NDA, sNDA, or ANDA approved by the FDA, so long as the representation, taken in  
3 its entirety, is not false, misleading or deceptive.

4 45. Nothing in this Judgment shall:

5 A. require GSK to take any action that is prohibited by the FDCA or any regulation  
6 promulgated thereunder, or by the FDA; or

7 B. require GSK to fail to take any action that is required by the FDCA or any regulation  
8 promulgated thereunder, or by the FDA; or

9 C. preclude GSK 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  
11 out its responsibilities for the selection of drugs for managed care or other similar  
12 organizations pursuant to the standards of Section 114 of the Food and Drug Administration  
13 Modernization Act of 1997 (FDAMA), if the information directly relates to an approved  
14 indication of a GSK Product, and if based on competent and reliable scientific evidence.

15 46. Nothing in this Judgment is intended to modify any prior settlement agreements  
16 between California and GlaxoSmithKline LLC formerly known as SmithKline Beecham  
17 Corporation, d/b/a GlaxoSmithKline, and SB Pharmco Puerto Rico, Inc.

18 47. Nothing will prevent the Attorney General from agreeing in writing to provide GSK  
19 with additional time to perform any act required by the Judgment. The Attorney General shall not  
20 unreasonably withhold her consent to the request for additional time.

21 48. To the extent that any provision of this Judgment obligates GSK to change any  
22 policy(ies) or procedure(s) and to the extent not already accomplished, GSK shall implement the  
23 policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 120 days after the  
24 Effective Date.

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26 ///

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

3 For GlaxoSmithKline LLC:

4 Matthew J. O'Connor  
5 Covington & Burling LLP  
6 1201 Pennsylvania Avenue, NW  
7 Washington, DC 20004-2401

8 For State of California:  
9 Judith Fiorentini, Deputy Attorney General  
10 California Attorney General's Office  
11 110 West A Street, Suite 1100  
12 San Diego, California 92101

13 50. The Clerk is ordered to enter this Judgment forthwith.

14 Dated: \_\_\_\_\_

15 \_\_\_\_\_  
16 JUDGE OF THE SUPERIOR COURT  
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1  
2 **ATTACHMENT A**

3 **Employee and Executive Incentive Compensation Policies and Practices**

4 Pursuant to its existing Patient First Program, GSK agrees that it will not provide financial  
5 reward (through compensation, including incentive compensation or otherwise) or discipline  
6 (through tangible employment action) to its prescribing-customer-facing field sales professionals  
7 (pharmaceutical sales representatives) or their direct managers based upon the volume of sales of  
8 GSK Products within a given employee's own territory or the manager's district. The Patient  
9 First Program includes evaluations for sales representatives based on business acumen, customer  
10 engagement, and scientific knowledge about GSK's Products. GSK shall continue its Patient  
11 First Program, or a substantially equivalent program through March 1, 2019. GSK commits to  
12 maintaining through at least March 1, 2019, absent agreement otherwise with the Multistate  
13 Executive Committee, the restrictions on such tangible employment decisions set forth in its Use  
14 of Territory/Individual Sales Data policy.  
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