#### 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 on behalf of the Office of Inspector General of the United States Department of Health and Human Services ("OIG-HHS"), the TRICARE Management Activity ("TMA"), the United States Department of Veteran's Affairs ("VA"), and the United States Office of Personnel Management ("OPM") (collectively the "United States"), Relators identified in the cases listed in Paragraph B of the Preamble to this Agreement ("Relators"), 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 pharmaccutical products in the United States, including drugs sold under the trade names of Paxil, Wellbutrin, Advair, Lamictal, Zofran, Imitrex, Lotronex, Flovent and Valtrex (collectively the "Covered Drugs").

B. The Relators listed herein have filed the following <u>qui</u> tam actions against GSK (collectively the "Civil Actions"):

- (1) <u>United States et al. ex rel. Thorpe, et al. v. GSK et al.</u>, Civ. No. 11-10398 (D. Mass.);
- (2) <u>United States et al. ex rel. Gerahty, et al. v. GSK et al.</u>, Civ. No. 03-10641 (D. Mass.);
- (3) <u>United States ex rel. Graydon v. GSK et al.</u>, Civ. No. 11-10741 (D. Mass);
- (4) <u>United States et al. ex rel. LaFauci v. GSK</u>, Civ. No. 11-10921 (D. Mass.);

The United States filed a notice of intervention on January 14, 2011 and filed its Complaint-In-Intervention on October 26, 2011 ("Complaint-in-Intervention").

C. 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 <u>United States of America v. GlaxoSmithKline LLC.</u>, Criminal Action No. [to be assigned] (District of Massachusetts) (the "Criminal Action") that will allege: (i) 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 (ii) 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, all in violation of the Food, Drug and Cosmetic Act ("FDCA").

D. 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. 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 alleges that GSK caused to be submitted claims for payment for the Covered Drugs to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§1395-1395kkk ("Medicare"), and to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid"). The United States further alleges that

GSK caused claims for payment for the Covered Drugs to be submitted to the TRICARE program, 10 U.S.C. §§ 1071-1110b; the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901-8914; the Federal Employees Compensation Act Program, 5 U.S.C. § 8101, <u>et seq</u>; and caused purchases of the Covered Drugs by the Department of Veterans' Affairs Programs, 38 U.S.C. §§ 1701-1743 (collectively, the "other Federal Health Care Programs").

F. 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 conduct set forth in the Complaint-in-Intervention and as described as follows (hereinafter referred to as the "Covered Conduct"):

- Paxil: During the period January 1, 1998 through December 31, 2003, (1)GSK knowingly: (a) promoted the sale and use of Paxil for conditions and for patients other than those for which its use was approved as safe and effective by the Food and Drug Administration ("FDA"), specifically for children and adolescents under the age of 18, and which uses were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Paxil; (b) made and/or disseminated unsubstantiated and/or false and/or misleading representations or statements about the safety and efficacy of Paxil concerning the uses described in section (a) of this subparagraph, including concealing, omitting or failing to disclose material information about the safety and efficacy of Paxil; and (c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Paxil, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). As a result of the foregoing conduct, GSK knowingly caused false or fraudulent claims for Paxil to be submitted to, or caused purchases by Medicaid and the other Federal Health Care Programs.
- (2) Wellbutrin: During the period January 1, 1999 through December 31, 2003, GSK knowingly: (a) promoted the sale and use of Wellbutrin for conditions (including weight loss, the treatment of obesity, sexual dysfunction and in combination with other antidepressants) and at dosages other than those for which its use was approved as safe and effective by the FDA, and some of which were not medically-accepted indications as defined by 42 U.S.C. §

1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Wellbutrin; (b) made and/or disseminated unsubstantiated and/or false and/or misleading representations or statements about the safety and efficacy of Wellbutrin; and (c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Wellbutrin, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). As a result of the foregoing conduct, GSK knowingly caused false or fraudulent claims for Wellbutrin to be submitted to, or caused purchases by Medicaid and the other Federal Health Care Programs.

