STATE OF MAINE
KENNEBEC, ss.

SUPERIOR COURT
CIVIL ACTION
Docket No.

STATE OF MAINE,	)	
	)	
	)	
Plaintiff,	)	
	)	
v.	)	**COMPLAINT**
	)	**(Injunctive Relief**
GLAXOSMITHKLINE LLC,	)	**Requested)**
	)	
Defendant.	)	
	)	

1. Plaintiff, State of Maine, in its sovereign capacity, by and through Janet T. Mills, Attorney General of the State of Maine, ("Attorney General" or "State") brings this action against Defendant GLAXOSMITHKLINE LLC for violating the Maine Unfair Trade Practices Act ("Maine UTPA"), 5 M.R.S. § 205-A, *et seq.*

2. The Attorney General brings this action pursuant to the Maine UTPA, in the public interest, to protect the public's health, safety and welfare and pursuant to her general statutory and common law authority powers and duties. *See* 5 M.R.S. § 205-A, *et seq.* The Attorney General has reason to believe that the above-named Defendant has violated and/or is continuing to violate the Maine UTPA. The Attorney General also has reason to believe that this action is in the public interest.

3. Upon interest and belief, the State of Maine alleges as follows:

JURISDICTION AND VENUE

4. This Court has jurisdiction over Defendant pursuant to 5 M.R.S. § 209 because

Defendant has transacted business within the State of Maine at all times relevant to this Complaint.

5. Venue for this action properly lies in Kennebec County, Maine, pursuant to 5 M.R.S. § 209.

PARTIES

6. Plaintiff is the State of Maine, represented by the Attorney General, who is charged with enforcing the Maine UTPA, which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce. Pursuant to the Maine UTPA, the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the Maine UTPA and to secure such equitable and other relief as may be appropriate in each case.

7. Defendant GLAXOSMITHKLINE LLC ("GSK") is a Delaware corporation with a principal place of business at 5 Crescent Drive, Philadelphia, Pennsylvania 19112. GSK transacts business in Maine by developing, manufacturing, promoting, selling, and distributing prescription drugs.

COMMERCE

8. Subsection 206(3) of the Maine Unfair Trade Practices Act, defines "trade and commerce" as follows:

> "Trade' and 'commerce' shall include the advertising, offering for sale, sale or distribution of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity or thing of value wherever situate, and shall include any trade or commerce directly or indirectly affecting the people of this State.

5 M.R.S. § 206(3).

9. Defendant was, at all times relative hereto, engaged in trade or commerce in the State of Maine by developing, manufacturing, promoting, selling, and distributing prescription

drugs.

ALLEGATIONS RELATING TO DEFENDANT'S MARKETING OF ADVAIR, PAXIL, AND WELLBUTRIN

I. ADVAIR

A. The Basic Medicine of Asthma

10. The National Institute of Health (NIH) published consensus guidelines for the diagnosis and treatment of asthma, which categorize patients into those with mild, moderate, and severe asthma.

11. Patients with occasional symptoms are categorized as mild "intermittent."

12. The NIH recommended treatment for mild intermittent asthma is a short-acting beta agonists (SABA), such as albuterol, on an as needed basis in response to symptoms.

13. Patients with regular asthma symptoms are categorized as persistent.

14. For persistent asthma, the NIH guidelines recommend using a "controller" in addition to a SABA.

15. For mild persistent asthma, the NIH Guidelines recommend an inhaled corticosteroid (ICS) used to treat inflammation in the airways as a "first line" treatment as a controller along with a SABA on an as needed basis as "rescue medicine" to open up airways during acute asthma attacks. In the asthma context, "first line" use refers to the first controller medication a patient is prescribed.

16. For moderate asthma, the NIH Guidelines recommend adding a second controller medication, such as a long-acting beta agonist (LABA), used to keep airways open and intended for chronic use, to the ICS along with as needed use of a SABA for acute episodes.

B. Advair's Label

17. The ADVAIR DISKUS® (Advair) is GSK's trade name for an inhaled combination drug for treatment of a number of respiratory conditions, including asthma.

18. Advair is a combination of two other GSK drugs: Flovent® (fluticasone propionate), an ICS, and Serevent® (salmeterol xinafoate), a LABA.

19. Advair is sold in three strengths: Advair Diskus 100/50, Advair Diskus 250/50, and Advair Diskus 500/50.

20. On August 24, 2000, the FDA approved Advair for sale in the United States.

21. At the time of FDA approval in August 2000, the Advair label's Indications section stated that it was "indicated for the long term, twice-daily, and maintenance treatment of asthma." However, the Dosage and Administration section of the label provided that Advair was for "patients who are not currently on an inhaled corticosteroid, whose disease severity warrants treatment with 2 maintenance therapies . . . ."

