**U.S. Department of Justice**

***Carmen M. Ortiz***
*United States Attorney*
*District of Massachusetts*

*Main Reception: (617) 748-3100*

*John Joseph Moakley United States Courthouse*
*1 Courthouse Way*
*Suite 9200*
*Boston, Massachusetts 02210*

June 27, 2012

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

Re: United States v. GlaxoSmithKline plc

Dear Counsel:

This letter ("Side Letter Agreement") will confirm that, in exchange for full performance of the Plea Agreement entered into by and among the United States of America, acting through the United States Attorney for the District of Massachusetts ("U.S. Attorney") and the Department of Justice (collectively referred to as "the United States") and your client, GlaxoSmithKline LLC ("GSK"), a copy of which Plea Agreement and related Information are attached hereto as Exhibits One and Two, and in exchange for certain other promises made herein between and among the United States and your client, GlaxoSmithKline plc, its direct and indirect subsidiaries (other than GSK) and its successors, the United States and GlaxoSmithKline plc hereby agree as follows:

1. No Criminal Prosecution of GlaxoSmithKline plc

The United States hereby declines prosecution of GlaxoSmithKline plc or any of its direct or indirect subsidiaries (other than GSK as set forth in the attached Plea Agreement and related Information) for conduct by or attributable to GlaxoSmithKline plc or any of its subsidiaries that:

(a) falls within the scope of the Information to which GSK is pleading guilty; or

(b) was either the subject of the grand jury investigation in the District of Massachusetts, or was known to the United States Attorney's Office for the District of Massachusetts or the Consumer Protection Branch of the Civil Division of the Department of Justice prior to the date of this agreement, relating to:

(i) GSK's sales, marketing and promotion of Imitrex, Lamictal, Lotronex, Flovent, Paxil, Valtrex, Wellbutrin, and Zofran between January 1998 and December 2004;

(ii) GSK's sales, marketing and promotion of Advair between January 1998 and June 2010;

(iii) GSK's communications with and reporting to the Food and Drug Administration in connection with Advair, Paxil, and Wellbutrin between July 1998 and December 2004;

(iv) GSK's sales, marketing and promotion of Avandia, Avandamet, and Avandaryl between January 2000 and December 2010; and

(v) GSK's communications with and reporting to the Food and Drug Administration in connection with Avandia, Avandamet, and Avandaryl.

The United States does not decline criminal prosecution of GlaxoSmithKline plc or any of GlaxoSmithKline plc's related entities for any other conduct beyond that set forth above.

This Side Letter Agreement is not intended to and does not affect the criminal liability of any individual.

It is understood among the parties to this Side Letter Agreement that the United States' promise not to prosecute GlaxoSmithKline plc is dependent upon and subject to GSK fulfilling its material obligations in the Plea Agreement and in the related Civil Settlement Agreements attached hereto as Exhibits Three through Five. If GSK does not fulfill its material obligations in the Plea Agreement and/or the Civil Settlement Agreements, GlaxoSmithKline plc agrees to waive any defenses regarding pre-indictment delay, statute of limitations, or Speedy Trial Act with respect to any and all criminal charges that could have been timely brought or pursued as of the date of this letter, as set forth above.

2. Who Is Bound By Agreement

With respect to matters set forth in Paragraph 1, this Agreement is binding upon GlaxoSmithKline plc and the Office of the United States Attorney for the District of Massachusetts, the United States Attorney's Offices for each of the other 92 judicial districts of the United States, and the Consumer Protection Branch of the Department of Justice. The non-prosecution provisions in Paragraph 1 are also binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of GlaxoSmithKline plc or any of its subsidiaries that are or may be conducted in the future by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of GlaxoSmithKline plc's or any of its subsidiaries' products to foreign customers, which investigations are specifically excluded from the release in Paragraph 1. A copy of the letter to United States Attorney Carmen M. Ortiz from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Agreement is attached as Exhibit Six. GlaxoSmithKline plc understands that this Agreement does not bind any state or local prosecutive authorities, the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury.

3. Complete Agreement

This Side Letter Agreement; the Plea Agreement and the three Civil Settlement Agreements with GSK attached hereto; the tolling agreement regarding Avandia dated September 21, 2011 attached as Exhibit Seven; and the tolling agreement regarding other drugs dated December 1, 2011 attached as Exhibit Eight are the complete and only agreements between the parties. No promises, agreements or conditions have been entered into other than those set forth or referred to in the above-identified documents. This agreement supersedes prior understandings, if any, of the parties, whether written or oral. This agreement cannot be modified other than in a written memorandum signed by the parties or on the record in court.

If this letter accurately reflects the agreement entered into between the United States and GlaxoSmithKline plc and if you are authorized to enter into this agreement on behalf of GlaxoSmithKline plc, please sign below and return the original of this letter to Assistant U.S. Attorneys Susan G. Winkler and Sara M. Bloom.

Very truly yours,

Carmen M. Ortiz

CARMEN M. ORTIZ
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

Sara Miron Bloom
Susan G. Winkler
Shannon T. Kelley
Amanda Strachan
Brian Perez-Dapple
Assistant U.S. Attorneys

STUART F. DELERY
ACTING ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION
DEPARTMENT OF JUSTICE

Patrick Jasperse
Jill Furman
Mark L. Josephs
David Frank
Timothy Finley
Trial Attorneys
Consumer Protection Branch
U.S. Department of Justice

## ACKNOWLEDGMENT OF AGREEMENT

I am authorized to execute this Side Letter Agreement on behalf of GlaxoSmithKline plc. GlaxoSmithKline plc has been advised of the contents of this Side Letter Agreement, the Plea Agreement and Civil Settlement Agreements with GSK and the criminal Information charging GSK, and has discussed them fully with its counsel. I am further authorized to acknowledge on behalf of GlaxoSmithKline plc that these documents fully set forth the agreements made between GlaxoSmithKline plc and the United States, and that no additional promises or representations have been made to GlaxoSmithKline plc by any officials of the United States Department of Justice in connection with the disposition of this matter, other than those set forth in those documents.

Dated: 6-28-12

Elpidio Villarreal
Senior Vice President, Global Litigation
GlaxoSmithKline LLC

Dated: 6/28/12

Geoffrey E. Hobart, Esq.
Matthew J. O'Connor, Esq.
Covington & Burling LLP
Counsel for Defendant

**U.S. Department of Justice**

Criminal Division

*Assistant Attorney General* *Washington, D.C. 20530*

February 3, 2012

The Honorable Carmen Milagros Ortiz
United States Attorney
District of Massachusetts
1 Courthouse Way
John Joseph Moakley Courthouse
Boston, Massachusetts 02210

Attention: Susan Winkler
Assistant United States Attorney

Re: Global Side Letter Agreement with GlaxoSmithKline plc

Dear Ms. Ortiz:

This is in response to your request for authorization to enter into a Side Letter Agreement with GlaxoSmithKline plc.

I hereby approve the terms of the agreement, including Paragraph 1, in which the United States agrees not to initiate further criminal proceedings as set out therein.

Sincerely,

Mary Patrice Brown
Deputy Assistant Attorney General
Criminal Division

**U.S. Department of Justice**

***Carmen M. Ortiz***
*United States Attorney*
*District of Massachusetts*

*Main Reception: (617) 748-3100*

*John Joseph Moakley United States Courthouse*
*1 Courthouse Way*
*Suite 9200*
*Boston, Massachusetts 02210*

June 27, 2012

Geoffrey E. Hobart
Matthew J. O'Connor
Covington & Burling, LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2401

Re: United States v. GlaxoSmithKline LLC

Dear Counsel:

This letter sets forth the Agreement between the United States Attorney for the District of Massachusetts ("the U.S. Attorney") and the United States Department of Justice ("collectively, the "United States") and your client, GlaxoSmithKline LLC ("GSK"), in the above-referenced case. The Agreement is as follows:

1. Change of Plea

At the earliest practicable date, GSK shall waive indictment and plead guilty to a three-count Information attached to this Agreement as Exhibit A. Count One charges GSK with delivery into interstate commerce of a misbranded drug, Paxil, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(a). Count Two charges GSK with delivery into interstate commerce of a misbranded drug, Wellbutrin, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f). Count Three charges GSK with failure to report data relating to clinical experience, along with other data and information, regarding Avandia to the FDA as required by law, in violation of 21 U.S.C. §§ 331(e), 333(a)(1), and 355(k)(1). GSK expressly and unequivocally admits that it committed the crimes charged in the Information, and is in fact guilty of those offenses. GSK also agrees to waive venue, to waive any applicable statute of limitations, and to waive any legal or procedural defects in the Information.

2. Penalties

GSK faces the following maximum penalties with respect to the counts of conviction:

a. Count One (21 U.S.C. §§ 331(a), 333(a)(1), 352(a) regarding Paxil):

i. A fine of $200,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greater. *See* 18 U.S.C. §§ 3571(c)(5) and (d). Given GSK's gross gain from the offense in Count One was $99,855,000, the maximum possible fine in connection with this Count is $199,710,000;

ii. A term of probation of not more than five (5) years. *See* 18 U.S.C. § 3561(c)(2);

iii. Restitution to any victims of the offense. *See* 18 U.S.C. § 3563; and

iv. A mandatory special assessment of $125. *See* 18 U.S.C. § 3013(a)(1)(B)(iii).

b. Count Two (21 U.S.C. §§ 331(a), 333(a)(1), 352(f) regarding Wellbutrin):

i. A fine of $200,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greater. *See* 18 U.S.C. §§ 3571(c)(5) and (d). Given GSK's gross gain from the offense in Count Two was $346,521,000, the maximum possible fine in connection with this Count is $693,042,000;

ii. A term of probation of not more than five (5) years. *See* 18 U.S.C. § 3561(c)(2);

iii. Restitution to any victims of the offense. *See* 18 U.S.C. § 3563; and

iv. A mandatory special assessment of $125. *See* 18 U.S.C. § 3013(a)(1)(B)(iii).

c. Count Three (21 U.S.C. §§ 331(e), 333(a)(1), 355(k)(1) regarding Avandia):

i. A fine of $200,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greater. *See* 18 U.S.C. §§ 3571(c)(5) and (d). Given GSK's gross gain from the offense in Count Three was $151,633,000, the maximum possible fine in connection with this Count is $303,266,000;

ii. A term of probation of not more than five (5) years. *See* 18 U.S.C. § 3561(c)(2);

iii. Restitution to any victims of the offense. *See* 18 U.S.C. § 3563; and

iv. A mandatory special assessment of $125. *See* 18 U.S.C. § 3013(a)(1)(B)(iii).

3. Fed. R. Crim. P. 11(c)(1)(C) Plea

This plea agreement is made pursuant to Fed. R. Crim. P. 11(c)(1)(C), and GSK's plea will be tendered pursuant to that provision. In accordance with Fed. R. Crim. P. 11(c)(1)(C), if the District Court ("Court") accepts this plea agreement, the Court must include the agreed disposition in the judgment. If the Court rejects any aspect of this plea agreement or fails to impose a sentence consistent herewith, this Agreement shall be null and void at the option of either the United States or GSK, with the exception of Paragraph 12 (Waiver of Defenses) which shall remain in full effect. GSK expressly understands that it may not withdraw its plea of guilty unless the Court rejects this Agreement under Fed. R. Crim. P. 11(c)(5) or fails to impose a sentence consistent herewith.

GSK may seek sentencing by the District Court immediately following the Rule 11 plea hearing. The United States does not object to the Court proceeding to sentence GSK immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. GSK understands that the decision whether to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the United States District Court.

4. Sentencing Guidelines

The parties agree that while the fine provisions of the United States Sentencing Guidelines ("U.S.S.G.") do not apply to organizational defendants for misdemeanor violations of the Food, Drug and Cosmetic Act, *see* U.S.S.G. § 8C2.1, the agreed upon fine is consonant with those guidelines and takes into account GSK's conduct under 18 U.S.C. §§ 3553 and 3572, as follows:

a. The parties agree that the base fine is $598,009,000 in that such amount was the reasonably estimated pecuniary gain to the organization from the offenses *See* U.S.S.G. §§ 8C2.4(a), 8C2.3;

b. Pursuant to U.S.S.G. § 8C2.5, the culpability score is eight (8), which is determined as follows:

i. Base culpability score is five (5) pursuant to U.S.S. G. § 8C2.5(a);

ii. Add five (5) points pursuant to U.S.S.G. § 8C2.5(b)(1)(A); and

iii. Deduct two (2) points for GSK's full cooperation and acceptance of responsibility for its criminal conduct pursuant to U.S.S.G. § 8C2.5(g)(2).

c. Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of eight (8) is 1.6 to 3.2; and

d. Thus, the advisory Guideline Fine Range is $956,814,400 to $1,196,018,000. *See* U.S.S.G. §§ 8C2.7(a), (b); 18 U.S.C. §§ 3571(c), (d).

The U.S. Attorney may, at her sole option, be released from her commitments under this Agreement, including, but not limited to, her agreement that Paragraph 5 constitutes the appropriate disposition of this case, if at any time between GSK's execution of this Agreement and sentencing, GSK:

(a) Fails to admit a complete factual basis for the plea;

(b) Fails to truthfully admit its conduct in the offenses of conviction;

(c) Falsely denies, or frivolously contests, relevant conduct for which GSK is accountable under U.S.S.G. § 1B1.3;

(d) Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which GSK is accountable under U.S.S.G. § 1B1.3;

(e) Engages in acts which form a basis for finding that GSK has obstructed or impeded the administration of justice under U.S.S.G. § 3C1.1;

(f) Commits a crime; or

(g) Attempts to withdraw its guilty plea.

5. Agreed Disposition

Pursuant to Fed. R. Crim. P. 11(c)(1)(C), the United States and GSK agree that the appropriate disposition of this case is as follows, and will result in imposition of a reasonable sentence that is sufficient, but not greater than necessary, taking into consideration all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572:

a. a criminal fine in the amount of $956,814,400 to be imposed as follows:

i. Count One: $159,768,000

ii. Count Two: $554,433,600

iii. Count Three: $242,612,800

GSK shall pay this fine within one week of the date of sentencing;

b. a mandatory special assessment in the amount of $375 pursuant to 18 U.S.C. § 3013;

c. forfeiture in the amount of $43,185,600 to be paid within one week of the date of sentencing;

d. The United States agrees that it will not seek a separate restitution order as to GSK as part of the resolution of the Information and the Parties agree that the appropriate resolution of this case does not include a restitution order for the following reasons:

i. Counts One and Two: In light of the pending civil actions, including United States et al. ex rel. Thorpe, et al. v. GSK et al., Civ. No. 11-10398 (D. Mass.), and the Civil Settlement Agreement between GSK and the United States and others (which is being signed contemporaneously with this Plea Agreement, and is attached hereto as Exhibit B), which requires payment of $1,042,612,800 plus interest from December 1, 2011, the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a restitution order outweighs the need to provide restitution to the non-federal victims, if any, in this case, given that numerous unknown individuals and insurance companies purchased Paxil and Wellbutrin, that many of those persons and companies have obtained restitution in private actions, and that tracing reimbursements to the various unknown insurance companies and patients and determining the apportionment of payment pertaining to the products at issue would be extraordinarily difficult, if not impossible. *See*, 18 U.S.C. § 3663(a)(3); *Cf.* 18 U.S.C. § 3663(a)(1)(B)(ii).

ii. Count Three: No identifiable economic loss appears to have been suffered by the federal Food and Drug Administration ("FDA"), and the parties were unable to determine any economic loss to others directly and proximately caused by this offense of conviction in this case. In addition, in light of the Civil Settlement Agreement between

the United States and GSK (being signed contemporaneously with this Plea Agreement, and attached hereto as Exhibit C) which requires the payment of $657,387,200, plus interest from December 1, 2011, the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a restitution order outweighs the need to provide restitution to any non-federal victims in this case if any such victims exist given that establishing causation of loss to others by the delay in providing this particular information to the FDA would be extraordinarily difficult, if not impossible. *Cf.* 18 U.S.C. § 3663(a)(1)(B)(ii).

e. The United States agrees that it will not seek a term of probation in light of (i) the Compliance Measures and Certifications attached hereto as Addendum A; and (ii) the Corporate Integrity Agreement entered into between GSK and the Office of Inspector General of the Department of Health and Human Services, attached as Exhibit D.