Advair: During the period January 1, 2001 through June 30, 2010, GSK (3) knowingly: (a) promoted the sale and use of Advair for conditions and dosing regimens other than those for which its use was approved as safe and effective by the FDA (including first line use for mild or all asthma, and for asthma previously treated by short-acting inhalers alone), and some of which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Advair; (b) made and/or disseminated unsubstantiated and/or false and/or misleading representations or statements about the safety and efficacy of Advair (including that Advair was superior to the single component, inhaled corticosteroid alone, for patients previously treated by short-acting inhalers alone); and (c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Advair, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b). As a result of the foregoing conduct, GSK knowingly caused false or fraudulent claims for Advair to be submitted to, or caused purchases by Medicaid, Medicare and the other Federal Health Care Programs.

(4) Lamictal: During the period January 1, 1999 through December 31, 2003, GSK knowingly: (a) promoted the sale and use of Lamictal for a variety of conditions other than those for which its use was approved as safe and effective by the FDA (including bi-polar depression, neuropathic pain, and various other mental diseases), and some of which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Lamictal; (b) made and/or disseminated unsubstantiated and/or false and/or misleading representations or statements about the safety and efficacy of Lamictal concerning the uses described in section (a) of this sub-paragraph; and (c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Lamictal, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b). As a result of the foregoing conduct, GSK knowingly caused

false or fraudulent claims for Lamictal to be submitted to, or caused purchases by Medicaid and the other Federal Health Care Programs.

- Zofran: During the period January 1, 2002 through December 31, 2004, (5) GSK knowingly: (a) promoted the sale and use of Zofran for a variety of conditions other than those for which its use was approved as safe and effective by the FDA (including hyperemesis or pregnancy-related nausea), and some of which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Zofran; (b) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Zofran concerning the uses described in section (a) of this sub-paragraph; and (c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b). As a result of the foregoing conduct, GSK knowingly caused false or fraudulent claims for Zofran to be submitted to, or caused purchases by Medicaid and the other Federal Health Care Programs.
- (6) Imitrex, Lotronex, Flovent and Valtrex: From January 1, 1999 through December 30, 2004, GSK paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs, advisory boards (including Local and Regional Advisory Boards and Special Issues Boards), Reprint Mastery Trainings, and provided gifts (including entertainment, cash, travel and meals) to health care professionals to induce them to promote and prescribe the drugs Imitrex, Lotronex, Flovent and Valtrex, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). As a result of the foregoing conduct, GSK caused false claims to be submitted to, or caused purchases by Medicaid and certain other Federal Health Care Programs.

G. The United States also contends that it has certain administrative claims against

GSK as specified in Paragraphs 4 through 6, below, for engaging in the Covered Conduct.

H. 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 and the Relators as set forth herein and in the Civil Actions and the Complaint-In-Intervention, and denies 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 or the Relators that their claims are not wellfounded. Neither this Agreement, nor the performance of any obligation arising under it, including any payment, nor the fact of settlement, is intended to be or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting on the merits of the dispute, except as set forth in this Paragraph.

I. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to reasonable expenses, attorneys' fees and costs, among other things. This agreement does not cover the claims of any Relator to a share of the proceeds or their attorneys' fees, costs, and expenses under 31 U.S.C. § 3730(d), and nothing in this Agreement shall constitute evidence or an admission that any Relator has filed a valid *qui tam* action under 31 U.S.C. § 3730 or is entitled to a share of the proceeds or attorneys' fees, costs, and expenses under 31 U.S.C. § 3730(d).