22. In 2001, GSK submitted a supplemental New Drug Application (sNDA) for Advair that sought a broader first-line dosing instruction by providing additional clinical data and by removing "whose disease severity warrants treatment with 2 maintenance therapies" from the Dosage and Administration section of the label.

23. The FDA did not approve the sNDA and in 2002, GSK withdrew the application.

24. In early 2003, GSK halted a clinical trial relating to salmeterol (one of Advair's component drugs).

25. In August 2003, the FDA required the addition of a black box warning to Advair's label that stated "data from a large placebo-controlled US study that compared the safety of salmeterol (SEREVENT® Inhalation Aerosol) or placebo added to usual asthma therapy showed a small but significant increase in asthma-related deaths in patients . . . ."

26. In March 2006, the Indications section of the Advair label was modified to state that Advair was not indicated for patients with asthma controlled on ICS and SABAs alone. The Dosage and Administration section of the Advair label was also changed to state that "physicians should only prescribe ADVAIR DISKUS® for patients not adequately controlled on the other asthma-controller medications . . . or whose disease severity clearly warrants initiation of treatment with 2 maintenance therapies."

27. In June 2010, the black box warning on the Advair label was revised to state that the currently available data were inadequate to determine if drugs like Advair provide a level of control that mitigates the increased risk of death from LABA, and that LABA increases the risk of asthma-related hospitalization in pediatric and adolescent patients.

28. The revised black box warning also directs physicians to "step down" patients and discontinue Advair if possible after asthma control is achieved and maintained.

29. This black box revision also added "[d]o not use ADVAIR DISKUS® for patients whose asthma is adequately controlled on low or medium dose inhaled corticosteroids."

C. GSK'S Marketing of Advair

30. From the time of Advair's launch in 2000 until the 2010 label changes, GSK used false and misleading representations to promote Advair as a first line treatment for all asthma patients, including mild asthma patients who were not on ICS medication and only used SABAs intermittently.

31. GSK also provided financial incentives to GSK sales representatives to promote Advair for mild asthma patients, which encouraged sales representatives to make false and misleading representations to health care professionals.

32. GSK also promoted Advair as a first line treatment for mild asthma patients by distributing clinical trials that had been determined by the FDA to be insufficient evidence for the first line treatment for mild asthma patients to health care professionals, without disclosing health care professionals that the FDA rejected that evidence as insufficient.

II. PAXIL

33. Paxil® is GSK's trade name for the drug paroxetine hydrochloride, which is one of a class of drugs known as selective serotonin reuptake inhibitors (SSRIs).

34. In 1992, the FDA approved Paxil to treat depression in adults, and it was subsequently approved for other uses in adults.

35. The FDA never approved Paxil for patients under the age of 18.

36. Nonetheless, between 1999 and 2003, GSK deceptively promoted Paxil as safe and effective for children and adolescents, despite lack of FDA approval and three GSK clinical trials that both failed to demonstrate Paxil's effectiveness in children and adolescents and raised concerns that Paxil may be associated with an increased risk of suicide in such patient population.

III. WELLBUTRIN

37. Wellbutrin® is GSK's trade name for the drug bupropion hydrochloride, which is one of a class of drugs known as norepinephrine-dopamine reuptake inhibitors (NDRIs).

38. In 1985, the FDA approved Wellbutrin to treat major depressive disorder in adults.

39. Between 1999 and 2003, Wellbutrin was not approved for any use other than treating major depressive disorder in adults.

40. Despite this limited indication, between 1999 and 2003, GSK promoted

Wellbutrin for various indications for which GSK had never submitted substantial evidence of safety and efficacy to the FDA, including weight loss and the treatment of obesity; treatment of sexual dysfunction; treatment of Attention Deficit Hyperactivity Disorder; treatment of addictions; treatment of anxiety; treatment of bipolar disorder; and treatment of patients under the age of 18.

41. GSK engaged in the off-label promotion of Wellbutrin by encouraging sales representatives to detail health care professionals directly on the off-label uses; through speaker programs that promoted off-label; through continuing medical education programs; by paying health care professionals to attend lavish meetings in places like Jamaica and Bermuda where GSK provided off-label information about Wellbutrin; and by paying health care professionals to be "consultants" on "advisory boards" where they were presented with information about off-label uses.

VIOLATIONS OF LAW: MAINE UTPA

42. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 41.