6. No Further Prosecution of GSK

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), the United States agrees that, other than the charges in the attached Information, it shall not further prosecute GSK for any additional federal criminal charges with respect to the conduct covered by the Information, conduct that was the subject of the grand jury investigation in the District of Massachusetts, or facts currently known to the United States regarding:

(a) GSK's sales, marketing and promotion of Imitrex, Lamictal, Lotronex, Flovent, Paxil, Valtrex, Wellbutrin, and Zofran between January 1998 and December 2004;

(b) GSK's sales, marketing and promotion of Advair between January 1998 and June 2010;

(c) GSK's communications with and reporting to the FDA in connection with Advair, Paxil, and Wellbutrin between July 1998 and December 2004;

(d) GSK's sales, marketing and promotion of Avandia, Avandamet, and Avandaryl between January 2000 and December 2010; and

(e) GSK's communications with and reporting to the FDA in connection with Avandia, Avandamet, and Avandaryl.

This declination is expressly contingent upon:

(1) the guilty plea of GSK to the attached Information being accepted by the Court and not withdrawn or otherwise challenged; and

(2) GSK's performance of all of its obligations as set forth in this Agreement and the attached Civil Settlement Agreements.

If GSK's guilty plea is not accepted by the Court or is withdrawn for any reason, or if GSK should fail to perform any obligation under this Agreement or the Civil Settlement Agreements, this declination of prosecution shall be null and void.

The United States expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of GSK, in connection with the conduct encompassed by this plea agreement, within the scope of the grand jury investigation, or known to the United States.

7. Payment of Mandatory Special Assessment

GSK shall pay the mandatory special assessment to the Clerk of the Court on or before the date of sentencing.

8. Waiver of Right to Appeal and to Bring Other Challenge

a. GSK has conferred with its attorneys and understands that it has the right to challenge its convictions in the United States Court of Appeals for the First Circuit ("direct appeal"). GSK waives any right it has to challenge its conviction on direct appeal or in any future proceeding;

b. GSK has conferred with its attorneys and understands that defendants ordinarily have a right to appeal their sentences and may sometimes challenge their sentences in future proceedings. GSK understands, however, that once the Court accepts this Rule 11(c)(1)(C) plea agreement, the Court is bound by the parties' agreed-upon sentence. GSK may not contest the agreed-upon sentence in an appeal or challenge the sentence in a future proceeding in federal court. Similarly, the Court has no authority to modify an agreed-upon sentence under 18 U.S.C. § 3582(c), even if the Sentencing Guidelines are later modified in a way that appears favorable to GSK. Given that a defendant who agrees to a specific sentence cannot later challenge it, and also because GSK desires to obtain the benefits of this Agreement, GSK agrees that it will not challenge the sentence imposed in an appeal or other future proceeding. GSK also agrees that it will not seek to challenge the sentence in an appeal or future proceeding even if the Court rejects one or more positions advocated by any party at sentencing; and

c. The United States agrees that it will not appeal the imposition by the Court of the sentence agreed to by the parties as set out in Paragraph 5, even if the Court rejects one or more positions advocated by a party at sentencing.

9. Probation Department Not Bound By Agreement

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the United States Probation Office.

10. Forfeiture

GSK will forfeit to the United States assets subject to forfeiture pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c) as a result of its guilty plea.

GSK admits that the value of the quantities of Paxil and Wellbutrin that were misbranded and distributed in violation of 21 U.S.C. § 331, totaled at least $43,185,600 in United States currency. GSK acknowledges and agrees that the quantities of Paxil and Wellbutrin which were misbranded and distributed in violation of 21 U.S.C. § 331 cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, GSK agrees that the United States is entitled to forfeit as "substitute assets" any other assets of GSK up to the value of the now missing directly forfeitable assets.

GSK agrees that, no later than one week after sentencing, it shall remit the amount of $43,185,600 in United States currency to the United States Marshals Service pursuant to wire instructions provided by the United States Attorney's Office. GSK and the United States agree that this payment shall satisfy any and all forfeiture obligations that GSK may have as a result of its guilty plea.

Forfeiture of substitute assets shall not be deemed an alteration of GSK's sentence. The forfeitures set forth herein shall not satisfy or offset any fine, restitution, cost of imprisonment, or other penalty imposed upon GSK, nor shall the forfeiture be used to offset GSK's tax liability or any other debt owed to the United States.

GSK agrees to consent to the entry of orders of forfeiture for the $43,185,600 in United States currency, and waives the requirements of Federal Rules of Criminal Procedure 32.2 and 43(a) regarding the notice of the forfeiture in the charging instrument, entry of a preliminary order of forfeiture, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment. GSK acknowledges that it understands that the forfeiture of assets is part of the sentence that may be imposed in this case and waives any failure by the Court to advise it of this, pursuant to Rule 11(b)(1)(J), at the time the guilty plea is accepted.

In addition to all other waivers or releases set forth in this Agreement, GSK hereby waives any and all claims arising from or relating to the forfeitures set forth in this section, including, without limitation, any claims arising under the Double Jeopardy Clause of the Fifth Amendment, or the Excessive Fines Clause of the Eighth Amendment, to the United States Constitution, or any other provision of state or federal law.

The United States District Court for the District of Massachusetts shall retain jurisdiction to enforce the provisions of this section.

11. Civil and Administrative Liability

By entering into this Agreement, the United States does not compromise any civil or administrative liability, including but not limited to any False Claims Act or tax liability, which GSK may have incurred or may incur as a result of its conduct and its plea of guilty to the attached Information.

GSK's civil liability to the United States in connection with certain of the matters under investigation by the United States is resolved in the attached Civil Settlement Agreements, according to the terms set forth in those Agreements.

12. Waiver of Defenses

If GSK's guilty plea is not accepted by the Court for whatever reason, if GSK's guilty plea is later withdrawn or otherwise successfully challenged by GSK for whatever reason, or if GSK breaches this Agreement, GSK hereby waives, and agrees it will not interpose, any defense to any charges brought against it which GSK might otherwise have under the Constitution for pre-indictment delay, any statute of limitations, or the Speedy Trial Act, except any such defense that GSK may already have for (a) conduct occurring before October 19, 2000, as further described in the parties' tolling agreement dated December 1, 2011, and attached hereto as Exhibit E; and (b) conduct occurring before May 1, 2010, as further described in the parties' tolling agreement dated September 21, 2011, attached hereto as Exhibit F. This waiver is effective provided that charges are filed within six months of the date on which such guilty plea is rejected, withdrawn, or successfully challenged, or a breach is declared by the United States.

13. Breach of Agreement

If the United States determines that GSK has failed to comply with any material provision of this Agreement (which shall not include a failure to comply with the provisions in Addendum A, any alleged breach of which is governed solely by the terms of Addendum A), the United States may, at its sole option, be released from its commitments under this Agreement in its entirety by notifying GSK, through counsel or otherwise, in writing. The United States may also pursue all remedies available under the law, even if it elects not to be released from its commitments under this

Agreement. GSK recognizes that no such breach by GSK of an obligation under this Agreement shall be grounds for withdrawal of its guilty plea. GSK understands that should it breach any material provision of this Agreement, the United States will have the right to use against GSK before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by GSK, and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation.

GSK understands and agrees that this Rule 11(c)(1)(C) plea agreement and its agreed upon criminal disposition:

a. are wholly dependant upon GSK's timely compliance with the material provisions of the attached Civil Settlement Agreements; and

b. failure by GSK to comply fully with the material terms of this Agreement (which, as described above, shall not include a breach of the provisions of Addendum A) or the attached Civil Settlement Agreements will constitute a breach of this Agreement.

In the event GSK at any time hereafter breaches any material provision of this Agreement (other than a failure to comply with the provisions in Addendum A, which, as described above, shall not constitute a breach of this Agreement), GSK understands that (1) the United States will as of the date of that breach be relieved of any obligations it may have in this Agreement and the attached Civil Settlement Agreements, including but not limited to the promise not to further prosecute GSK as set forth in this Agreement; and (2) GSK will not be relieved of its obligation to make the payments set forth in this Agreement and the attached Civil Settlement Agreements, nor will it be entitled to return of any monies already paid. Moreover, in the event of a material breach of this Agreement, GSK understands and agrees that the United States may pursue any and all charges that might otherwise have been brought but for this Agreement, and GSK hereby waives, and agrees it will not interpose, any defense to any charges brought against it which it might otherwise have under the Constitution for pre-indictment delay, any statute of limitations, or the Speedy Trial Act, except any such defense that GSK may already have for conduct occurring before October 19, 2000 as further described in the tolling agreement attached as Exhibit E, and for conduct occurring before May 1, 2010, as further described in the tolling agreement attached as Exhibit F.

Any breach of the provisions of Addendum A shall not constitute a breach of this Agreement and shall be resolved solely under the breach provision of that Addendum.

14. Who Is Bound By Agreement

With respect to matters set forth in Paragraph 6, this Agreement is binding upon GSK and the Office of the United States Attorney for the District of Massachusetts, the United States Attorney's Offices for each of the other 92 judicial districts of the United States, and the Consumer Protection Branch of the Civil Division of the Department of Justice. The non-prosecution provisions in Paragraph 6 are also binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of GSK that are or may be conducted in the future by the

Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of GSK's products to foreign customers, which investigations are specifically excluded from the release in Paragraph 6. A copy of the letter to United States Attorney Carmen M. Ortiz from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Agreement is attached as Exhibit G. GSK understands that this Agreement does not bind any state or local prosecutive authorities, the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury.

15. Corporate Authorization

GSK's acknowledgment of this Agreement and execution of this Agreement on behalf of the limited liability company is attached as Exhibit H. GSK shall provide to the U.S. Attorney and the Court a certified copy of a resolution of the governing authority of GSK, affirming that it has authority to enter into the Plea Agreement and has (1) reviewed the Information in this case and the proposed Plea Agreement; (2) consulted with legal counsel in connection with the matter; (3) authorized execution of the proposed Plea Agreement; (4) authorized GSK to plead guilty to the charge specified in the Information; and (5) authorized the corporate officer identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement. A copy of the resolution is attached as Exhibit I. GSK agrees that either a duly authorized corporate officer or a duly authorized attorney for GSK, at the discretion of the Court, shall appear on behalf of GSK and enter the guilty plea and will also appear for the imposition of sentence.

16. Complete Agreement

This Agreement and the attachments hereto, together with an additional Civil Settlement Agreement and attachments thereto that is set forth as Exhibit J (civil agreement regarding pricing), and the side letter with GlaxoSmithKline plc (attached as Exhibit K), set forth the complete and only agreement between the parties relating to the disposition of this case and are the complete and only agreements between the parties. No promises, agreements, or conditions have been entered into other than those set forth or referred to in the above-identified documents. This Agreement supersedes prior understandings, if any, of the parties, whether written or oral. This Agreement cannot be modified other than in a written memorandum signed by the parties or on the record in court.

If this letter accurately reflects the Agreement between the United States and your client, GSK, please have the authorized representative of GSK sign the Acknowledgment of Agreement below. Please also sign below as Witness. Return the original of this letter to Assistant U.S. Attorneys Sara

Miron Bloom and Susan G. Winkler of the United States Attorney's Office for the District of Massachusetts.

Very truly yours,

CARMEN M. ORTIZ
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

Sara Miron Bloom
Susan G. Winkler
Shannon T. Kelley
Amanda Strachan
Brian Perez-Dapple
Assistant U.S. Attorneys

STUART F. DELERY
ACTING ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION
DEPARTMENT OF JUSTICE

Patrick Jasperse
Jill Furman
Mark L. Josephs
David Frank
Timothy Finley
Trial Attorneys
Consumer Protection Branch
U.S. Department of Justice

## ADDENDUM A

## COMPLIANCE MEASURES AND CERTIFICATIONS

GlaxoSmithKline LLC ("GSK") agrees that, prior to entering its plea of guilty, it has instituted and will maintain policies and procedures to prevent further violations of the Federal Food, Drug and Cosmetic Act ("FDCA") in its sales, marketing and promotion of prescription pharmaceutical products, and specifically for at least five years following entry of the plea, will do the following:

### I. COMPLIANCE MEASURES

#### A. Compensation and Incentives Not Based on Sales

GSK will maintain policies and procedures that shall (1) be designed to ensure that financial incentives do not inappropriately motivate prescriber-facing field sales professionals or their direct managers to engage in improper promotion, sales, and marketing of GSK's prescription pharmaceutical products; and (2) include mechanisms, where appropriate to exclude from incentive compensation sales that may indicate off-label promotion of prescription pharmaceutical products. These policies and procedures are collectively referred to as the "Patient First Program." Pursuant to the Patient First Program, which GSK has already implemented, GSK shall not provide financial reward (through compensation, including incentive compensation or otherwise) or discipline (through tangible employment action) to its prescriber-facing field sales professionals or their direct managers based upon the volume of sales of GSK products within a given employee's own territory or the manager's district. Instead, GSK will evaluate its sales representatives based on business acumen, customer engagement, and scientific knowledge about GSK's products.

#### B. Full, Fair and Accurate Reporting of Scientific Data

For at least the next five years, GSK will continue to maintain standards, policies and practices (consistent with GSK's Policy 408) regarding full, fair, and accurate reporting and transparency in scientific data in the following ways:

(1) GSK will, in relation to GSK-sponsored studies of prescription pharmaceutical products, publicly disclose: (a) at the time of primary publication of a human research study, the full clinical study protocol (with the removal of any personally identifiable information), (b) a protocol summary before enrollment begins and after completion of the study, a summary of primary and secondary efficacy endpoints, and safety results for interventional human subject research studies (in which participants are administered medical care, medicinal products, and/or medical/scientific procedures as described in a research protocol), (c) a

summary protocol and, after completion, a summary of the results for observational studies designed to inform safety, efficacy, or effectiveness (including cost-effectiveness); and (d) a protocol summary or plan for analysis and, after completion, a summary of results for meta-analyses and pooled analyses designed to inform appropriate, effective, or safe use.

(2) GSK will register summary results from all applicable GSK-sponsored clinical trials of GSK prescription pharmaceutical products, and report results of such clinical trials on the National Institutes of Health sponsored website (www.clinicaltrials.gov) in compliance with all federal requirements, and any changes to those requirements.

(3) GSK will seek to publish the results of GSK-sponsored research studies, certain GSK-sponsored observational research studies and certain GSK-sponsored meta-analyses and pooled analyses, in peer-reviewed, searchable journals. GSK will also continue its operating practices that require, among other requirements, implementation of data dissemination plans that establish prospective publication strategies for GSK-sponsored research and address requirements for appropriateness, accuracy, and balance in publications of GSK-sponsored research. In all publications about GSK-sponsored research, GSK shall acknowledge its role as the funding source.