J. 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 one billion, forty-two million, six hundred twelve thousand, eight hundred dollars (\$1,042,612,800), 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 is allocated to the drugs set forth in the Covered Conduct and at issue in the Civil Actions as follows:

Paxil:	\$52,622,130
Wellbutrin:	\$166,979,130
Advair-Asthma:	\$686,049,841
Advair-COPD July 2008 to June 2010:	\$25,273,910
Lamictal:	\$54,729,862
Zofran:	\$2,320,640
Kickbacks for Paxil, Wellbutrin, Advair, Lamictal, Zofran, Imitrex, Lotronex, Flovent, and Valtrex:	\$54,637,287

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 eight hundred thirty-two million, four hundred eighty-five thousand, four hundred and thirty-six dollars (\$832,485,436), 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 (the "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 C 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 two hundred and ten million, one hundred and twenty-seven thousand, three hundred and sixty-four dollars (\$210,127,364), 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 (the "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 C 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, except to the extent such defenses were available on the day on which the <u>qui tam</u> complaints listed in Preamble Paragraph B, above, were filed.

2. Subject to the exceptions in Paragraph 7 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. Conditioned upon the United States' receipt of the payments described in Paragraph 1(a) above, and in consideration of the obligations of GSK in this Agreement, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns and any other person or entity acting on their behalf or asserting their rights, release GSK together with its predecessors, and its current and former divisions, parents, direct and indirect affiliates, divisions, subsidiaries, transferees, successors, and assigns, and all of their current and former directors, officers, employees, representatives, servants, agents, consultants and attorneys, individually and collectively, from any civil monetary claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733, for the Covered Conduct and from all

liability, claims, demands, actions or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that they, their heirs, successors, attorneys, agents and assigns otherwise would have standing to bring as of the date of this Agreement, including any liability to Relators arising from or relating to the claims Relator asserted or could have asserted in the Civil Actions. Provided, however, that Relators and Relators' counsel do not release GSK for any claims they may have for reasonable attorneys' fees, expenses and costs pursuant to 31 U.S.C. § 3730(d); or for any claims Relators may have pursuant to 31 U.S.C. § 3730(h).

4. 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-7b(f)) against GSK under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, or against GSK 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 C above, except as reserved in Paragraph 7 (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 7, below.

5. 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 7 (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 7, below.

6. 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 7 (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 7, below.

7. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including GSK and the Relators) 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 Federal 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 or charged, or are convicted, or who enter into a criminal plea agreement related to the Covered Conduct.

8. (A) Each Relator and his/her respective heirs, successors, attorneys, agents, and assigns agree not to object to this Agreement and agree and confirm that this Agreement and the amounts set forth in Paragraph 1(a) are fair, adequate and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Each Relator and his/her respective heirs, successors, attorneys, agents, and assigns, expressly waives the opportunity for a hearing on any objection to this agreement pursuant to 31 U.S.C. § 3730(C)(2)(B).

(B) Of the federal and states drug claims listed in Paragraphs 1(a), the following were alleged in <u>United States et al. ex rel. Thorpe, et al. v. GSK et al.</u>, Civ. No. 11-10398 (D. Mass.) and/or <u>United States et al. ex rel. Gerahty, et al. v. GSK et al.</u>, Civ. No. 03-10461 (D. Mass): Paxil, Wellbutrin, Advair-Asthma, Lamictal, Zofran, Flovent, Imitrex, Lotronex, Valtrex, and kickbacks. Of the federal and state drug claims listed in paragraph 1(a), Advair-COPD (July 2008-June 2010) was alleged in <u>United States ex rel. Graydon v. GSK et al.</u>, Civ. No. 11-10741 (D. Mass) and <u>United States et al. ex rel. La Fauci v. GSK</u>, Civ. No. 11-10921 (D. Mass). The Parties incorporate herein by reference the fairness, adequacy and reasonableness letters executed by each Relator and their counsel. Nothing in this subparagraph (B) is intended to address whether or to what extent any of the relators in these actions are entitled to a share of any of the proceeds allocated to the federal and state drug claims listed in Paragraph 1(a).

(C) All parties reserve all rights under the False Claims Act unless expressly waived or released herein. This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relators arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

9. 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.

10. 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 and prosecution of the Civil Actions and the Criminal Action.

11. Should this Agreement be challenged by any person as not fair, adequate or reasonable pursuant to 31 U.S.C. § 3730(c)(2)(B), the Parties agree that they will take all reasonable and necessary steps to defend this Agreement and the allocation set forth herein.