43. Defendant, in the course of engaging in the development, manufacture, promotion, sales, and interstate distribution of prescription drugs, has engaged in a course of trade or commerce which constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under the 5 M.R.S. § 207, by making representations about Advair, Paxil, and Wellbutrin when Defendant knew the representations were not true.

44. Defendant, in the course of marketing, promoting, selling, and distributing the prescription drugs Advair, Paxil, and Wellbutrin, has engaged in a course of trade or commerce which constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under 5

M.R.S. § 207, by representing that Advair, Paxil, and Wellbutrin have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, State of Maine, respectfully request that this honorable Court enter an order:

A. That pursuant to 5 M.R.S. § 209, this Court permanently enjoin Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in the aforementioned unfair, deceptive or misleading conduct acts or practices which violate the Maine UTPA;

B. Ordering Defendant to pay civil penalties of up to $10,000 for each and every intentional violation of the Maine UTPA;

C. Ordering Defendant to pay all costs for the prosecution and investigation of this action, as provided by 5 M.R.S. § 209; and

D. Granting Plaintiff such other and further relief as the Court deems equitable and proper.

Dated at Augusta, Maine this 4th day of June, 2014.

Respectfully submitted,

JANET T. MILLS
ATTORNEY GENERAL

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STATE OF MAINE
KENNEBEC, SS.

SUPERIOR COURT
CIVIL ACTION
Docket No. CV-14-107

STATE OF MAINE,

Plaintiff,

vs.

GLAXOSMITHKLINE LLC

Defendant.

CONSENT JUDGMENT

Plaintiff, State of Maine, has filed a Complaint for a permanent injunction and other relief in this matter pursuant to 5 M.R.S. § 209 of the Maine Unfair Trade Practices Act alleging that Defendant GLAXOSMITHKLINE LLC (hereinafter "GSK") committed violations of the aforementioned Act. Plaintiff, by its counsel, and GSK, by its counsel, have agreed to the entry of this Consent 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.

I. DEFINITIONS

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

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

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

3. "Clinically Relevant Information" shall mean information that reasonably prudent clinicians would consider relevant when making prescribing decisions regarding a GSK Product.

4. "Clinical Response" shall mean a non-Promotional, scientific communication to address

Unsolicited Requests for medical information.

5. "Covered Conduct" shall mean GSK's Promotional practices, dissemination of information, and remuneration to HCPs regarding the prescription drugs Advair®, Paxil®, and Wellbutrin® in the United States.

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

7. "GlaxoSmithKline LLC," "GlaxoSmithKline," or "GSK" shall mean GlaxoSmithKline LLC, including all of its predecessors, subsidiaries, successors, and assigns.

8. "GSK Law Department" shall mean personnel of the GSK Law Department or its designee providing legal advice to GSK.

9. "GSK Marketing" shall mean GSK personnel responsible for marketing GSK Products.

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

11. "GSK Product" or "GSK Products" shall mean: (1) Advair®; (2) Paxil®: (3) Wellbutrin®; (4) any pharmaceutical or biological product approved by the Food and Drug Administration for the treatment of major depressive disorder; (5) any selective serotonin reuptake inhibitor (SSRI); and (6) any norepinepherine dopamine reuptake inhibitor (NDRI),that GSK Promotes or for which it directs Promotion.

12. "GSK Sales" shall mean the GSK sales force responsible for selling GSK Products.

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

14. "Health Care Professional" or "HCP" shall mean any physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical products.

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

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

17. "Multistate Working Group" shall mean the Attorneys General and their staff representing Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the

District of Columbia, Florida, Georgia[1], Hawaii[2], Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, 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[3], Vermont, Virginia, Washington, Wisconsin, and Wyoming.

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

19. "Parties" shall mean the Maine Attorney General and GSK.

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

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

22. "Relevant State Consumer Protection Statutes" shall mean the consumer protection laws

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1 With regard to Georgia, the Administrator of the Fair Business Practices Act, appointed pursuant to O.C.G.A. § 10-1-395, is statutorily authorized to undertake consumer protection functions for the State of Georgia. References to the "States," "Parties," or "Attorneys General," with respect to Georgia, include the Administrator of the Fair Business Practices Act.

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

3 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.

under which the Attorneys General have conducted the investigation.[4]

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

24. "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.

II. FINDINGS

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

2. The terms of this Consent Judgment shall be governed by the laws of the State of Maine.

3. Entry of this Consent Judgment is in the public interest and reflects a negotiated agreement among the Parties.

4. GlaxoSmithKline, at all times relevant hereto, engaged in trade and commerce affecting consumers, within the meaning of the Maine Unfair Trade Practices Act in the State of Maine, including, but not limited to, Kennebec County.