(4) GSK will require all GSK-sponsored research to be approved by its medical and/or research organizations. GSK will maintain its current policy that no sales, marketing or other commercial personnel may participate in the design, conduct, or publication of GSK-sponsored research, with limited exceptions relating to non-interventional health outcome studies (for which a relevant GSK medical group has oversight). GSK will continue to assure its human subject research and resulting publications are intended to foster increased understanding of scientific, clinical or medical issues.

(5) GSK will require as a condition of its funding that all researchers disclose in any publication of GSK-sponsored research GSK's support and any financial interest the researcher may have in GSK (including any interest in any GSK prescription pharmaceutical product). GSK will require all authors of journal articles about GSK-sponsored research to adhere to International Committee of Medical Journal Editors (ICMJE) requirements regarding authorship except when a journal requires an alternative procedure.

(6) GSK will, by September 1, 2012, require that its employees and medical writing contractors complete, and GSK will maintain for ten years, as to any publication regarding GSK-sponsored research on which the employee or contractor is listed as an author, a certification that the publication provides a fair, accurate, and balanced summary of the GSK-sponsored research.

(7) GSK will require that a person will be represented as an "author" on any GSK publication of GSK-sponsored research only if he or she has made substantial contributions to the study and has final approval of the version to be published.

(8) GSK will properly report adverse event data to the FDA. GSK will maintain policies and procedures designed to ensure that all periodic reports to the FDA contain all required information and data regarding clinical studies. GSK will require investigators to report study-related information and data, including data about adverse events before receiving final payment from GSK.

**C. Payer Related Obligations**

For a period of at least five years from the entry of the plea, GSK will adopt and maintain policies and procedures governing its strategies and practices in contracting, Payer negotiations and interactions, providing of discounts and rebates, and interactions relating to formularies and co-pay status and amounts ("Payer-Related Functions"), which policies shall provide that GSK will perform these functions in compliance with all applicable laws and federal and state health care program requirements, and shall be consistent with GSK U.S. Commercial Practices Policy regarding "Administration of Contracts with Payers."

**D. No Sales and Marketing Role in Independent Medical Education**

GSK will maintain policies that prohibit commercial involvement in independent medical education ("IME") programs, while also ensuring that this programming is focused on genuine educational need and scientific development. GSK will require that the content, organization, and operation of the IME program (including the faculty, educational methods, materials, and venue) be independent of GSK's control. GSK's commercial organization (including the sales and marketing departments) will have no involvement in, or influence over, the review and approval of independent medical education grants.

**E. Require Confirmation That Requests for Information Were Unsolicited**

GSK will maintain its policy that prohibits sales personnel from engaging in off-label promotion (directly or indirectly) and requiring sales personnel to refer all requests for

information about off-label uses to Medical Affairs personnel. GSK will require sales personnel to obtain a signature from the medical professional who verbally requested written information regarding off-label uses in order to confirm the information requested and that the request was unsolicited.

## II. NOTIFICATION OF SETTLEMENT

Within ninety (90) days of the public announcement of the settlement, GSK will send a letter to health care providers that GSK currently details regarding the products at issue in this resolution, the terms of the resolution, and a link to a website that will contain all of the relevant public resolution documents relating to this matter.

Within ninety (90) days of the public announcement of the settlement, GSK will send a letter to all payers with whom GSK currently has contracts or enters into contracts for formulary access or rebates (including all state Medicaid programs) regarding the products at issue in this resolution, the terms of the resolution, and a link to a website that will contain all of the relevant public resolution documents relating to this matter.

## III. CERTIFICATIONS AND REPORTING TO THE UNITED STATES

In addition to any commitment to provide any certifications and reports to other government agencies or entities, GSK shall provide the following reports and certifications to the United States Department of Justice for a period of five years commencing on the date of sentencing. The certifications and reports shall be sent to:

Chief, Health Care Fraud Unit
U.S. Attorney's Office
One Courthouse Way, Suite 9200
Boston, MA 02210

and

Director, Consumer Protection Branch
Civil Division
Department of Justice
450 5th Street, NW
Washington, DC 20530

### A. Annual GSK's U.S. President Certification

The President of GSK's North America Pharma division ("GSK's U.S. President") shall conduct a review of the effectiveness of GSK's Compliance Program as it relates to the marketing, promotion, and sale of prescription pharmaceutical products during the preceding year. The first review period shall run from the date of sentencing through December 31, 2013. Thereafter, the reviews will be conducted on an annual basis. Based on his or her review, GSK's

U.S. President shall submit to the United States a signed certification stating that, to the best of his or her knowledge, during the period [insert time period]: (1) GSK's Compliance Program continued to include the compliance policies and procedures set forth in the section of this Addendum entitled "COMPLIANCE MEASURES," and (2) to the extent that a Reportable Incident (as that term is defined below) has been determined to have occurred, GSK has fully complied with the Reportable Incident reporting requirements of this Addendum. The certification by GSK's U.S. President shall summarize the review described above that he or she conducted to provide the required certification. If GSK's U.S. President is unable to provide any part of this certification regarding GSK's compliance, he or she shall provide an explanation of why he or she is unable to provide such certification. This certification shall be provided within 60 calendar days following the end of each review period.

**B. Annual Board of Directors Resolution**

The Board of Directors of GlaxoSmithKline plc, or a designated Committee thereof (the "Board"), shall conduct a review of the effectiveness of GSK's Compliance Program as it relates to the marketing, promotion, and sale of prescription pharmaceutical products. This review shall be conducted on an amual basis and shall include, but not be limited to, updates and reports by GSK's Compliance Officer and other compliance personnel. The Board shall evaluate the effectiveness of the Compliance Program, including, among other means, by receiving updates about the activities of the Compliance Officer and other compliance personnel and updates about adoption and implementation of policies, procedures, and practices designed to ensure compliance with applicable Federal health care program and FDA requirements. The first review will cover the time period from the date of sentencing through December 31, 2013. Thereafter the reviews will be conducted on an annual basis. Based on its review, the Board shall submit to the United States a resolution that summarizes its review and oversight of GSK's compliance with Federal health care program requirements and FDA requirements and, at a minimum, includes the following language:

> The Board of Directors has made a reasonable inquiry into the operations of GSK's Compliance Program for the time period [insert time period], including the performance of the Compliance Officer and the compliance personnel who are Covered Persons under the Corporate Integrity Agreement ("CIA") between GSK and the Office of Inspector General of the United States Department of Health and Human Services ("OIG-HHS"). The Board has concluded that, to the best of its knowledge, GSK has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the requirements of the Addendum to the Plea Agreement.

If the Board is unable to provide any part of this statement, it shall include in the resolution an explanation of the reasons why it is unable to provide such a statement about the effectiveness of GSK's Compliance Program. This resolution shall be provided within 60 calendar days following the end of each review period.

## C. Reportable Incidents

Fifteen days after the end of each calendar quarter (that is, by January 15 for the calendar quarter ending December 31, April 15 for the calendar quarter ending March 31, July 15 for the calendar quarter ending June 30, and October 15 for the calendar quarter ending September 30) GSK shall submit a report to the United States in writing stating whether any Reportable Incidents have been determined to have occurred during the preceding calendar quarter, and providing updated information about Reportable Incidents that occurred during any other calendar quarters. A Reportable Incident is any matter that a reasonable person would consider a probable violation of the FDCA, 21 U.S.C. §§ 331(a) or (k), related to the misbranding of a prescription pharmaceutical product within the meaning of 21 U.S.C. § 352; and/or a probable violation of 21 U.S.C. §§ 331(e) and 355(k) related to the failure to provide required reports for prescription pharmaceutical products, including reports of data relating to clinical experience and other information as required by the FDA. A Reportable Incident may be the result of an isolated event or a series of occurrences. The written report to the United States shall include: (i) a complete description of the Reportable Incident, including the relevant facts, identity of persons involved, and legal authorities implicated; (ii) a description of GSK's actions taken to investigate and correct the Reportable Incident; and (iii) a description of any further steps GSK plans to take to address the Reportable Incident and prevent it from recurring. Any Reportable Incident determined to have occurred by GSK shall be promptly reported to the President of GSK's North America Pharma division. The first calendar quarter for which a report shall be due under this Paragraph is the quarter ending December 31, 2012.

## D. SEC Filings

Within seven (7) days of filing, GSK shall submit copies of each Securities and Exchange Commission Form 6-K.

## E. DEFINITIONS

For the purpose of this addendum, the following terms shall have the following meaning:

1. The term "certification" shall mean a statement sworn to under the pains and penalties of perjury and which shall set forth that the representations contained therein may be provided to, relied upon and material to the government of the United States, and that a knowing false statement could result in criminal or civil liability for the signatory.

2. The term "Compliance Officer" refers to the Vice President and Compliance Officer for GSK's North America Pharma division. For at least the term of this Addendum, the Compliance Officer shall be a member of GSK's senior management of the North America Pharma division and GSK's U.S. Compliance Committee. Not later than thirty

(30) days after the date of sentencing, GSK shall notify the United States in writing of the name of the Compliance Officer and provide a written description of that person's responsibilities with respect to complying with the FDCA and FDA's regulations and guidance documents relating to the marketing, promotion, and sale of prescription pharmaceutical products. GSK shall, in writing, report to the United States any changes in the identity of or any material changes in the position and responsibilities of the Chief Compliance Officer within fifteen (15) days of any such change.

3. The term "U.S. Compliance Committee" refers to the North America Pharma Risk Management & Compliance Board which, in conjunction with the Compliance Officer, assists in the implementation and enhancement of the Compliance Program. For at least the term of this Addendum, this committee shall, at a minimum, include the Chief Compliance Officer and other members of North America Pharma division senior management with responsibilities concerning the marketing, promotion, and sale of GSK's prescription pharmaceutical products. Not later than thirty (30) days after the date of sentencing, GSK shall notify the United States in writing of the names of the members of the U.S. Compliance Committee and provide a written description of their responsibilities with respect to complying with the FDCA and FDA's regulations and guidance documents relating to the marketing, promotion, and sale of prescription pharmaceutical products. GSK shall, in writing, report to the United States any changes in the composition of the U.S. Compliance Committee. This report shall be provided within fifteen (15) days of any such change.

4. The term "Compliance Program" refers to the policies, procedures, practices, and other measures that GSK has established or will establish to address regulatory compliance issues relating to the marketing, promotion and sale of prescription pharmaceutical products, including GSK's compliance with FDCA and FDA regulations and guidance documents.

5. The term "prescription pharmaceutical products" means drugs marketed, promoted, or sold in the United States and intended for use by humans which must be used under the supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1).

6. The term "Payers" refers to entities that provide a drug health benefit program for prescription pharmaceutical products, including but not limited to government payers (e.g., Medicaid and Medicare) or individuals or entities under contract with or acting on behalf of government payers and commercial health plans.

## IV. BREACH OF THIS ADDENDUM

GSK recognizes that each of the terms in this Addendum constitutes a material term of this Addendum. As a contractual remedy, GSK and the United States agree that failure to comply with the obligations set forth in this Addendum may lead to the imposition of the following monetary penalties (hereafter referred to as "Stipulated Penalties") in accord with the following provisions.

A. A Stipulated Penalty of $20,000 per day for each day GSK (1) fails to maintain each of the compliance measures set forth in Subsection I, above (if more than one compliance measure fails to be maintained, the Stipulated Penalty will apply separately to each compliance measure); or (2) fails to timely supply any of the certifications or reports required in Subsection III, above. With regard to the certifications and reports, the Stipulated Penalty will begin to accrue on the day after the date the obligation was due, subject to the provisions for extension of time for compliance and the opportunity to cure set forth below.

B. GSK may submit a timely written request for an extension of time to provide any certification or report required in Subsection III. A written request is timely if received by the Chief of the Healthcare Fraud Unit for the U.S. Attorney's Office for the District of Massachusetts at least five business days prior to the date by which the certification or report is due. Timely requests for extension will not be unreasonably denied. If an extension of time is granted in writing, Stipulated Penalties shall not accrue until one day after GSK fails to meet the revised deadline. If not granted, Stipulated Penalties shall not begin to accrue until three business days after GSK receives the United States' written denial of such request or the original due date, whichever is later.

C. Upon the United States' sole reasonable determination that GSK has failed to comply with any of the obligations described herein, the United States shall notify GSK in writing of GSK's failure to comply and the United States' exercise of its contractual right to demand payment of the Stipulated Penalties (the "Demand Letter"). The Demand Letter shall set forth: (i) the provision breached; (ii) the date of the breach; (iii) a description of the breach sufficient to permit GSK to cure (as described below); and (iv) the amount of Stipulated Penalties claimed by the United States as of the date of the Demand Letter. Within fourteen (14) days after receipt of the Demand Letter, or such other period as the United States may agree in writing, GSK shall cure the breach to the United States' reasonable satisfaction ("Cure Period"). If GSK cures the breach within the Cure Period, no Stipulated Penalties shall be due. If GSK fails to cure the breach during the Cure Period, Stipulated Penalties calculated from the date of breach to the date of payment shall be immediately payable to the United States. The Stipulated

Penalties shall be paid by electronic fund transfer according to wire instructions that will be provided by the United States. A joint reasonable determination by the United States Attorney for the District of Massachusetts and the Assistant Attorney General for the Civil Division regarding GSK's failure to comply with any of the obligations described herein will be final and non-appealable. GSK agrees that the United States District Court for the District of Massachusetts shall have jurisdiction over any action to collect such a penalty.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

| | |
|---|---|
| UNITED STATES OF AMERICA | ) Crim. No. |
| v. | ) Violations: ) 21 U.S.C. §§ 331(a),333(a)(1), ) 352 (Misbranding) |
| GLAXOSMITHKLINE LLC | ) |
| Defendant | ) 21 U.S.C. §§ 331(e),333(a)(1), ) 355(k)(1)(Failure to Report ) Data to FDA) |

**INFORMATION**

The United States Attorney charges that:

**GENERAL ALLEGATIONS**

At all times material hereto, unless otherwise alleged:

1. From 1999 through 2003, **GLAXOSMITHKLINE LLC** or entities for which it is the corporate successor (hereinafter "**GSK**") promoted the sale of its drugs Paxil and Wellbutrin for uses other than those approved as safe and effective by the Food and Drug Administration ("FDA"). Specifically, GSK

a. promoted Paxil for children and adolescents, and

b. promoted Wellbutrin for weight loss, the treatment of sexual dysfunction, substance addictions, Attention Deficit Hyperactivity Disorders, among other unapproved uses.

2. From 2001 through September 2007, **GSK** failed to report data relating to clinical experience and other data and information as required by law, regarding Avandia, a diabetes

medication, to the FDA.

**The Defendant**

3. Defendant **GSK** was a pharmaceutical company originally organized as a corporation under the laws of Pennsylvania, and later converted to a Delaware Limited Liability Company, GlaxoSmithKline LLC. **GSK's** operational headquarters were in Philadelphia, Pennsylvania, and Research Triangle Park, North Carolina. **GSK** manufactured, distributed, and sold pharmaceutical drugs for human use, including for sale and use in Massachusetts.