12. In consideration of the obligations of the Relators set forth in this Agreement, GSK, on behalf of itself, its predecessors, and its current and former divisions, parents, subsidiaries, agents, successors, assigns, and their current and former directors, officers and employees, fully and finally release, waive, and forever discharge the Relators and their respective heirs, successors, assigns, agents, and attorneys from any claims or allegations GSK has asserted or could have asserted, arising from the Covered Conduct and from all liability, claims, demands, actions or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or

regulation, or in common law, that they, their heirs, successors, attorneys, agents and assigns otherwise would have standing to bring as of the date of this Agreement, including any liability to GSK arising from or relating to the claims Relator asserted or could have asserted in the Civil Actions. Provided, however, that GSK expressly reserves any defenses or claims as to Relators' and Relators' counsel's claims for reasonable attorneys' fees, expenses and costs pursuant to 31 U.S.C. § 3730(d) and as to any claims Relators may have pursuant to 31 U.S.C. § 3730(h), which are reserved pursuant to Paragraph 3 above.

13. 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.

14. GSK agrees to the following:

(a) <u>Unallowable Costs Defined</u>: 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. §§ 1395-1395kkk 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 Medicare and Medicaid Programs and other Federal 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 and any payments that GSK may make to Relators (including costs and attorneys' fees);
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to:
  (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to OIG-HHS. However, nothing in this paragraph 14 affects the status of costs that are not allowable based on any other authority applicable to GSK.

(b) <u>Future Treatment of Unallowable Costs</u>: 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) <u>Treatment of Unallowable Costs Previously Submitted for Payment:</u> 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 theUnited States to audit, examine or reexamine GSK's books and records to determine that noUnallowable Costs have been claimed in accordance with the provisions of this Paragraph.

15. 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 and 16 below (waiver for beneficiaries paragraph).

16. 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.

17. 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, dclay, 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).

18. Within seven (7) business days following payment of the Settlement Amount, the Parties shall seek dismissal of the Complaint-in-Intervention and each of the Civil Actions. Each

dismissal shall be with prejudice as to all claims of the United States and the Relators with the exception of the following claims, if any, and over which the Court shall retain jurisdiction: (a) Relators' claims for a share of the proceeds of the Civil Actions pursuant to 31 U.S.C. § 3730(d); (b) Relators' claims against GSK for reasonable attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d); (c) Relators' claims against GSK under 31 U.S.C. § 3730(h); and (d) Relators' claims against the States for Relators' Shares. This provision shall not limit the rights of the United States to in any way challenge or contest claims under subsection (a) above, including but not limited to challenging or contesting those claims under 31 U.S.C. § 3730(b)(5) and/or 31 § U.S.C. 3730(e)(4), or as to GSK, to in any way challenge or contest claims under subsection (b) and (c) above.

19. Each party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement, except Relators reserve their rights against GSK to seek attorneys' fees, costs and expenses under 31 U.S.C. § 3730(d).

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

21. 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, including any issues regarding relators' share or payment of Relators' attorneys' fees, expenses and costs, 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.

22. 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.

23. This Agreement including any documents incorporated by reference herein 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.

24. The individuals signing this Agreement on behalf of GSK represent and warrant that they are authorized by GSK to execute this Agreement. The individuals signing this Agreement on behalf of each Relator represent and warrant that they are authorized by that Relator 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.

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

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

26. This Agreement is binding on Relators' successors, transferees, heirs, attorneys and assigns.

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

28. 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

CARMEN M. ORTIZ United States Attorney

By: SÁŘÁ MIRON BLOOM

AMANDA STRACHAN BRIAN PEREZ-DAPLE Assistant United States Attorneys District of Massachusetts

Men Dated: 7/2/2012

United States Attorney John Walsh

By:

4400 á

ľ

EDWIN WINSTEAD Assistant United States Attorney District of Colorado

Dated: Ju 2012 1y 2,

STUART F. DELERY Acting Assistant Attorney General

7/2/12 Dated:

DANIEL R. ANDERSON JAMIE ANN YAVELBERG ANDY MAO BRIAN MCCABE DOUGLAS ROSENTHAL Attorneys Commercial Litigation Branch, Civil Division United States Department of Justice

By:

By:

Patner. Ma JILL FURMAN

Dated: 7/2/12

JILL FURMAN / PATRICK JASPERSE DAVID FRANK Attorneys Consumer Protection Branch, Civil Division United States Department of Justice

By:

April Cumio GREGORY E. DEMSKE

Dated: 6/28/2012

GREGORY E. DEMSKE Chief Counsel to the Inspector General Office of Counsel to the Inspector General Office of Inspector General U.S. Department of Health and Human Services

PAUL J. HUTTER General Counsel TRICARE Management Activity United States Department of Defense

Dated: 6/37/12

By:

By:

SHIRLY R. PATTERSON Assistant Director for Federal Employee Insurance Operations United States Office of Personnel Management

Dated: 6/7/12

Cer By: J. DAVID COPE

Debarring Official Office of the Assistant Inspector General for Legal Affairs United States Office of Personnel Management

Dated: 6/7/12

#### GLAXOSMITHKLINE LLC

ELPIDIO VILLARREAL

By:

Dated: 6, 28-12

Senior Vice President, Global Litigation, GlaxoSmithKline LLC

By:

GÉOFFREY HOBART MATTHEW O'CONNOR Covington & Burling LLP Counsel to GlaxoSmithKline LLC.

Dated: 6/28/12

**RELATOR GREG THORPE** 

By:

GREG THORPE

Dated:

**RELATOR BLAIR HAMRICK** 

By:

BLAIR HAMRICK

BRIAN KENNEY

By: BRIAN KENNEY M.. TAVY DEMING KENNEY & McCAFFERTY, PC Counsel to Relators Greg Thorpe & Blair Hamrick

Dated: 6/27/12

Dated:

# RELATOR GREG THORPE

By: GREG THORPE

Dated: 6/27/12

#### **RELATOR BLAIR HAMRICK**

By:

BLAIR HAMRICK

#### BRIAN KENNEY

By:

Dated:

Dated:

BRIAN KENNEY M. TAVY DEMING KENNEY & McCAFFERTY, PC Counsel to Relators Greg Thorpe & Blair Hamrick **RELATOR GREG THORPE** 

By:

GREG THORPE

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

**RELATOR BLAIR HAMRICK** 

BLAIR HAMRICK

Dated: 6. 27. 12

Dated:

BRIAN KENNEY

By:

By:

BRIAN KENNEY M. TAVY DEMING KENNEY & McCAFFERTY, PC Counsel to Relators Greg Thorpe & Blair Hamrick

# **RELATOR THOMAS GERAHTY**

By:

THOMAS GERAHTY

## **RELATOR MATTHEW BURKE**

By:

BÜRKE U

Dated:

Dated: 6-26-12 Dated: 6/26/12

By:

ERIKA KELTON Phillips & Cohen Counsel to Relators Thomas Gerahty and Matthew Burke

## **RELATOR THOMAS GERAHTY**

By: THOMAS GERAHT

Dated: 6/26/2012

# **RELATOR MATTHEW BURKE**

By:

Dated:

MATTHEW BURKE By:

Dated: 6/26/2012

ERIKA KELTON Phillips & Cohen Counsel to Relators Thomas Gerahty and Matthew Burke

1.4

LOIS C GRAYDON

5 B

#### **RELATOR LOIS GRAYDON**

By:

LOIS GRAYDON

By:

REUBEN GUTTMAN Grant & Eisenhofer, PA Counsel to Relator Lois Graydon

6/27/2012 Dated:

6/26/2018 Dated:

RELATOR MICHAEL LAFAUCI 27/12 Dated: By: MICHAEL LAFAUCI Dated: By: DAVED S STONE ROBERT A. MAGNANINI Stone & Magnanini LLP Counsel to Relator Michael LaFauci 31