SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into by and among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the United States Department of Health and Human Services ("HHS"), the TRICARE Management Activity ("TMA"), the United States Department of Veteran Affairs ("VA"), and the United States Office of Personnel Management ("OPM") (collectively the "United States"), and GlaxoSmithKline LLC ("GSK"), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. GlaxoSmithKline LLC is a Delaware limited liability company and an indirect subsidiary of GlaxoSmithKline plc, a public limited company incorporated under English law with headquarters in Brentford, England. At all relevant times, GSK developed, manufactured, distributed, marketed and sold pharmaceutical products in the United States, including drugs sold under the trade names Avandia, Avandamet, and Avandaryl (collectively, the "Covered Drugs"), which were medications for treatment of Type 2 diabetes.

B. On such date as may be determined by the Court, GSK will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the "Plea Agreement") to an Information to be filed in United States of America v. GlaxoSmithKline LLC, Criminal Action No. [to be assigned] (District of Massachusetts) (the "Criminal Action") that will allege violations of Title 21, United States Code, Sections 331(a), 333(a)(1) and 352, namely, the introduction into interstate commerce of the misbranded drugs Wellbutrin and Paxil, and a violation of Title 21, United States Code, Sections 331(e), 333(a)(1), and 355(k)(1), namely, that GSK failed to report data
relating to clinical experience, along with other data and information, regarding Avandia to the Food and Drug Administration ("FDA") in mandatory reports, in violation of the Food, Drug and Cosmetic Act ("FDCA").

C. GSK has entered into or will be entering into separate settlement agreements, described in Paragraph 1(b) below (hereinafter referred to as the "Medicaid State Settlement Agreements") with certain states and the District of Columbia in settlement of the Covered Conduct described in Preamble Paragraph E, below. States with which GSK executes a Medicaid State Settlement Agreement in the form to which GSK and the National Association of Medicaid Fraud Control Units ("NAMFCU") Negotiating Team have agreed, or in a form otherwise agreed to by GSK and an individual State, shall be defined as "Medicaid Participating States."


E. The United States contends that it and the Medicaid Participating States have certain civil claims, as specified in Paragraph 2, below, against GSK for engaging in the following conduct at certain times between January 2000 and December 2010 (hereinafter referred to as the "Covered Conduct"): 
(i) GSK promoted Avandia to physicians and other health care providers with false and misleading representations about Avandia’s lipid profile, effect on cardiovascular biomarkers, and the overall safety of Avandia and as a result, GSK knowingly caused false or fraudulent claims for Avandia to be submitted to, or caused purchases by, one or more of the Government Health Care Programs. This alleged conduct included:

(a) GSK communicated messages to physicians regarding the effect of Avandia on diabetics’ lipid profiles that were based upon inadequate scientific data. At times between 2001 and April 2005, GSK misleadingly represented that Avandia had a “positive lipid profile,” and trained its sales force to promote the positive lipid profile as one of three core selling messages, despite having no well-controlled studies sufficient to establish those representations. Moreover, those representations were inconsistent with the FDA-approved label for Avandia which included information that Avandia was associated with statistically significant increases in low density lipoprotein particles (“LDL” or the “bad” cholesterol), high density lipoprotein particles (“HDL” or the “good” cholesterol), and total cholesterol. Lipid information was particularly important for diabetics, a patient population that was at a significantly increased risk of suffering from cardiac-related illnesses.

(b) GSK represented that use of Avandia resulted in more “light and fluffy” or “buoyant” LDL, despite having no well-controlled studies sufficient to establish those representations. At times between 2001 and April 2005, GSK falsely stated in certain sales brochures that data showing more buoyant LDL particles came from “a randomized, placebo-controlled, pharmacodynamic study,” when it did not; GSK also promoted the light and fluffy LDL theory to physicians by bringing “popcorn lunches” to physicians’ offices to highlight the purported change in density of the LDL particles.
(c) In 2001, GSK conducted a small, randomized control trial of Actos, a competitor diabetes drug, that suggested that treatment with Actos resulted in more buoyant LDL particles. GSK did not publish this scientific data about Actos because it was unhelpful to GSK’s marketing message on lipids. In March 2001, a GSK Vice President, Metabolism Therapeutic Area, North American Medical Affairs directed that the results of this Actos study not be published, stating that the trial was done “way under the radar” and that “[p]er Sr Mgmt request, these data should not see the light of day to anyone outside of GSK.” When later concerned that Actos’ manufacturer intended to publish new clinical trial results regarding Actos’ lipid profile, GSK, as part of the “lipid war games,” again instructed sales representatives to emphasize Avandia’s purportedly favorable lipid profile with physicians.