**The FDA and the FDCA**

4. The FDA was the federal agency of the United States responsible for protecting the health and safety of the public. The FDA was responsible for enforcing the Food, Drug, and Cosmetic Act ("FDCA") and ensuring, among other things, that drugs intended for use in humans were safe and effective for their intended uses and that the labeling of such drugs contained true and accurate information.

5. With certain limited exceptions not pertinent here, a drug could not be distributed in interstate commerce without FDA approval. To gain FDA approval, data from adequate and well-controlled clinical studies had to demonstrate that the drug would be safe and effective for a particular use. As part of the approval process, the FDA had to approve the drug's labeling,

which was required to set forth detailed information about the drug, including the approved medical conditions of use, dosages, and patient population(s).

6. Once the FDA found a drug to be safe and effective for a particular use and approved it for that use, doctors were free to exercise their medical judgment to prescribe the drug for other, unapproved (or "off-label") uses.

7. Under the FDCA, however, the manufacturer could not lawfully market and promote the drug for off-label uses.

8. The FDCA provided that a drug was misbranded if, among other things, "its labeling is false or misleading in any particular." 21 U.S.C. § 352(a). Labeling includes written, printed, or graphic information on or accompanying a drug, including information that explains the uses of the drug and is used in connection with the sale of the drug, whether or not it physically accompanies the drug when distributed. False and misleading safety and efficacy claims in a drug's labeling rendered the drug misbranded.

9. The FDCA also provided that a drug was misbranded if its labeling did not bear "adequate directions for use." 21 U.S.C. § 352(f)(1). As the phrase was used in the FDCA and its regulations, "adequate directions for use" meant directions under which a layperson could use a drug safely and effectively for the

purposes for which it was intended. 21 C.F.R. § 201.5. A prescription drug, by definition, could not bear adequate directions for use by a layperson, but an FDA-approved prescription drug, bearing the FDA-approved labeling, could be exempt from the adequate directions for use requirement if it met a number of conditions, including that it was sold only for an FDA-approved use. A prescription drug that was marketed for unapproved, off-label uses would not qualify for this exemption and therefore was misbranded. 21 C.F.R. § 201.100.

10. The FDCA prohibited causing the introduction or delivery for introduction into interstate commerce of, or introducing or delivering for introduction into interstate commerce, any drug that was misbranded. 21 U.S.C. § 331(a).

## COUNT ONE - PAXIL

**(Distribution of a Misbranded Drug: False and Misleading Labeling: 21 U.S.C. §§ 331(a), 333(a)(1), & 352(a))**

11. The allegations contained in paragraphs 1 and 3 through 10 are realleged and incorporated herein as if set forth in full.

## GSK'S OFF-LABEL PROMOTION OF PAXIL FOR CHILDREN AND ADOLESCENTS

12. **GSK** manufactured, distributed, and sold the prescription drug Paxil for human use. Paxil was **GSK**'s trade name for the drug paroxetine hydrochloride. Paxil was part of a class of drugs known as selective serotonin reuptake inhibitors ("SSRIs").

13. In December 1992, the FDA approved Paxil to treat depression in adults. The FDA subsequently approved Paxil for other uses in adults.

14. The FDA never approved Paxil for any purpose for patients under age 18 ("children and adolescents").

15. **GSK** promoted the use of Paxil to doctors through a sales force of approximately 1,900 sales representatives who made personal visits ("sales calls") to doctors to encourage those doctors to prescribe Paxil to their patients.

16. **GSK** sales representatives wrote "call notes" to document what happened during their sales calls with doctors.

Once sales representatives entered their call notes into **GSK**'s computer system, the call notes could be read by the sales representatives' colleagues and supervisors.

17. Paxil became one of the 10 top-selling drugs in the United States and for a time the most commonly prescribed SSRI. Paxil sales in the United States surpassed $1.8 billion per year in 2001 and 2002.

**Placebo-Controlled Clinical Trials**

18. The safety and efficacy of pharmaceutical drugs were tested in clinical trials or studies.

19. In a "placebo-controlled" clinical study, one group of patients was treated with the drug being studied and another group of patients received a placebo. A placebo looked like the drug that was being studied, but contained no active ingredient.

20. In a "double-blinded" clinical study, neither the patient nor the treating doctor knew whether the patient was receiving the drug being studied or a placebo.

21. In a placebo-controlled clinical study, the efficacy of a drug was measured by primary and secondary "endpoints" that typically were identified before the study began in a protocol prepared by the sponsor of the study. The primary endpoint or endpoints were the main measures of whether the drug worked. The secondary endpoints contained additional measures to assess the

drug's efficacy.

22. At the end of the study, the study was "unblinded" and the results on the endpoints of patients who had received the drug being studied were compared to the results on the endpoints of the patients who received a placebo.

23. In determining whether a study had demonstrated a drug's efficacy, the FDA typically looked at whether there was a statistically significant difference on the primary endpoints between the patients in the study who received the drug being studied and patients in the study who received a placebo.

**Three Clinical Studies Failed to Establish Paxil's Efficacy for Treating Depression in Children and Adolescents**

24. Between 1994 and 2001, **GSK** conducted three placebo-controlled clinical studies that studied Paxil's safety and efficacy in treating depression in children and adolescents. These studies were known as Study 329, Study 377, and Study 701.

25. Study 329 compared the efficacy of Paxil and a second drug, imipramine, to placebo in treating depression in patients age 12 to 18. Imipramine was part of a class of drugs known as tricyclic antidepressants ("TCAs"). The acute phase of Study 329 began in April 1994 and ended in May 1997. **GSK**'s internal clinical report summarizing the results of Study 329 was issued on November 24, 1998.

26. Paxil failed to demonstrate efficacy on Study 329's two primary endpoints. Paxil also failed to demonstrate efficacy on the five secondary endpoints identified in Study 329's protocol. Paxil demonstrated efficacy on four other secondary endpoints that were not identified in the protocol, but that were identified as secondary endpoints by the clinical investigators before Study 329's results were unblinded.

27. Study 377 compared the efficacy of Paxil to placebo in treating depression in patients age 13 to 18. Study 377 began in April 1995 and was completed in May 1998. **GSK**'s internal clinical report summarizing the results of Study 377 was issued on November 19, 1998.

28. Paxil failed to demonstrate efficacy on any of the primary or secondary endpoints in Study 377.

29. Study 701 compared the efficacy of Paxil to placebo in treating depression in patients age 7 to 17. Study 701 began in March 2000 and ended in January 2001. **GSK**'s internal clinical report summarizing the results of Study 701 was issued on July 30, 2001.

30. Paxil failed to demonstrate efficacy on any of the primary or secondary endpoints in Study 701.

**GSK Helped Write and Approved a Medical Journal Article Which Stated that Study 329 Demonstrated that Paxil Was Effective in Treating Depression in Adolescents**

31. **GSK** hired a contractor to help write an article about the results of Study 329. The contractor wrote the first draft of the article based on GSK's internal final clinical report on Study 329. The contractor then incorporated into subsequent drafts of the article revisions made by the clinical investigators and a **GSK** employee involved in the study.

32. The article about Study 329 was published in July 2001 in the Journal of the American Academy of Child and Adolescent Psychiatry ("JAACAP"). The article listed 22 authors, including 20 clinical investigators who were not **GSK** employees and two **GSK** employees. In addition, the contractor was identified as having provided "editorial assistance." **GSK** and the authors approved the article before it was submitted to JAACAP.

33. The JAACAP article identified Study 329's two primary endpoints. The JAACAP article also listed five secondary endpoints "that were declared a priori." Three of these five secondary endpoints were not identified before the study began, but had been identified as secondary endpoints by the clinical investigators before Study 329's results were unblinded. Elsewhere, the article contained a chart that showed the results of eight endpoints. The chart did not indicate which endpoints

were primary, which endpoints were identified as secondary in the protocol before the study began, and which endpoints had been added after the study had begun but before the results were unblinded.

34. The JAACAP article was false and misleading. Although the article's text identified the two primary endpoints and the article's chart reported the results on those endpoints, the article never explicitly stated that Study 329 failed to demonstrate efficacy on either of its two primary endpoints. The article at one point inaccurately stated that Paxil "separated statistically from placebo" on a primary endpoint. The article also did not explicitly state that Paxil failed to demonstrate efficacy on all of the secondary endpoints that had been identified in the protocol.

35. The JAACAP article presented the results of Study 329 as favorable, based on Paxil having demonstrated efficacy on the four secondary endpoints that were not identified in the protocol and which were added after the study had begun but before the results were unblinded. The JAACAP article's abstract stated that Paxil "is generally well tolerated and effective for major depression in adolescents." The JAACAP article's conclusion stated that "[t]he findings of this study provide evidence of the efficacy and safety of the SSRI, [Paxil], in the treatment of

adolescent depression."

36. The article disclosed that serious adverse events ("SAEs") were experienced by 11 patients in Study 329 who received Paxil, five patients who received imipramine, and two patients who received the placebo. An earlier draft of the article stated that of the 11 SAEs experienced by Paxil patients, "worsening depression, emotional lability, headache, and hostility were considered related or possibly related to treatment." A **GSK** employee suggested that the contractor change this section of the article. The revised version printed in JAACAP stated: "Of the 11 patients [who had serious adverse events while taking Paxil], only headache (1 patient) was considered by the treating investigator to be related to [Paxil] treatment."

**GSK Used the Article in JAACAP to Promote Paxil for Children and Adolescents**

37. The contractor hired by **GSK** to help prepare the medical journal article provided drafts of the article to the head of **GSK**'s Paxil marketing team.

38. On or about August 16, 2001, **GSK**'s Paxil marketing team sent a copy of the JAACAP article to all of the approximately 1,900 **GSK** sales representatives who sold Paxil. A cover memorandum summarizing the article (the "**GSK** Cover Memo") stated

in bold type:

> This 'cutting-edge,' landmark study is the first to compare efficacy of an SSRI and a TCA with placebo in the treatment of major depression in adolescents. *Paxil* demonstrates REMARKABLE Efficacy and Safety in the treatment of adolescent depression.

39. The **GSK** Cover Memo also stated:

> In conclusion, the findings of this study provide evidence of the efficacy and safety of Paxil in the treatment of adolescent depression. Here's another example of GlaxoSmithKline's commitment to Psychiatry by bringing forth "cutting edge" scientific data. Paxil is truly a REMARKABLE product that continues to demonstrate efficacy, even in this understudied population.

40. The **GSK** Cover Memo did not disclose that Paxil failed to demonstrate efficacy on the protocol-defined primary and secondary endpoints of the same study. The **GSK** Cover Memo also did not disclose that **GSK** had completed two other studies that also did not demonstrate that Paxil was effective in treating depression in children and adolescents.

41. The **GSK** Cover Memo did not state that Paxil was not approved for the treatment of children and adolescents. The **GSK** Cover Memo stated that the article was for sales representatives' information only and should not be used with or distributed to doctors, and both the Cover Memo and the article were stamped "FOR REPRESENTATIVES' INFORMATION ONLY."

42. Some **GSK** sales representatives used the JAACAP article

to urge doctors to prescribe Paxil to treat depression in children and adolescents.

**GSK Did Not Publicize the Results of Studies 377 and 701**

43. **GSK** learned the results of Study 377 in 1998 and the results of Study 701 in 2001. Paxil failed to demonstrate efficacy on any of the endpoints in either study.

44. **GSK** did not hire a contractor to help write medical journal articles about the results of Studies 377 and 701, as it had with Study 329.

45. **GSK** did not inform its sales representatives about the results of Studies 377 and 701.

**Safety Issues**

46. After **GSK** provided to the FDA the results of Studies 329, 377, and 701, as well as additional statistical analyses performed by GSK, some of which suggested a possible increased suicidality associated with Paxil use in patients under age 18, the FDA conducted a broad inquiry into the safety of Paxil, other SSRIs, and other antidepressants to treat depression in patients under age 18.

47. On or about June 19, 2003, the FDA recommended that Paxil not be used to treat depression in patients under age 18.

48. On or about October 27, 2003, the FDA stated that antidepressants should be used only with caution to treat

depression in patients under age 18.

49. On or about October 15, 2004, the FDA required all antidepressants, including Paxil, to include on their labels a "black box warning" stating that antidepressants increased the risk of suicidal thinking and behavior in short-term studies in patients under age 18.

**GSK Provided Sales Representatives With Other Information Which Was Used to Promote the Use of Paxil in Children and Adolescents**

50. In 1999, **GSK** created a 150-person neuroscience specialty sales force to promote Paxil to psychiatrists. On or about September 28, 1999, **GSK** paid a child psychiatrist, whose research primarily dealt with patients under age 18, to speak at the launch meeting of **GSK**'s neuroscience specialty sales force. According to a subsequent internal **GSK** newsletter reporting on the event, this child psychiatrist discussed the results of Study 329 and said that **GSK** had a "window of opportunity." According to the internal **GSK** newsletter, this child psychiatrist told the neuroscience sales representatives that, as a result of Study 329, "We can say that paroxetine has both efficacy and safety data for treating depression in adolescents."

51. On or about February 14, 2001, **GSK** sent a copy of a medical journal article about the use of Paxil for adolescent obsessive compulsive disorder ("OCD") to all of the approximately

1,900 **GSK** sales representatives who sold Paxil. An accompanying memorandum summarizing the article stated: "This study suggests that *Paxil* is an effective short-term treatment for OCD in children [and] adolescents (aged 9-15 years) and has fewer AE's [adverse events]." The memorandum stated that the information was for sales representatives' information only and should not be used with or distributed to doctors.

52. From 2000 to 2002, some **GSK** sales representatives used information provided by **GSK** to urge doctors to use Paxil to treat children and adolescents with depression, OCD, and other psychiatric conditions.

**GSK Used Paxil Forum Events to Promote Paxil for Children and Adolescents**

53. **GSK** held eight "Paxil Forum" events at resorts in Puerto Rico, Hawaii, and California in 2000 and 2001. **GSK** invited psychiatrists who prescribed large amounts of SSRIs to attend the events. Each of **GSK**'s approximately 150 neuroscience sales representatives could attend up to two of the events per year, and each representative could invite up to two different psychiatrists to each event. The 3-day Paxil Forum events included presentations about Paxil and other topics. The events also included dinners and recreational activities such as deep sea fishing, kayaking, snorkeling, sailing, horseback riding,

balloon rides, and golf. **GSK** paid for the psychiatrists' air fare, lodging, meals, recreational activities, and provided to each of them an honorarium of $750. The Paxil marketing team organized, attended, and participated in the Paxil Forum events.

54. **GSK** paid a leading child psychiatrist to speak at four of the eight Paxil Forum events in 2000 and 2001. At each of these four Paxil Forum events, this child psychiatrist encouraged other doctors to use SSRIs to treat depression and social anxiety disorder in patients under age 18. This child psychiatrist claimed that patients treated with Paxil in Study 329 showed "significantly greater improvement" than patients who received the placebo.

55. To promote the use of Paxil in children and adolescents, some **GSK** sales representatives purposely invited psychiatrists with a significant percentage of patients under age 18 to attend the Paxil Forum events at which the child psychiatrist recommended the use of SSRIs for children and adolescents.

56. Following the Paxil Forum events, some **GSK** sales representatives gave doctors during sales calls copies of the slides shown during the Paxil Forum events by the child psychiatrist referenced in Paragraph 52 above. The slides reported only select, favorable results from Study 329. The

slides did not report the unfavorable results from Study 329 or other studies of Paxil's efficacy in treating depression in children and adolescents. The slides also did not state that the FDA had not approved the use of Paxil in patients under age 18. The slides distributed by the **GSK** sales representatives were false and misleading.