5. The Attorneys General conducted an investigation regarding the Covered Conduct. The Parties have agreed to resolve the concerns related to the Covered Conduct under the Relevant State Consumer Protection Laws by entering into this Consent Judgment. This Consent Judgment reflects a negotiated agreement entered into by the Parties as their own free and voluntary act, and with full knowledge and understanding of the nature of the proceedings and the obligations and duties imposed by this Consent Judgment. GSK is entering into this Consent Judgment solely for the purpose of settlement, and nothing contained herein may be taken as or

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[4] In Maine, the relevant state consumer protection statute is the Maine Unfair Trade Practices Act, 5 M.R.S. §§ 205-A *et seq.*

construed to be an admission or concession of any violation of law or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which GSK expressly denies. Through this Consent Judgment, GSK does not admit any violation of law, and does not admit any wrongdoing that was or could have been alleged by any of the signatory Attorneys General before the date of the Consent Judgment. No part of this Consent Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by GSK. This Consent Judgment does not constitute an admission by GSK that the Covered Conduct violated or could violate the Relevant State Consumer Protection Laws. It is the intent of the Parties that this Consent Judgment shall not be admissible or binding in any other matter, including, but not limited to, any investigation or litigation, other than in connection with the enforcement of this Consent Judgment. No part of this Consent Judgment shall create a private cause of action or convert any right to any third party for violation of any federal or state statute or law, except that an Attorney General may file an action to enforce the terms of this Consent Judgment. Nothing contained herein prevents or prohibits the use of this Consent Judgment for purposes of enforcement by the Maine Attorney General.

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

terms of this Consent Judgment.

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

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

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

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

11. This Consent Judgment relates solely to GSK's business in the United States.

12. This Consent Judgment (or any portion thereof) shall in no way be construed to prohibit GSK from making representations with respect to any GSK Product that are permitted under Federal law or labeling for the drug under the most current draft or final standard promulgated by the FDA or the most current draft or final FDA Guidance for Industry, or permitted or required under any IND, NDA, sNDA, or ANDA approved by FDA, so long as the representation, taken in its entirety, is not false, misleading or deceptive.

13. Nothing in this Judgment shall require GSK to:

a) take any action that is prohibited by the FDCA or any regulation promulgated

thereunder, or by the FDA; or

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

or shall preclude GSK from providing health care economic information to a formulary committee or similar entity or its members in the course of the committee or entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations pursuant to the standards of Section 114 of the Food and Drug Administration Modernization Act of 1997 (FDAMA), if the information directly relates to an approved indication of a GSK Product, and if based on competent and reliable scientific evidence.

III. COMPLIANCE PROVISIONS

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

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

1. contain a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience;

2. contain a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by

selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated;

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

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

F. When presenting information about a clinical study regarding GSK Products in any Promotional Materials, GSK shall not do any of the following for information that may be material to an HCP prescribing decision:

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

2. use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results; or

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

formal statistical evaluations.

Clinical Research

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

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

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

1. adhere to the ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications, including authorship criteria, unless the applicable journal or congress to which the publication is submitted has more stringent requirements, in which case the journal or congress criteria for authorship will be followed;
2. acknowledge GSK's role as a funding source of the study which is the subject of the manuscript; and
3. disclose any change to the plan for the statistical analysis for that clinical study if such change is inconsistent with GSK's standard operating procedure for Development, Review and Approval of Reporting and Analysis Plans. GSK's

standard operating procedure for Development, Review and Approval of Reporting and Analysis Plans shall include requirements that such plans shall be consistent with the study protocol and shall be finalized before the date of final database release or interim database release (for an unblinded interim analysis).

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

Product Sampling

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

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

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

Reprints

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

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

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

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

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

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

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

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

Clinical Responses

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

P. GSK, through GSK Scientifically Trained Personnel, shall have ultimate responsibility for developing and approving all Clinical Responses regarding a GSK Product, including any that may describe Off-Label information. Additional approvals may be provided by the GSK

Law Department. GSK shall not distribute any such 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.

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

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

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

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

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

Grants

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

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

Y. GSK Medical Affairs shall manage all requests for funding related to medical education grants relating to a GSK Product. Approval decisions shall be made by GSK Medical Affairs, and shall be kept separate from the GSK Sales and GSK Marketing organizations.

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

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

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

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

CC. GSK Sales and GSK Marketing personnel shall not approve grant requests regarding a

GSK Product, nor attempt to influence the awarding of grants to any customers or HCPs for their prescribing habits, practices, or patterns.