(d) Some GSK sales aids also contained certain implied cardiovascular claims for which GSK did not have adequate scientific support, such as the message that Avandia may reduce cardiovascular risk by decreasing insulin resistance. That message was inconsistent with the FDA approved label for Avandia which always contained a warning on congestive heart failure associated with use of the drug, and later contained additional cardiovascular warnings regarding use of the drug. From 2001 to 2005, GSK sponsored the CardioAlliance, a program through which cardiologists gave speeches to other doctors about the available Avandia data, including data suggesting cardiovascular benefits from Avandia therapy. Some of the CardioAlliance materials included information about the relationship between insulin resistance and cardiac risk factors and stated that Avandia has “beneficial effects on cardiovascular risk factors” and the “potential to reduce cardiovascular disease” but failed to disclose that GSK did not have cardiovascular outcome data for Avandia. In purpose and effect, GSK paid cardiologists to influence endocrinologists and general practitioners to prescribe
Avandia on the suggestion that the drug may be cardioprotective, despite having no cardiovascular outcome data regarding Avandia.

(ii) GSK made false and misleading representations about Avandia’s lipid profile, effect on cardiovascular biomarkers, and the overall safety of Avandia in labeling used during the promotion of Avandia to physicians and other health care providers in violation of the FDCA, 21 U.S.C. §§ 331(a) and 352(a), and through the sale and distribution of a misbranded product, GSK obtained proceeds and profits to which it was not entitled; and

(iii) GSK made false representations concerning the lipid profile, effect on cardiovascular biomarkers, and the overall safety of Avandia to state Medicaid agencies on which state Medicaid agencies relied to their detriment in making formulary and prior authorization decisions.

The United States contends that engaging in the Covered Conduct gives rise to civil liability under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et. seq.; or common law.

F. The United States also contends that it has certain administrative claims against GSK as specified in Paragraphs 3 through 6, below, for engaging in the Covered Conduct.

G. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by GSK. GSK expressly denies the allegations of the United States as set forth herein that it engaged in any wrongful conduct in connection with the Covered Conduct, except as to such admissions GSK makes in connection with the Plea Agreement. This Agreement is not a concession by the United States that its claims are not well founded. Neither is this Agreement, nor the performance of any obligation arising under it, including any payment, nor the fact of settlement, intended to be, or shall be understood as, an
admission of liability or wrongdoing, or other expression reflecting the merits of the dispute by GSK, except as set forth in this paragraph.

H. To avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these claims, the Parties desire to reach a final settlement as set forth below.

**TERMS AND CONDITIONS**

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. GSK agrees to pay to the United States and the Medicaid Participating States, collectively, the sum of six hundred fifty seven million three hundred eighty seven thousand two hundred dollars ($657,387,200), plus interest at the rate of 1.625% per annum from December 1, 2011, and continuing until and including the day before payment is made under this Agreement (collectively, the “Settlement Amount”). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) GSK shall pay to the United States the sum of five hundred eight million one hundred sixty one thousand sixty three dollars ($508,161,063), plus interest accrued thereon at the rate of 1.625% per annum from December 1, 2011, continuing until and including the day before payment is made (“Federal Settlement Amount”). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than seven (7) business days after (i) this Agreement is fully executed by the Parties and
delivered to GSK’s attorneys; or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea
as described in Preamble Paragraph B in connection with the Criminal Action and imposes the
agreed upon sentence, whichever occurs later.

(b) GSK shall pay to the Medicaid Participating States the sum of one
hundred forty nine million two hundred twenty six thousand one hundred thirty seven dollars
($149,226,137), plus interest accrued thereon at the rate of 1.625 % per annum from December
1, 2011, continuing until and including the day before payment is made (“Medicaid State
Settlement Amount”). The Medicaid State Settlement Amount shall be paid by electronic funds
transfer to an interest bearing account pursuant to written instructions from the NAMFCU
Negotiating Team and under the terms and conditions of the Medicaid State Settlement
Agreements that GSK will enter into with the Medicaid Participating States.

(c) If GSK’s agreed-upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C)
in the Criminal Action described in Preamble Paragraph B is not accepted by the Court or the
Court does not impose the agreed-upon sentence for whatever reason, this Agreement shall be
null and void at the option of either the United States or GSK. If either the United States or GSK
exercises this option, which option shall be exercised by notifying all Parties, through counsel, in
writing within five (5) business days of the Court’s decision, the Parties will not object and this
Agreement will be rescinded. If this Agreement is rescinded, GSK will not plead, argue or
otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or
similar theories, to any civil or administrative claims, actions or proceedings arising from the
Covered Conduct that are brought by the United States within 90 calendar days of rescission,
unless such defenses were available to GSK prior to the effective date of this Agreement and
excluding time periods covered by the tolling agreement dated September 21, 2011.
2. Subject to the exceptions in Paragraph 6 below (concerning excluded claims), in consideration of the obligations of GSK set forth in this Agreement, conditioned upon GSK’s payment in full of the Settlement Amount, the United States (on behalf of itself, its officers, agencies, and departments) agrees to release GSK, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees, and assigns and their current and former directors, officers, and employees, individually and collectively, from any civil or administrative monetary claim that the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq.; any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, 0.45(d), and common law claims for fraud, payment by mistake, breach of contract, disgorgement and unjust enrichment.