57. **GSK** monitored the prescriptions written by psychiatrists who attended the Paxil Forum events in 2000 to determine whether the events increased Paxil's market share. **GSK** concluded that the Paxil Forum events in 2000 "had a significant impact on Paxil market share in the months after attendance." GSK found that the percentage of Paxil prescriptions relative to other SSRI prescriptions prescribed by psychiatrists who attended the Paxil Forum events in 2000 increased when compared to the percentage prescribed by psychiatrists who had not attended the Paxil Forum events. Individual **GSK** sales representatives continued to monitor whether psychiatrists who attended the Paxil Forum events in 2001 increased their Paxil prescriptions after attending the events.

## GSK Used Dinner Programs to Promote the Use of Paxil in Children and Adolescents

58. **GSK** sponsored dinner programs, lunch programs, spa programs, and similar activities to promote the use of Paxil in

children and adolescents. At such events, **GSK** paid a speaker to talk to an audience of doctors. **GSK** paid for the meal or spa treatment for the doctors who attended. These events were approved in advance by **GSK**'s district sales managers and by **GSK**'s speakers bureau.

## GSK Used Samples to Promote the Use of Paxil in Children and Adolescents

59. **GSK** provided each sales representative with a list of doctors on whom the sales representatives should make sales calls. The lists specified how frequently sales representatives should make sales calls on each doctor. Sales representatives were required to call most frequently on doctors who prescribed the most SSRIs.

60. **GSK** encouraged its sales representatives to give doctors free Paxil samples during the sales calls. **GSK**'s purpose in distributing free samples was to allow doctors to start patients on Paxil, with the hope that the patient would be shifted to a paid Paxil prescription if the treatment was successful.

61. Beginning in or around August 2003, **GSK** began attempting to remove from its Paxil call lists doctors who exclusively treated patients under age 18. This process continued until at least on or about May 11, 2005. Thus, prior

to in or around August 2003, **GSK** required its sales representatives to make sales calls on, and encouraged its sales representatives to provide Paxil samples to, doctors who treated only patients under age 18. There was no FDA-approved use for Paxil in patients under age 18.

**DISTRIBUTION OF PAXIL**

62. Throughout the relevant time period of the above-described actions, **GSK** distributed Paxil in Massachusetts and elsewhere and held Paxil for sale in Massachusetts and elsewhere.

**DISTRIBUTION OF MISBRANDED PAXIL**

63. From on or about April 3, 1998, through in or around the end of August 2003, in the District of Massachusetts, and elsewhere, defendant

**GlaxoSmithKline LLC**

did introduce and cause the introduction into interstate commerce, directly and indirectly, into Massachusetts and elsewhere from outside of Massachusetts, Paxil, a drug within the meaning of the FDCA, 21 U.S.C. § 321(g), that was misbranded, in that its labeling was false and misleading.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a).

## COUNT TWO - WELLBUTRIN

**(Distribution of a Misbranded Drug: Inadequate Directions for Use 21 U.S.C. §§ 331(a), 333(a)(1) & 352(f)(1))**

64. The allegations contained in paragraphs 1 and 3 through 10 are realleged and incorporated herein as if set forth in full.

## GSK'S PROMOTION OF WELLBUTRIN FOR UNAPPROVED USES

65. **GSK** manufactured, distributed, and sold the prescription drug Wellbutrin for human use. Wellbutrin was **GSK**'s trade name for the drug bupropion hydrochloride.

66. At all times relevant to the Information, Wellbutrin was approved by the FDA only as a treatment for major depressive disorder in adults age 18 or older.

67. From 1999 to 2003, Wellbutrin was not approved for any use other than to treat major depressive disorder in adults.

68. To increase its profits from Wellbutrin, from in or about 1999 through 2003, **GSK** promoted the sale and use of Wellbutrin for a variety of uses for which **GSK** had not received FDA approval including:

a. for weight loss and the treatment of obesity;

b. to treat sexual dysfunction;

c. as an "add-on" drug to treat the side effects of other antidepressant medications, including weight gain and sexual dysfunction;

d. to treat Attention Deficit Hyperactivity Disorder ("ADHD") and other attention disorders;

e. to treat addiction to drugs, alcohol, or gambling;

f. to treat other mental diseases such as anxiety and bipolar disorder;

g. to treat patients under age 18; and

h. with dosing regimens different than those in the label.

69. **GSK** encouraged sales representatives to provide messages about off-label uses of Wellbutrin during one-on-one sales calls with doctors.

70. **GSK** sales representatives sometimes referred to Wellbutrin as "the happy, horny, skinny pill" as a way to remind doctors of the unapproved uses for Wellbutrin that they were promoting.

71. **GSK** used speaker programs to spread off-label information about Wellbutrin to doctors. **GSK** trained and paid doctors to speak to other doctors at hundreds of promotional events per year that were organized by **GSK**'s sales representatives. At many of these events, speakers recommended the use of Wellubutrin for unapproved uses. Some of these speakers also made additional false and misleading claims about Wellbutrin's safety and efficacy for approved and unapproved uses.

72. Two of **GSK**'s most frequently used speakers, who each

spoke more than 800 times and were each paid more than $1.5 million by **GSK** from 2000 to 2003, recommended Wellbutrin for a wide variety of unapproved uses, including for weight loss, to treat sexual dysfunction, to treat ADHD and other attention disorders, and even for patients with bulimia or who were abruptly discontinuing alcohol (both of which were specifically contraindicated in Wellbutrin's labeling).

73. **GSK** paid doctors to attend lavish meetings in places such as Jamaica and Bermuda during which **GSK** provided off-label information about Wellbutrin in a manner to encourage doctors to write Wellbutrin prescriptions for unapproved uses of the drug. **GSK** tried to disguise the promotional nature of these meetings by characterizing them as "speaker training" meetings.

74. **GSK** paid doctors to attend "Local Advisory Boards," "Regional Advisory Boards," and Special Issues Boards" during many of which **GSK** provided information about unapproved uses of Wellbutrin.

75. **GSK** called these meetings "advisory board" or "consultant" meetings to create the pretense that **GSK** was gathering information and feedback from the doctors. In fact, there generally was little consulting provided by the doctors during these meetings and **GSK** made no real effort to capture and disseminate the advice it supposedly obtained.

76. **GSK** held such sham advisory board meetings repeatedly and frequently, sometimes holding more than one such meeting on the same day in the same city or hotel, with similar off-label agendas for many events, and the same speakers.

77. **GSK** also sponsored extensive continuing medical education ("CME") programs for doctors during which off-label information about Wellbutrin was disseminated. Although CME programs were ostensibly independent, in certain CME programs, **GSK** influenced the content and frequently selected the location and the speakers and invited many of the attendees, and **GSK** in some instances determined how much the speaker was paid.

78. **GSK**'s sales representatives frequently arranged for the speakers at CME programs to be the same doctors who spoke most frequently at **GSK**'s Wellbutrin promotional events. In some instances, **GSK**'s sales representatives knew that these speakers would deliver at the CME programs the same off-label information they provided during promotional programs.

79. **GSK** sales representatives distributed and played for doctors certain purportedly independent CME materials in the form of audiocassettes or DVDs that **GSK** had funded and/or prepared and which contained messages about unapproved uses of Wellbutrin.

**DISTRIBUTION OF WELLBUTRIN**

80. Throughout the relevant time period of the above-described actions, **GSK** distributed Wellbutrin in Massachusetts and elsewhere and held Wellbutrin for sale in Massachusetts and elsewhere.

**DISTRIBUTION OF MISBRANDED WELLBUTRIN**

81. From in or about January 1999 through in or about December 2003, in the District of Massachusetts, and elsewhere, defendant

**GlaxoSmithKline LLC**

did introduce and cause the introduction into interstate commerce, directly and indirectly, into Massachusetts and elsewhere, from outside of Massachusetts, Wellbutrin, a drug within the meaning of the FDCA, 21 U.S.C. § 321(g), which was intended for use for the treatment of sexual dysfunction, for weight loss, addiction, ADHD, and as an add-on to other antidepressant drugs and for other conditions and which was misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that its labeling lacked adequate directions for such uses.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1).

## COUNT THREE - AVANDIA

**(Failure to Report Data to FDA: 21 U.S.C. §§ 331(e), 333(a)(1) & 355(k)(1))**

82. The allegations in paragraphs 2 through 4 are realleged and incorporated by reference herein.

**REQUIRED REPORTING OF INFORMATION REGARDING DRUGS TO THE FDA**

83. Under the FDCA, the term "drug" included articles that (1) were intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans; and (2) were intended to affect the structure or any function of the human body. 21 U.S.C. § 321(g)(1)(B) and (C).

84. A drug was a "new drug" if it was, in part, "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof ...." 21 U.S.C. § 321(p)(1). To be lawfully introduced into interstate commerce, new drugs required an approved marketing or investigational application. 21 U.S.C. §§ 331(d) and 355. Approved marketing or investigational applications included New Drug Applications ("NDAs"). 21 U.S.C. § 355.

85. To obtain FDA approval of an NDA, the sponsor was required to demonstrate, to FDA's satisfaction, that the drug was

both safe and effective for each of its claimed uses. 21 U.S.C. § 355(b). Toward this end, the NDA sponsor was required to provide, to the satisfaction of FDA, substantial evidence, including data generated in adequate and well-controlled clinical investigations, that demonstrated that the drug was safe and effective when used in accordance with the proposed labeling for its intended uses. 21 U.S.C. § 355(d). An NDA sponsor was not permitted to promote or market the drug until the FDA had approved the NDA.

86. Once the NDA had been approved, the holder of the NDA was required to provide the FDA certain periodic reports of data relating to clinical experience to permit the FDA to determine, among other things, whether grounds for withdrawal of the NDA existed based upon clinical experience showing that the drug was unsafe for use under the conditions of use for which it was approved. 21 U.S.C. §§ 355(k)(1), (e). These periodic reports of data were intended to provide the FDA an overview of all safety-related information learned by the holder of the NDA during that quarter or year, and thereby facilitate the FDA's ability to spot drug safety trends.

87. Among other reporting, the holder of the NDA was required to submit to the FDA certain reports regarding postmarketing adverse drugs experiences. 21 C.F.R. § 314.80.

These reports were required to include, among other information, "a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated)." 21 C.F.R. § 314.80(c)(2)(ii)(c).

88. Also among other reporting, the holder of the NDA was required to file an Annual Report each year regarding the approved drug. 21 C.F.R. § 314.81(b)(2). Among other information required to be included in the Annual Report was a "status report of each postmarketing study of the drug product concerning clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology that is required by the FDA . . . ." 21 C.F.R. § 314.81(b)(2)(vii); and a "status report of any postmarketing study not included under paragraph (b)(2)(vii) of this section that is being performed by, or on behalf of, the applicant." 21 C.F.R. § 314.81(b)(2)(viii).

89. At all times material to this Information, it was a crime, in violation of Title 21 United States Code, Section 331(e) to fail to make reports required by Section 355(k)(1), including reports of data relating to clinical experience, and other data and information, as necessary for the FDA to determine whether the NDA approval should be withdrawn or suspended for any reason set forth in Section 355(e).

## DEVELOPMENT OF AND STUDIES REGARDING AVANDIA

90. One of the prescription drugs that was developed by **GSK** was Avandia (rosiglitazone maleate), a diabetes medication. Avandia was one of a class of drugs known as thiazolidediones that were designed to increase insulin sensitivity. The FDA approved the NDA application for Avandia in May 1999. Thereafter, **GSK** promoted, sold, and distributed Avandia into interstate commerce in the United States, including within the District of Massachusetts.

91. In 2001, **GSK** initiated two separate studies at the request of European regulatory authorities as postmarketing commitments to further evaluate the cardiovascular safety of Avandia. Those two studies were known as Study 211 and RECORD.

A. The **GSK** protocol for Study 211 indicated that this study was initiated because "rosiglitazone (like other thiazolidnediones) causes a mild increase in plasma volume. An increase in plasma volume might aggravate existing cardiac failure unless appropriate diuretic therapy is initiated . . . . This study will investigate the effect of rosiglitazone in addition to background anti-diabetic therapy on cardiac structure and function and cardiovascular morbidity and mortality in type 2 diabetic patients with pre-existing CHF [congestive heart failure[(NYHA grade I/II). . . ."

B. The **GSK** protocol for RECORD indicated that this study was initiated because rosiglitazone "also increases body weight (albeit without altering known weight-associated cardiovascular risk factors), has a multifactoral effect on lipids (some effects putatively beneficial, some putatively adverse), and leads to a modest increase in plasma volume . . . . There is a need formally to evaluate long term cardiovascular outcome, both for those who receive the most widely used oral combination therapy (sulphonylurea (SU) plus metformin (MET), and for those who are given rosiglitazone in addition to their first-line therapy (metformin or SU)."

92. In its 2001 Periodic Report for Avandia, **GSK** did not notify the FDA of the initiation of Study 211 and RECORD, despite the regulatory requirement that each periodic report contain "a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated)." 21 C.F.R. § 314.80(c)(2)(i)(c).

93. Moreover, in each of its Annual Reports for Avandia between 2001 and 2007, **GSK** did not provide the FDA with a status report on certain postmarketing studies being performed by, or on behalf of, **GSK**, despite the regulatory requirement to provide that information in 21 C.F.R. § 314.81(b)(2)(viii). Some of the studies that were omitted from certain of those Annual Reports

included Study 211, RECORD, and APPROACH, all of which involved cardiovascular safety issues.

94. Additionally, in its 2007 Annual Report for Avandia that was submitted to the FDA, **GSK** did not provide the FDA with a status report of the post-marketing study, ADOPT, which concerned clinical efficacy, despite the regulatory requirement to provide that information in 21 C.F.R. § 314.81(b)(2)(vii).

**FAILURE TO MAKE REQUIRED REPORTING TO FDA**

95. Beginning in or about 2001 and continuing until in or about September 2007, in the District of Maryland and elsewhere, the defendant,

**GLAXOSMITHKLINE LLC**

did fail to make required reporting of data relating to clinical experience and other data and information regarding Avandia, as required by law, to the United States Food and Drug Administration.

All in violation of 21 U.S.C. §§331(e), 333(a)(1), and 355(k)(1).

## FORFEITURE ALLEGATIONS

**(21 U.S.C. §§ 334, 853 and 28 U.S.C. § 2461(c))**

96. Upon conviction of one or more of the offenses charged in Counts One and Two of this Information, defendant

**GlaxoSmithKline LLC**

shall forfeit to the United States pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c), any quantities of Paxil that between April 3, 1998 and the end of August 2003, and any quantities of Wellbutrin that between January 1999 and December 2003, were introduced into interstate commerce in violation of 21 U.S.C. §§ 331(a) and 352(a) and 352(f)(1).

97. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to 21 U.S.C. § 853(p), incorporated by reference in 28 U.S.C. § 2461(c), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture, that is $43,185,600.

All pursuant to 21 U.S.C. §§ 334 and 853, and 28 U.S.C. § 2461(c), and Rule 32.2 of the Federal Rules of Criminal Procedure.