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

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

IV. DISBURSEMENT OF PAYMENTS: PAYMENT TO THE STATES

Within 30 days of the Effective Date of this Consent Judgment, GSK shall pay $105 million to be divided and paid by GSK directly to each Attorney General of the Multistate Working Group in an amount designated by and in the sole discretion of the Multistate Executive Committee.[5] Said payment shall be used by the Attorneys General for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, consumer education or litigation or local consumer aid or revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted by state law, at the sole discretion of each Attorney General. The Parties acknowledge that the payment described herein is not a fine or penalty, or payment in lieu thereof.

[5] The State of Maine's share is $1,260,968.03.

V. REPRESENTATIONS AND WARRANTIES

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

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

VI. RELEASE

A. By execution of this Consent Judgment, the State of Maine releases and forever discharges GSK and all of its past and present, assigns, directors, divisions, employees, officers, parents, predecessors, shareholders, subsidiaries, successors, and transferees (collectively, the "Released Parties"), from the following: all civil claims, causes of action, parens patriae claims, damages, restitution, fines, costs, attorneys' fees, remedies and/or penalties that were or could have been asserted against the Released Parties by the Attorney General under the Maine Unfair Trade Practices Act or any amendments thereto, or by common law claims concerning unfair, deceptive, or fraudulent trade practices resulting from the Covered Conduct, up to and including the Effective Date of this Consent Judgment (collectively, the "Released Claims").

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

of the following:

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

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

    a. State or federal antitrust violations;

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

    c. Claims involving "best price," "average wholesale price," or "wholesale acquisition cost;"

    d. State false claims violations; and

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

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

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

VII. CONFLICTS

If, subsequent to the Effective Date of this Consent Judgment, the federal government or any state, or any federal or state agency, enacts or promulgates legislation or regulations with

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

VIII. DISPUTE RESOLUTION

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

B. Upon receipt of written notice from any of the Attorneys General, GSK shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why GSK believes it is in compliance with the Consent Judgment or a detailed

explanation of how the alleged violation occurred and statement explaining how and when GSK intends to remedy the alleged violation.

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

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

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

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

IX. COMPLIANCE WITH ALL LAWS

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

1. relieving GSK of its obligation to comply with all applicable state laws,

regulations, or rules, or granting permission to engage in any acts or practices prohibited by any law, regulation, or rule; or

2. limiting or expanding in any way any right any state represented by the Multistate Working Group may otherwise have to enforce applicable state law or obtain information, documents, or testimony from GSK pursuant to any applicable state law, regulation, or rule, or any right GSK may otherwise have to oppose any subpoena, civil investigative demand, motion, or other procedure issued, served, filed, or otherwise employed by the State pursuant to any such state law, regulation, or rule.

X. GENERAL PROVISIONS

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

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

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

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

For GlaxoSmithKline LLC:

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

For State of Maine:

Christina M. Moylan, AAG
Consumer Protection Division
Maine Attorney General's Office
6 State House Station
Augusta, Maine 04333-0006

APPROVED:

FOR DEFENDANT GLAXOSMITHKLINE LLC

By: _____ 5/30/2014

Date

Geoffrey E. Hobart
Matthew J. O'Connor
Covington & Burling LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401
(202) 662-5469

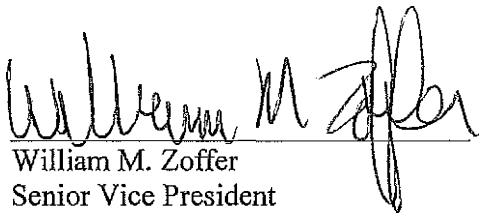
APPROVED:

FOR DEFENDANT GLAXOSMITHKLINE LLC

By: _____ 5/19/14
Robert H. Stier, Jr. Date
Maine Bar No. 3740
Pierce Atwood LLP
Merrill's Wharf
254 Commercial Street
Portland, ME 04101

APPROVED:

FOR DEFENDANT GLAXOSMITHKLINE LLC

By:  27 May 2014

William M. Zoffer
Senior Vice President
GlaxoSmithKline LLC

Date

APPROVED:

PLAINTIFF, STATE OF MAINE

By: Christina M. Moylan 6-4-14

Christina M. Moylan, AAG
Consumer Protection Division
Maine Bar No. 7095
Maine Attorney General's Office
6 State House Station
Augusta, Maine 04333-0006

Date

APPROVED BY THE COURT:

MAINE SUPERIOR COURT JUSTICE

Date Entered: 6/10/14