3. In consideration of the obligations of GSK in this Agreement and the Corporate Integrity Agreement (CIA) entered into between OIG-HHS and GSK, and conditioned upon GSK’s full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7(b)(f)) against GSK under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or under 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, or under 42 U.S.C. § 1320a-7(b)(1) based on GSK’s agreement to plead guilty to the charges set forth in the Information in the Criminal Action referenced in Paragraph
B above, except as reserved in Paragraph 6 (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude GSK from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

4. In consideration of the obligations of GSK set forth in this Agreement, conditioned upon GSK’s full payment of the Settlement Amount, TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion or suspension from the TRICARE Program against GSK under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 6 (concerning excluded claims), below, and as reserved in this Paragraph. TMA expressly reserves authority to exclude GSK under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

5. In consideration of the obligations of GSK in this Agreement, conditioned upon GSK’s full payment of the Settlement Amount, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action against GSK under 5 U.S.C. § 8902a or 5 C.F.R. Part 970 for the Covered Conduct, except as reserved in Paragraph 6 (concerning excluded claims), below, and except if excluded by the OIG-HHS pursuant to 42 U.S.C. § 1320a-7(a) or required by 5 U.S.C. § 8902a(b), or 5 C.F.R. Part 970. Nothing in this
Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

6. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person are the following claims of the United States:

(a) Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
(b) Any criminal liability;
(c) Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Government Health Care programs;
(d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
(e) Any liability based upon such obligations as are created by this Agreement;
(f) Any liability for express or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;
(g) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
(h) Any liability for failure to deliver items or services due; or
(i) Any liability of individuals (including current or former directors, officers, employees, or agents of GSK) who receive written notification that they are the target of a criminal investigation, are criminally indicted, charged,
or convicted, or who enter into a criminal plea agreement related to the Covered Conduct.

7. GSK waives and shall not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

8. GSK fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorneys’ fees, costs, and expenses of every kind and however denominated) which GSK has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct or arising from the United States’ investigation, settlement of this matter, and prosecution of the Criminal Action.

9. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any state payer, related to the Covered Conduct; and GSK agrees not to resubmit to any Medicare carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

10. GSK agrees to the following:
(a) **Unallowable Costs Defined:** that all costs (as defined in the Federal Acquisition Regulations (FAR) 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395k(k) and 1396-1396w-5, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of GSK, its present or former officers, directors, employees, shareholders, and agents in connection with the following shall be “Unallowable Costs” on government contracts and under the Government Health Care Programs:

1. the matters covered by this Agreement and the related Plea Agreement;
2. the United States’ audit and civil and criminal investigation of the matters covered by this Agreement;
3. GSK’s investigation, defense, and any corrective actions undertaken in response to the United States’ audit and civil and criminal investigation in connection with the matters covered by this Agreement (including attorneys’ fees);
4. the negotiation and performance of this Agreement, the Plea Agreement, and the Medicaid State Settlement Agreements;
5. the payments GSK makes to the United States or any State pursuant to this Agreement, the Plea Agreement, or the Medicaid State Settlement Agreements;
6. the negotiation of, and obligations undertaken pursuant to the CIA to:
   1. retain an independent organization to perform annual reviews as described in Section III of the CIA; and
   2. prepare and submit reports to...
OIG-HHS. However, nothing in this paragraph 10.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to GSK.

(b) Future Treatment of Unallowable Costs: These Unallowable Costs shall be separately determined and accounted for by GSK, and GSK shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid Program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by GSK or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: GSK further agrees that within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by GSK or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. GSK agrees that the United States, at a minimum, shall be entitled to recoup from GSK any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.
Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by GSK or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on GSK’s or any of its subsidiaries’ or affiliates’ cost reports, cost statements, or information reports.

(d) Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine GSK’s books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

11. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 2 above or 12 below (waiver for beneficiaries paragraph).

12. GSK agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

13. GSK expressly warrants that it has reviewed its financial situation and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain solvent following payment of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants and obligations set forth herein constitute a contemporaneous exchange for new value given to GSK, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that
these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which GSK was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

14. Each party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

15. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion.

16. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the District of Massachusetts, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA.

17. For purposes of construction, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any party for that reason in any dispute.

18. This Agreement constitutes the complete agreement between the Parties with respect to the issues covered by the Agreement. This Agreement may not be amended except by written consent of all the Parties.

19. The individuals signing this Agreement on behalf of GSK represent and warrant that they are authorized by GSK to execute this Agreement. The United States’ signatories
represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement.

20. This Agreement may be executed in counterparts, each of which constitutes an original and all of which shall constitute one and the same Agreement.

21. This Agreement is binding on GSK's successors, transferees, heirs and assigns.

22. All parties consent to the disclosure of this Agreement, and information about this Agreement, to the public after the Effective Date.

23. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles or electronic versions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

UNITED STATES OF AMERICA

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United States Attorney

By: [Signature]

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Dated: 6/26/12

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Dated: 6/22/12

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