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

By: _____
Sara Miron Bloom

_____
Susan G. Winkler
Shannon T. Kelley
Amanda Strachan
Brian Perez-Dapple
Assistant U.S. Attorneys
United States Attorney's Office
District of Massachusetts

STUART F. DELERY
ACTING ASSISTANT ATTORNEY GENERAL
U.S. DEPARTMENT OF JUSTICE

By: _____
Patrick Jasperse
Jill Furman
Mark Josephs
David Frank
Timothy Finley
Trial Attorneys
Consumer Protection Branch
U.S. Department of Justice

Date: July 2, 2012

it is the intent of the United States, pursuant to 21 U.S.C. § 853(p), incorporated by reference in 28 U.S.C. § 2461(c), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture, that is $43,185,600.

All pursuant to 21 U.S.C. §§ 334 and 853, and 28 U.S.C. § 2461(c), and Rule 32.2 of the Federal Rules of Criminal Procedure.

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

By: _____
Sara Miron Bloom

_____
Susan G. Winkler
Shannon T. Kelley
Amanda Strachan
Brian Perez-Dapple
Assistant U.S. Attorneys
United States Attorney's Office
District of Massachusetts

STUART F. DELERY
ACTING ASSISTANT ATTORNEY GENERAL
U.S. DEPARTMENT OF JUSTICE

By: Patrick Jasperse /PF
Patrick Jasperse
Jill Furman
Mark Josephs
David Frank
Timothy Finley
Trial Attorneys
Consumer Protection Branch
U.S. Department of Justice

Date: July 2, 2012

# 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 pharmaceutical 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 qui tam actions against GSK (collectively the "Civil Actions"):

(1) United States et al. ex rel. Thorpe, et al. v. GSK et al., Civ. No. 11-10398 (D. Mass.);

(2) United States et al. ex rel. Gerahty, et al. v. GSK et al., Civ. No. 03-10641 (D. Mass.);

(3) United States ex rel. Graydon v. GSK et al., Civ. No. 11-10741 (D. Mass);

(4) United States et al. ex rel. LaFauci v. GSK, 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 United States of America v. GlaxoSmithKline LLC., 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, et seq; 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"):

(1) **Paxil**: During the period January 1, 1998 through December 31, 2003, 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 sub-paragraph, 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 anti-depressants) 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.

(3) **Advair**: During the period January 1, 2001 through June 30, 2010, GSK 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.

(5) **Zofran**: During the period January 1, 2002 through December 31, 2004, 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 well-founded. 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 qui tam 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 United States et al. ex rel. Thorpe, et al. v. GSK et al., Civ. No. 11-10398 (D. Mass.) and/or United States et al. ex rel. Gerahty, et al. v. GSK et al., 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 United States ex rel. Graydon v. GSK et al., Civ. No. 11-10741 (D. Mass) and United States et al. ex rel. La Fauci v. GSK, 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) 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. §§ 1395-1395kkk 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) 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 audit, 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.

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, 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).

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: _____ Dated: 7/2/2012

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

United States Attorney John Walsh

By: _____ Dated: July 2, 2012

EDWIN WINSTEAD
Assistant United States Attorney
District of Colorado

STUART F. DELERY
Acting Assistant Attorney General

By: _____ Dated: 7/2/12

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

By: _____ Dated: 7/2/12

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

By: Abigail Cummings Dated: 6/28/2012

for 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

By: 

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

Dated: 6/27/12

By: _____

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

Dated: 6/7/12

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

By: _____ Dated: 6.28.12

ELPIDIO VILLARREAL
Senior Vice President, Global Litigation, GlaxoSmithKline LLC

By: _____ Dated: 6/28/12

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

**RELATOR GREG THORPE**

By: _____ Dated: _____
GREG THORPE

**RELATOR BLAIR HAMRICK**

By: _____ Dated: _____
BLAIR HAMRICK

**BRIAN KENNEY**

By: _____ Dated: 6/27/12
BRIAN KENNEY
M.. TAVY DEMING
KENNEY & McCAFFERTY, PC
Counsel to Relators Greg Thorpe & Blair Hamrick

**RELATOR GREG THORPE**

By:  Dated: 6/27/12

GREG THORPE

**RELATOR BLAIR HAMRICK**

By: _____ Dated: _____

BLAIR HAMRICK

**BRIAN KENNEY**

By: _____ Dated: _____

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

**RELATOR GREG THORPE**

By: _____ Dated: _____
GREG THORPE

**RELATOR BLAIR HAMRICK**

By:  Dated: 6.27.12
BLAIR HAMRICK

**BRIAN KENNEY**

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

**RELATOR THOMAS GERAHTY**

By: _____ Dated: _____
THOMAS GERAHTY

**RELATOR MATTHEW BURKE**

By: Matthew Burke Dated: 6-26-12
MATTHEW BURKE

By: Erika Kelton Dated: 6/26/12
ERIKA KELTON
Phillips & Cohen
Counsel to Relators Thomas Gerahty and Matthew Burke

**RELATOR THOMAS GERAHTY**

By: _____ Dated: 6/26/2012
THOMAS GERAHTY

**RELATOR MATTHEW BURKE**

By: _____ Dated: _____
MATTHEW BURKE

By: _____ Dated: 6/26/2012
ERIKA KELTON
Phillips & Cohen
Counsel to Relators Thomas Gerahty and Matthew Burke

**RELATOR LOIS GRAYDON**

By: Lois Graydon Dated: 6/27/2012
LOIS GRAYDON

By: Dated: 6/26/2012
REUBEN GUTTMAN
Grant & Eisenhofer, PA
Counsel to Relator Lois Graydon

**RELATOR MICHAEL LAFAUCI**

By: Michael LaFauci
MICHAEL LAFAUCI

Dated: 6/27/12

By:
DAVID S. STONE
ROBERT A. MAGNANINI
Stone & Magnanini LLP
Counsel to Relator Michael LaFauci

Dated: 6/27/12

# SETTLEMENT AGREEMENT

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

## RECITALS

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 and/or its predecessors, including Glaxo, Inc. ("Glaxo"), Glaxo Wellcome, Inc. ("GW"), and SmithKline Beecham Corporation ("SKB") (all of which are incorporated within the above term "GSK") had business operations in Philadelphia, Pennsylvania, and Research Triangle Park, North Carolina. In 2000, GW and SKB merged to form SmithKline Beecham Corporation d/b/a GlaxoSmithKline (now known as GlaxoSmithKline LLC).

B. At all relevant times, GSK manufactured, distributed, and sold pharmaceutical products in the United States.

C. At all relevant times, GSK participated in the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v. Pursuant to the Medicaid Drug Rebate Program, GSK entered into national rebate agreements with HHS, and GSK's covered outpatient drugs were covered by state Medicaid plans that provided medical assistance for prescription drugs. Under

the Medicaid Drug Rebate Program and the rebate agreements with HHS, GSK agreed: (i) to report quarterly to the Health Care Financing Administration, currently known as, and hereinafter referred to as, the Centers for Medicare and Medicaid Services ("CMS"), the Average Manufacturer Price ("AMP") for all its covered outpatient drugs and Best Price for its single-source and innovator multiple-source covered outpatient drugs, as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C); and (ii) to pay quarterly rebates to the states. For single-source and innovator multiple source covered outpatient drugs, the quarterly rebates are based on the product of (a) the units of each dosage form and strength paid for under the State Medicaid plan during the rebate period as reported by the state, and (b) the greater of the difference between the AMP and the Best Price, or a minimum rebate percentage of AMP, as further described in 42 U.S.C. § 1396r-8(c)(1).

D. Under 42 U.S.C. § 1396r-8(c)(1)(C)(ii), the term "Best Price": (I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section); (II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and (III) shall not take into account prices that are "merely nominal in amount." Under the rebate agreement, the best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

E. Under the rebate agreement, a "nominal price" is, for purposes of excluding prices from the Best Price calculation, any price less than 10% of the AMP in the same quarter for which the AMP is computed.

F. Under the rebate agreement, a "bundled sale" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is

purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement.

G. The 1996 Medicaid Drug Rebate Operational Training Guide states that "[t]he key to identifying a bundled sale is that the sale is contingent on the purchase of another product" and that "Bundled Sales will affect the AMP and BP calculations. The value of the discounted or free product should be proportionately distributed among the other products in the bundle."

H. The 2001 Medicaid Drug Rebate Operational Training Guide states that "[t]he key to identifying a bundled sale is that the sale is contingent upon an additional purchase requirement(s) of the retail purchaser (e.g. pharmacies, beneficiaries, etc.)" and that "Bundled Sales will affect the AMP and BP calculations. The discounted or contingent drug product's value is proportionately distributed among the other drug products in the bundle."

I. At all relevant times, GSK participated in the Drug Pricing Program, 42 U.S.C. § 256b, which is part of the Public Health Service ("PHS") Act, 42 U.S.C. §§ 201-300gg-92. Pursuant to the Drug Pricing Program, GSK entered into agreements with HHS in connection with the pricing of its drug products sold to entities such as AIDS drug purchasing assistance programs, community health centers, and disproportionate share hospitals, as defined in 42 U.S.C. § 256b(a) (the "PHS entities"). Under the Drug Pricing Program, GSK agreed that the amount the PHS entities would pay for their drug products would not exceed certain limits derived in part from the AMPs and Best Prices reported by GSK to CMS for such drugs in the previous calendar quarter, as further described in 42 U.S.C. § 256b(a).

J. The United States contends that it has certain civil claims against GSK, as specified in Paragraph 2 of the Terms and Conditions section below, arising from the following conduct during the time period from January 1, 1994, to December 31, 2003 (hereinafter referred to as the "Covered Conduct"):

i. The United States contends that GSK entered into contracts with hospitals, universities, group purchasing organizations, managed care organizations, and other customers, pursuant to which the customers received discounts and/or rebates on one or more GSK drugs that appeared, on their face, to yield a purportedly nominal price, *i.e.*, a price of less than 10% of the AMP for a drug, but which were contingent on the customer agreeing to meet one or more of the following requirements for a drug with a different National Drug Code number: (a) purchase all of its requirements of a certain drug type or class of drug from GSK rather than from other drug manufacturers, (b) purchase a minimum quantity of a certain GSK product or products, (c) maintain or achieve a minimum market share of a certain GSK product or products within a therapeutic class of drugs, (d) place and/or keep a certain GSK product or products on formulary and/or unrestricted in its institutions or systems, or (e) make a certain GSK product or products the exclusive or preferred drug on a formulary within a particular therapeutic or multi-source class of products available in its institutions or systems.

More specifically, GSK generally referred to such contracts as "committed contracts" or "portfolio contracts." A 1991 internal GSK training document explained that, "[i]n a committed contract (sometimes referred to as a bundle), pricing is contingent on all terms of the contract. The purpose of a committed contract is to establish an agreement that an account will use multiple [GSK] products and/or use exclusively [GSK] brands of [certain drug products]. Further, the commitment may require the unrestricted availability of all forms of

[another drug product]. In return, the account receives better pricing level and/or rebates." Another internal GSK document explained: "Portfolio adds value [by] pulling weaker products on formulary that would otherwise have been excluded (achieved by increasing discounts on stronger (levered) products) . . . [and] minimizing discounts on a key product by giving concessions on less important products."

The United States contends that, like other deep discounts, purportedly nominal pricing on certain products included in these portfolio contracts was regarded by GSK as an investment and a tool to guarantee contract compliance, consistent with the company's overall portfolio approach to contracting.

ii. The United States further contends that the GSK contracts described in paragraph (i) above are "bundled sales" under the rebate agreements between GSK and HHS. As such, the discounts and/or rebates on the drugs sold under those contracts should have been reallocated among all drugs in the bundled sales, including those drugs sold at a price of less than 10% of AMP, as required by the rebate agreements, in calculating and reporting to CMS quarterly AMP and Best Price figures for the drugs, and that GSK did not reallocate those discounts and/or rebates.

iii. The United States further contends that if GSK had reallocated the discounts and/or rebates as required under its rebate agreements, the effective prices on the purportedly nominal-priced drugs in the bundled sales would, in some cases, have exceeded 10% of AMP and resulted in reportable Best Prices that were lower than the Best Prices GSK reported to CMS for such drugs. Further, those reallocations would have lowered the effective prices for certain other drugs included in the alleged bundled sales and would, in some cases, have resulted in

reportable Best Prices for one or more of those other drugs that were lower than the Best Prices GSK reported to HHS for those drugs.

iv. The United States further contends that in failing to reallocate discounts and/or rebates in bundled sales that included purportedly nominal-priced drugs, GSK knowingly reported false Best Prices to HHS and underpaid quarterly rebates to the states under the Medicaid Drug Rebate Program, and knowingly overcharged the PHS entities under the Drug Pricing Program. Such underpayment of quarterly rebates to the states caused the United States to be overcharged for its quarterly contributions to the states for the Medicaid Program.

v. In some instances, GSK treated certain prices as nominal when, in fact, those prices were contingent on other requirements and the United States contends they did not qualify as nominal prices within the meaning of the rebate agreements. The United States contends that if GSK had factored certain of the contingencies into the transactions and not treated those transactions as nominal, GSK would have reported Best Prices that were lower than those that they reported to HHS for such drugs. As a result, GSK knowingly reported false Best Prices to HHS and underpaid quarterly rebates to the states under the Medicaid Drug Rebate Program, and knowingly overcharged the PHS entities under the Drug Pricing Program. Such underpayment of quarterly rebates to the states caused the United States to be overcharged for its quarterly contributions to the states for the Medicaid Program.

K. The United States contends that, as a result of the Covered Conduct, GSK knowingly made or caused to be made false claims or made or caused to be made false statements material to false claims and/or obligations relating to the payment of rebates to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v, and thereby also inflated the prices paid for certain drugs under the Drug Pricing Program, which is part of

the PHS Act, 42 U.S.C. § 201-300gg-92.

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

M. GSK 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") have agreed, or in a form otherwise agreed to by GSK and an individual state, are referred to herein as "Medicaid Participating States."

N. 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: (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, in violation of the Food, Drug and Cosmetic Act ("FDCA").

O. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of liability by GSK nor a concession by the United States that its claims are not well founded. GSK expressly denies the allegations of the United States as set forth herein,

and denies that it has engaged in any wrongful conduct in connection with the Covered Conduct. GSK further states that, neither this settlement, its execution, nor the performance of any obligation under it, including any payment, nor the fact of the settlement, is intended to be, or should be understood as, an admission of any fact or of any liability or wrongdoing, or other expression reflecting on the merits of the dispute by GSK.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties reach a full and final settlement pursuant to the terms and conditions below:

TERMS AND CONDITIONS

1. GSK shall pay to the United States, the Medicaid Participating States, and the PHS entities, collectively, the sum of Three Hundred Million Dollars ($300,000,000) plus interest accrued thereon at a rate of 1.625% per annum from December 1, 2011, to and including the day before payment is made under this Agreement (the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States, the Medicaid Participating States, and the PHS entities on the Effective Date of this Agreement. The debt shall be discharged by payments to the United States, the Medicaid Participating States, and the PHS entities as follows:

a. GSK shall pay to the United States the sum of $160,972,069 plus interest accrued thereon at a rate of 1.625% per annum from December 1, 2011, to 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 to be provided by the United States. GSK shall make this electronic funds transfer no later than seven (7) business days after: (i) the Effective Date of this Agreement or (ii) the Court accepts a

Fed. R. Crim. P. 11(c)(1)(c) guilty plea as described in Preamble Paragraph N 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 $118,792,931 plus interest accrued thereon at a rate of 1.625% per annum from December 1, 2011, to and including the day before payment is made under this Agreement (the "State Settlement Amount"). The State Settlement Amount shall be paid by electronic funds transfer to an interest bearing account in accordance with the written instructions from the NAMFCU negotiating team pursuant to the terms and conditions agreed upon by GSK and the NAMFCU negotiating team and as set forth in the Medicaid State Settlement Agreements that GSK will enter into with the Medicaid Participating States.

c. GSK and the United States agree that GSK shall pay the sum of $20,235,000 plus interest accrued thereon at a rate of 1.625% per annum from December 1, 2011, to and including the day before payment is made under this Agreement, as the PHS share (the "PHS Amount") of the Settlement Amount. GSK shall transfer the PHS Amount into a segregated, interest-bearing bank account (the "PHS Account") no later than seven (7) business days after: (i) the Effective Date of this Agreement or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(c) guilty plea as described in Preamble Paragraph N in connection with the Criminal Action and imposes the agreed upon sentence, whichever occurs later. Pursuant to the process agreed to by the Parties in a separate letter, GSK will use its best efforts to identify affected PHS entities and the amounts they were overcharged as a result of the Covered Conduct. GSK shall disburse funds from the PHS Account pursuant to the terms set forth in the aforementioned letter.

d. 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 N 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 May 19, 2004.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, in consideration of the obligations of GSK in this Agreement, and conditioned upon GSK's full payment of the Settlement Amount, the United States releases GSK, together with its predecessors, current and former parents, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively, from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. §§ 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8; the Drug Pricing Program, 42 U.S.C. § 256b; any statutory provision applicable to the federally funded programs in this Agreement 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 the common law theories of

payment by mistake, fraud, 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-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, except as reserved in Paragraph 4 (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 4, below.

4. Notwithstanding any term of this Agreement, the following claims of the United States are specifically reserved and are not released:

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 obligations created by this Agreement;

f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

g. Any liability for failure to deliver goods or services due;

h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; 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.

5. GSK waives and shall not assert any defenses GSK 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.

6. GSK fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of

every kind and however denominated) that GSK has asserted, could have asserted, or may assert in the future against the United States, and its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

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

8. GSK agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 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:

(1) the matters covered by this Agreement;

(2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;

(3) GSK's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement or the Medicaid State Settlement Agreements;

(5) the payments GSK makes to the United States or any State pursuant to this Agreement or the Medicaid State Settlement Agreements; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent 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 8.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;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: 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 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 audit, examine, or re-examine GSK's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

9. 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 Paragraph 10 below.

10. 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.

11. GlaxoSmithKline LLC 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 GlaxoSmithKline LLC, 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, to the best of their respective knowledge individually, 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 GlaxoSmithKline LLC was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

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

13. GSK represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

14. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is 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.

15. For purposes of construing this Agreement, 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 subsequent dispute.

16. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

17. 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.

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

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

20. GSK consents to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

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

**THE UNITED STATES OF AMERICA**

STUART F. DELERY
ACTING ASSISTANT ATTORNEY GENERAL

DATED: _____ BY: _____
JOYCE R. BRANDA
JAMIE ANN YAVELBERG
JEFFREY A. TOLL
LISA KATZ SAMUELS
JENNIFER A. STALZER
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____
GREGORY E. DEMSKE
Chief Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

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

**THE UNITED STATES OF AMERICA**

STUART F. DELERY
ACTING ASSISTANT ATTORNEY GENERAL

DATED: 7/2/12 BY: _____
JOYCE R. BRANDA
JAMIE ANN YAVELBERG
JEFFREY A. TOLL
LISA KATZ SAMUELS
JENNIFER A. STALZER
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____
GREGORY E. DEMSKE
Chief Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

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

**THE UNITED STATES OF AMERICA**

STUART F. DELERY
ACTING ASSISTANT ATTORNEY GENERAL

DATED: _____ BY: _____
JOYCE R. BRANDA
JAMIE ANN YAVELBERG
JEFFREY A. TOLL
LISA KATZ SAMUELS
JENNIFER A. STALZER
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 6/28/2012 BY: _____
for GREGORY E. DEMSKE
Chief Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

**GLAXOSMITHKLINE LLC**

DATED: 6-28-12 BY: _____

ELPIDIO VILLARREAL
Senior Vice President
Global Litigation
GlaxoSmithKline LLC

DATED: 6/28/12 BY: _____

MARK D. SELTZER
BRIAN K. FRENCH
Nixon Peabody LLP
Counsel for GlaxoSmithKline LLC

DATED: 6/28/12 BY: _____ BVF

THOMAS H. LEE, II
Dechert LLP
Counsel for GlaxoSmithKline LLC

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

| | | |
|---|---|---|
| UNITED STATES *ex rel.* GREG THORPE, ET AL. [Consolidated]<br>Plaintiffs,<br>v.<br>GLAXOSMITHKLINE PLC, and GLAXOSMITHKLINE LLC,<br>Defendants | ) | C.A. No. 11-10398-RWZ<br><br>**FILED UNDER SEAL** |

## UNITED STATES' COMPLAINT

1. The United States brings this action to recover treble damages and civil penalties under the False Claims Act, damages and other monetary relief under common law and equity against the defendants GlaxoSmithKline plc and GlaxoSmithKline LLC (together "GSK") for causing the submission of false or fraudulent claims to federal health care programs.

2. From 1999 through 2010 in some instances, GSK engaged in a fraudulent scheme to deceive and defraud physicians, patients, regulators, and federal health care programs to cause prescribing and payment for certain of GSK's drugs. This conduct includes repeatedly publishing and promoting false and misleading accounts of studies and treatment guidelines to convince physicians to use GSK drugs. GSK misrepresented clinical evidence, downplayed or ignored safety risks, and failed to disclose the rejection by the United States Food and Drug Administration ("FDA") of some of the exact claims GSK was making to physicians. GSK promoted these products for uses that the FDA had not approved as safe and effective ("off-label" or "unapproved" uses), and for uses that were not medically accepted indications covered by federal health care programs. GSK also used a wide variety of gifts, payments and other forms of remuneration to induce physicians to prescribe GSK's drugs, including trips to Bermuda and Jamaica, spa treatments and bunting trips, and sham consulting fees.

3. GSK's fraudulent promotion of its drugs included the following:

(a) Promoting Paxil, an antidepressant drug, as safe and effective for children and adolescents, despite the lack of FDA approval for this use and three GSK clinical trials that failed to demonstrate Paxil's effectiveness while raising concerns regarding an increased risk of suicide among such patients.

(b) Promoting Wellbutrin SR ("WBSR"), an antidepressant drug, for unapproved uses including for children and adolescents, to treat Attention Deficit Disorder ("ADD"), Attention Deficit and Hyperactivity Disorder ("ADHD"), bipolar disorder, weight loss, obesity, sexual dysfunction, anxiety, and as an "add-on" therapy to other antidepressants, despite the fact that the drug was not demonstrated to be safe and effective for any of these uses.

(c) Promoting Advair, a combination of asthma drugs, for first-line use in mild asthma patients whose asthma could be controlled on one component alone---contrary to the FDA-approved label, specific FDA guidance, and established asthma treatment guidelines. In falsely claiming that Advair was superior to each of its components for this use, GSK relied on a study the FDA had specifically evaluated and rejected as showing superiority in GSK's application for an indication for this use.

(d) Promoting certain GSK drugs listed below with various forms of illegal remuneration, including cash payments disguised as consulting fees, expensive meals, weekend boondoggles, and lavish entertainment to prescribers and other health care professionals to induce them to prescribe and recommend GSK's drugs, including those paid for by federal health care programs, all in violation of the federal anti-kickback statute. 42 U.S.C. § 1320a-7b.

4. GSK's conduct, including its false and fraudulent statements, illegal promotion and payment of illegal inducements to prescribers, caused false or fraudulent claims to be submitted to federal health care programs for GSK's drugs, including claims for Advair, Paxil and WBSR, for uses that were not eligible for payment and for physician services relating to the prescribing of those drugs.

## I. THE PARTIES

5. The United States brings this action on behalf of the federal health care programs the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare and Medicaid programs.

6. This is the United States' Complaint as to the claims as to which it has intervened

in Civil Action Nos. 11-10398-NG, 03-10641-NG; 11-10741-NG, 11-10931-NG (D. Mass), which were filed by various relators and are consolidated as C.A. No. 11-10398-NG.

7. Defendant GlaxoSmithKline plc is a public limited company, incorporated under English law, with headquarters in Brentford, England. GlaxoSmithKline plc was formed in 2000 by the merger of GlaxoWellcome plc and SmithKline Beecham plc. It has operational headquarters in Research Triangle Park, North Carolina, and in Philadelphia, Pennsylvania.

8. Defendant GlaxoSmithKline LLC, a Delaware limited liability company, is the United States subsidiary of GlaxoSmithKline plc. GlaxoSmithKline LLC is the successor of SmithKline Beecham Corporation, which was the successor of SmithKline Beckman Corporation. GlaxoSmithKline LLC has headquarters in Philadelphia, Pennsylvania and Research Triangle Park, North Carolina.

## II. JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1345. The Court may exercise personal jurisdiction over GSK pursuant to 31 U.S.C. § 3732(a) and because GSK transacts business in the District of Massachusetts.

10. Venue is proper in the District of Massachusetts under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because GSK has transacted business in this District.

## III. GSK'S OFF-LABEL MARKETING OF PAXIL

11. Paxil (paroxetine) is an antidepressant approved by the FDA for adults with major depressive disorder ("MDD" or "depression"), and other mental diseases.

12. The FDA has never approved Paxil to treat depression in children or adolescents under the age of 18. Nevertheless, from 1999 through at least 2003, GSK promoted Paxil for use in this population, while concealing the fact that Paxil failed to show efficacy on any of the primary endpoints in three controlled trials funded by GSK to study Paxil for this population. To

drive these promotional efforts, GSK touted a medical journal article that it paid to have drafted and that exaggerated Paxil's efficacy while downplaying risks identified during one of the trials.

13. The risks identified in GSK's trials, once uncovered, led the FDA to require in 2004 that GSK and other manufacturers of a class of drugs known as "selective serotonin reuptake inhibitors" ("SSRIs") place a "black box" warning on the labels of these products to warn doctors about the potential suicidality risks to children and adolescents. A black box warning is the strongest type of warning the FDA can require in a product label.

14. By misstating and exaggerating Paxil's efficacy and downplaying and concealing its risks during sales calls and promotional events, GSK misled the medical community about the risks and benefits of Paxil use in patients under 18 and caused false and medically inappropriate claims for Paxil prescriptions to be submitted to federal health care programs.

A. Three GSK Clinical Trials Failed To Demonstrate Paxil's Effectiveness In Treating Depressed Children

15. Between 1994 and 2001, GSK conducted three clinical trials of Paxil's safety and efficacy in treating depression in persons under 18. In all three studies, Paxil failed to reach statistical significance on the primary and secondary efficacy measures (or endpoints) in the study protocols. Due to these negative results, internally described as "disappointing" and "equivocal," GSK never sought FDA approval of Paxil for childhood or adolescent depression. As described below, GSK published false and misleading reports of these results, misrepresenting positive results while down-playing significant safety risks, including an increased risk of suicide in child and adolescent patients.

**1. Study 329 Failed to Show Efficacy of Paxil for Children or Adolescents.**

16. The centerpiece of GSK's efforts to market Paxil for childhood depression was the GSK funded Study 329, which ran from April 1994 to February 1998. This was a double-

blind, placebo-controlled study of the efficacy of Paxil in depressed children.

17. Study 329's clinical trial protocol contained two "primary" efficacy measures and five "secondary" efficacy measures. A "protocol" is a document created prior to commencement of the trial that describes the objectives, design, methodology, and statistical plan for the clinical trial. Pre-specified protocols are required by the FDA and scientific community to prevent post-hoc selection of favorable data and endpoints—i.e. "cherry-picking." A primary efficacy endpoint is a specific event or outcome that the clinical trial is designed to assess—such as whether a drug is more effective than a placebo in treating a condition. A "secondary" endpoint is typically related to the primary endpoint and may be of interest, but is not one the study is independently statistically-powered to assess.

18. The first primary endpoint in Study 329 was the degree to which a patient's Hamilton Rating Scale for Depression ("HAM-D") total score changed from a baseline. The HAM-D is a questionnaire to rate the severity of a patient's depression. The other primary endpoint: the patients' "response" to medication, as defined as (a) a 50% or greater reduction in the patient's HAM-D score, or (b) a HAM-D score of less than or equal to 8.

19. Study 329 did not show that Paxil was more effective than a placebo on either of its primary endpoints or any of its predefined secondary endpoints.

20. The 329 Study investigators later added several additional efficacy measures not specified in the protocol. Paxil separated statistically from placebo on certain of these measures.

**2. Studies 377 and 701 Also Failed to Show Paxil Works in Patients Under 18.**

21. In addition to Study 329, GSK conducted two other double-blind, placebo-controlled studies of Paxil for pediatric and adolescent depression: Study 377 from April 1995 to May 1998 and Study 701 from March 2000 to January 2001.

22. Like Study 329, both studies failed to demonstrate any statistically significant

difference in efficacy between Paxil and the placebo on any pre-specified primary or secondary endpoint. GSK noted in an internal report on Study 377, "the results failed to show any superiority for Paxil over placebo in the treatment of adolescent depression."

23. Internally, GSK acknowledged that its studies failed to provide sufficient support for the FDA to approve Paxil for childhood depression. In August 1998, six months after Study 329 closed, GSK noted in a Monthly Management Summary that:

> In both 329 (US) and 377 (EU) unable to detect a clinically or statistically significant difference between treatment groups in the prospectively defined primary variable - therefore no submission (MAA/NDA) for label indication for use of [Paxil] in Adolescent Depression.

24. Similarly in October 1998, GSK noted in a discussion of Studies 329 and 377:

> As you w[e]ll know, the results of the [329 and 377] studies were disappointing in that we did not reach statistical significance on the primary end points and thus the data do not support a label claim for the treatment of Adolescent Depression. The possibility of obtaining a safety statement from this data was considered but rejected. The best which could have been achieved was a statement that, although safety data was reassuring, efficacy had not been demonstrated. Consultation of the Marketing Teams via Regulatory confirmed that this would be unacceptable commercially and the decision to take no regulatory action was recently endorsed[.]

GSK concluded: "it would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of [Paxil]." Exhibit ("Exh.") 1.

25. As for Study 701, GSK noted in its final clinical report on that study that "[t]he results of this study failed to provide evidence for the primary and secondary endpoints that [Paxil] is more efficacious than placebo in treating children and adolescents with MDD."

B. GSK Published an Article That Misstated Paxil's Efficacy and Safety for Children and Adolescents

26. In April 1998, GSK hired Scientific Therapeutics Information, Inc. (STI) to prepare a journal article about Study 329. GSK worked closely with STI on the article by providing a draft clinical report to "serve as a template for the proposed publication,"

commenting on multiple drafts, and approving the final version.

### 1. In Publishing Study 329, GSK Falsely Claimed that It Demonstrated Paxil's Efficacy in Treating Depression in Patients Under 18.

27. The abstract of the article sent to JAMA stated that Paxil was "a safe and effective treatment for major depression in adolescents." The article, however, did not expressly identify the two protocol-specified primary efficacy measures---or that Paxil failed to show superiority to placebo on those two measures. Instead, the article claimed that there were eight efficacy measures and Paxil was statistically superior to placebo on four of them.

28. JAMA rejected the article in December 1999 and provided comments to the article's lead author, which he then circulated to GSK and STI. Some of the comments were extremely critical of how the article portrayed the study's results. One comment provided:

> [t]he major finding of this study was the high placebo response rate, nearly 50%. Paroxetine produced only a 20% higher response rate than placebo and then on some but not all of the scales used.... Readers of this paper might receive the wrong impression and believe that a 65 to 70% response rate could be achieved with paroxetine without the education and supportive psychotherapy that the placebo-treated patients in this study received. The outcome is particularly worrisome in this age of health cost containment. Thus, this study could do more harm than good unless the authors devote much more attention in their discussion to the fact that the bulk of the effect in this study was the result of good clinical management and not the medication.

Another noted that the "description of 'numerically superior' is not appropriate and results should be described as superior only when significant.... There is a bias in reporting [Paxil] results as numerically superior but failing to emphasize this is also the case for many of the outcome measures with imipramine."

29. Given the comments received, GSK and the lead author decided to revise the article and send it to what they called "a less demanding journal." GSK then worked closely with STI to revise and resubmit the article.

30. In June 2000, a revised version of the article was submitted to the Journal of the

American Academy of Child and Adolescent Psychiatry (JAACAP). In July 2000, JAACAP returned the article. Like JAMA, JAACAP questioned whether the article accurately characterized Study 329's results on Paxil's efficacy. For example, one comment stated:

> Overall, this is an important study due to its large size and its design of SSRI vs. TCA vs. Placebo. However, the results do not clearly demonstrate efficacy for [Paxil]. Therefore, the authors need to clearly note this.... [E]fficacy was not demonstrated for [Paxil]. It should be clearly noted that [Paxil] was not found to be superior to placebo on [three of the seven] completed measures of antidepressant efficacy in the Results subsection.

31. Another commenter noted the article obscured the primary endpoint results.

> The authors should clearly note that [three of the seven] outcome measures did not show [Paxil] was superior to placebo[.] Therefore the authors should not overstate the efficacy of [Paxil]. The fact that there was not a single a priori primary outcome measure is quite unusual for an industry sponsored study. If this is the case, this should be clearly noted as a methodological shortcoming. If there was a "primary" outcome measure, the authors should clearly note what that was.

32. GSK worked closely with STI to address the reviewers' comments and the article was resubmitted to JAACAP. JAACAP ultimately accepted the article in February 2001 and published it in July 2001. The article was titled "Efficacy of Paroxetine in the Treatment of Adolescent Major Depression: A Randomized, Controlled Trial." Exh. 2.

33. The final published article still mischaracterized the results of Study 329, even with the changes. Although Paxil failed to separate statistically from placebo on both the primary efficacy measures, as well as the five protocol-defined secondary efficacy measures, the article abstract flatly stated that "[Paxil] is generally well tolerated and effective for major depression in adolescents" and concluded that "[t]he findings of this study provide evidence of the efficacy and safety of the SSRI, [Paxil], in the treatment of adolescent depression."

34. Although the JAACAP article identified the study's two primary endpoints in the abstract, the article did not explicitly state that Paxil failed to show superiority to placebo on either of the primary efficacy measures (the only measures that the Study 329 was specifically

designed to assess). Instead, the article falsely stated that Paxil met one of the primary endpoints, noting how Paxil "separated from placebo at endpoint among four of the parameters: response (i.e., primary outcome measure)...." Since one of the protocol-defined primary endpoints was "response," the article's statement that Paxil "separated from placebo" on "response," falsely stated that Paxil had met that primary efficacy measure.

35. The final article's description of Paxil's performance on the protocol-defined secondary efficacy measures was also misleading. While the article abstract listed the five protocol-defined secondary endpoints, the text of the article omitted any discussion regarding three of the secondary measures on which Paxil failed to statistically demonstrate its superiority to placebo and instead focused on the five secondary measures that GSK added belatedly and never incorporated into the Study 329 protocol. The article claimed that these five secondary measures had been identified "a priori," thereby incorrectly suggesting that all the secondary endpoints discussed had been part of the original study protocol.

36. In short, the article distorted the study results and gave the false impression that the study's findings were primarily positive, when they were, in fact, primarily negative and as discussed below, contained a significant safety signal.

**2. GSK Caused the JAACAP Article to Misrepresent and Minimize Paxil's Risks to Children and Adolescents.**

37. At the same time that the JAACAP article exaggerated Paxil's efficacy for treating childhood depression, it downplayed the risks that Study 329 revealed. These risks eventually led the FDA to require all SSRI manufacturers to add a black box warning about the heightened risks of suicidality to adolescents taking Paxil and other drugs in the class.

38. An earlier draft of the JAACAP article (prior to the version ultimately published) disclosed that eleven (11) patients who had received Paxil had experienced serious adverse

events ("SAEs") potentially related to the drug. It stated:

> Serious adverse effects occurred in 11 patients in the paroxetine group, 5 the imipramine group, and 2 in the placebo group. An event was defined as serious if it resulted in hospitalization, was associated with suicidal gestures, or was described by the treating physician as serious. The serious adverse effects in the paroxetine group consisted of headache during down-titration (1 patient), and various psychiatric events (10 patients): worsening depression (2); emotional lability (e.g, suicidal ideation/gestures, overdoses), (5); conduct problems or hostility (e.g, aggressiveness, behavioral disturbance in school) (2); and mania (1). Of these, worsening depression, emotional lability, headache, and hostility were considered related or possibly related to treatment.

39. When JAMA rejected the article, one reviewer noted: "[T]here is a major omission from the tables. The serious adverse events should be at the top of any table of adverse events and these do not favor paroxetine. In fact, it is troubling that the authors do not note a significant increase in SAEs after paroxetine (but not IMI) relative to placebo." That comment was never addressed by GSK in the article. The JAACAP article had a table listing adverse events, but did not break out serious adverse events.

40. At the time GSK was circulating the draft article to JAMA and JAACAP, GSK had concerns about disclosing and publishing the increased serious adverse events associated with Paxil, particularly due to recent events in patients taking SSRIs committing violent acts, including the Columbine High School shootings.

41. GSK and STI instead revised the article to falsely state that only one of the 11 serious adverse events in Paxil patients was considered related to treatment—and failed to mention the fact that others had been listed by the study investigators as possibly related to treatment. The final article stated: "Of the 11 patients [who had serious adverse events while taking Paxil], only headache (1 patient) was considered related to paroxetine treatment."

### 3. The FDA Found Paxil Was Not Proven To Be Safe and Effective To Treat Children and Adolescents and Required Warning of the Risks.

42. In April 2002, GSK provided the FDA the results of its three pediatric depression

studies while attempting to gain an extension on Paxil's patent exclusivity period. In October 2002, the FDA informed GSK that the depression studies failed to demonstrate Paxil's efficacy in treating depression in individuals under age 18.

43. Moreover, the FDA asked for additional information about patients in the studies who had experienced adverse events and who had withdrawn from the study prematurely, as well as why GSK used the term "emotional lability" to describe the five patients who attempted to commit suicide or exhibited other self-injurious behavior. In May 2003, GSK for the first time provided the FDA with additional safety data from the studies.

44. Although GSK told the FDA there was no statistically significant difference in suicidality between placebo and Paxil in all the Paxil pediatric depression studies cumulatively, the difference between the potential suicide-related events among Paxil patients versus potential suicide-related events among placebo patients became statistically significant when the first 30 days after therapy were included in the analysis.

45. Likewise, upon closer examination the number of possible suicide-related events among the Study 329 Paxil patients increased beyond the five patients that GSK described in the JACAAP article as having "emotional lability." While collecting safety information for the FDA, GSK admitted that there were four more possible suicide-related events among Paxil patients in Study 329. In addition, the FDA later identified yet another possibly suicide-related event in the Study 329 Paxil patients, which also was not among the 11 serious adverse events listed in the JAACAP article. Thus, altogether, 10 of the 93 Paxil patients in Study 329 experienced a possibly suicidal event, compared to one of the 87 patients on placebo. This is a fundamentally different picture of Paxil's pediatric safety profile than the one painted by the JAACAP article, which listed at most five possibly suicidal events among Paxil patients, brushed those off as unrelated to Paxil, and concluded that treating children with Paxil was safe.

46. In June 2003, the FDA announced that although it had not completed its review of the data, it recommended that Paxil not be used to treat depression in patients under age 18.

47. In March 2004, the FDA issued a public health advisory requesting that SSRI manufacturers, including GSK, change the labels on their drugs to include "a [w]arning statement that recommends close observation of adult and pediatric patients treated with these agents for worsening depression or the emergence of suicidality."

48. In June 2004, the British Medical Journal published an article that accused the JAACAP article of "biased reporting." Regarding serious adverse events, the article said: "[D]espite five of these patients being admitted to hospital with events known to occur with the use of selective serotonin reuptake inhibitors, including suicidality, only one serious event (headache) was judged by the treating investigator to be related to paroxetine treatment. The criteria for determining causation of serious events were not stated."

49. In October 2004, the FDA directed GSK and other antidepressant manufacturers to include on their labels a black box warning to alert physicians about the potential for increased risk of suicidality in children and adolescents taking these drugs. The black box warning stated that "[a]ntidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders." The FDA also required the labels to state:

> The risk of suicidality for these drugs was identified in a combined analysis of short-term (up to 4 months) placebo-controlled trials of nine antidepressant drugs, including the selective serotonin reuptake inhibitors (SSRIs) and others, in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders. A total of 24 trials involving over 4400 patients were included. The analysis showed a greater risk of suicidality during the first few months of treatment in those receiving antidepressants.

50. In May 2006, GSK sent letters to physicians and updated Paxil's label to include an advisory regarding Paxil and suicidal tendencies in children, adolescents and young adults.

C. GSK Off-Label Marketed Paxil For Depression In Children and Adolescents

51. Despite the failure of its three clinical trials and the absence of FDA approval, GSK actively promoted Paxil to treat adolescent and childhood depression from 1999 to at least 2003. As reflected in internal GSK business plans, expanding Paxil's reach into the adolescent depression market was a key strategic goal well before the clinical trials were completed and well after GSK learned of the disappointing results of its three depression studies.

52. Likewise, notwithstanding Paxil's failure to meet the primary endpoints of Studies 329 and 377, GSK's 2000-2002 Paxil operating plan was to "[d]evelop/grow adolescent market by leveraging recently completed studies in adolescent depression and OCD."

53. Similarly, in 2000, a GSK consultant prepared a 32-page report titled, "Positioning Paxil in the adolescent depression market – getting a headstart." The purpose of the report, prepared at GSK's request, was "to assess the efficacy data relating to the use of Paxil for the treatment of depression and anxiety-related disorders in adolescents and to make recommendations on how to gain a headstart on the competition." The report acknowledged that "[t]he fact that Paxil failed to separate from placebo according to four of the outcome measures in the [329] study could be used as a weakness by competitors and may be an obstacle if filing for an extension of the product license." Nonetheless, the report recommended ways to spin the study to make Paxil the drug of choice in treating depressed children, including:

> If successfully managed, this initiative will extend use of Paxil to another population. There are 2.5 million adolescents suffering from depression in the USA. This represents a large market, though uptake is likely to be slow. To tackle this market would provide contact with a large number of psychiatrists who specialize in pediatrics.

54. In an August 2002 strategic brand plan, GSK continued to list pediatric use, including pediatric depression, as an opportunity for Paxil, even though it was four years after it knew the negative results of Studies 329 and 377, and a year after the results of Study 701.

### 1. GSK Provided its Sales Force Off-Label Information about Paxil for Children.

55. In September 1999, at a training for some of GSK's sales force promoting Paxil, Dr. Karen Wagner, a child psychiatrist, told the sales force that depression in adolescents was a lethal disorder that, if untreated, could lead to suicide and linger into adulthood. According to a GSK newsletter (Exh. 3), Dr. Wagner recommended Paxil for this population as follows:

> Obviously, therapy is needed and *Paxil* is one of the few pharmaceutical approaches that has safety and efficacy data to support its use in this [adolescent] patient population. And more data is on its way.
>
> As many of you know, [GSK] is preparing an indication for adolescent depression for *Paxil* next year! [GSK's] clinical study demonstrating the success of *Paxil* in treating depression among adolescents will be published in a peer reviewed journal during first quarter 2000.

56. According to the same GSK newsletter, Dr. Wagner discussed Study 329 (the results of which had not yet been published), explained that the results supporting Paxil use in pediatric patients were "statistically significant," and stated that "[a]s a result of this large study, we can say that [Paxil] has both efficacy and safety data for treating depression in adolescents."

### 2. GSK Provided the JAACAP Article to Its Sales Representatives.

57. In August 2001, the Paxil marketing team sent the JACAAP article to all 2,000 sales representatives who were selling Paxil, including 160 neuroscience specialty representatives. The article was accompanied by a cover memorandum created by a member of the Paxil marketing team ("Paxil cover memo"). This memorandum stated in bold type:

> **This 'cutting-edge,' landmark study is the first to compare efficacy of an SSRI and a TCA with placebo in the treatment of major depression in adolescents. *Paxil* demonstrates REMARKABLE Efficacy and Safety in the treatment of adolescent depression.**

(Emphasis in original). Exh. 4. The Paxil cover memo also stated that:

> Paxil was significantly more effective than placebo with regard to achievement of both HAM-D total score <8; CGI score of 1 (very much improved) or 2 (much

improved), and improvements in the depressed mood items of the HAM-D and the K-SADS-L.

58. The memo further provided that Paxil "was generally well tolerated in this adolescent population, and most adverse events were not serious," and concluded:

> [T]he findings of this study provide evidence of the efficacy and safety of Paxil in the treatment of adolescent depression. Here's another example of GlaxoSmithKline's commitment to Psychiatry by bringing forth "cutting edge" scientific data. Paxil is truly a REMARKABLE product that continues to demonstrate efficacy, even in this understudied population.

59. Notably, the Paxil cover memo did not disclose that Paxil had failed to show statistical superiority over placebo for any of the study's protocol-specified primary and secondary endpoints. The memo did not say that adolescents in the study who received Paxil displayed more suicidal thinking and behavior than those who received a placebo. The memo did not say that GSK had completed two additional pediatric studies (Study 377 and Study 701), neither of which demonstrated that Paxil was effective in treating depression in children. The memo also did not say that Paxil was approved for use only in patients age 18 or older.

60. Although the Paxil cover memo noted that "[t]his article is for pharmaceutical consultants' information only" and instructed "Do not use it with, or distribute to, physicians," the memo's message was delivered to and used by the sales force to promote Paxil. The sales representatives and managers, who were all compensated and received bonuses based upon increased sales, including sales for off-label use in children, relayed the incorrect messages of the JAACAP article and Paxil cover memo to falsely promote Paxil as safe and efficacious for children and adolescents to health care providers around thc country.

**3. GSK's Sales Force Used the JAACAP Article to Promote Paxil Off-Label.**

61. Relying on the Wagner lecture and JAACAP article, GSK sales representatives encouraged doctors to prescribe Paxil for children. GSK sales representatives documented their

doctor visits in "call notes" that were recorded in the notes that sales representatives' routinely prepared at or about the time of calls on prescribing physicians to record what had been discussed. These notes were available for review by managers as well as others representatives and reflect the one-sided picture that the sales force painted of Paxil's efficacy and safety for treating childhood depression. These call notes also demonstrate that the sales force ignored the Paxil cover memo's instruction not to use the JAACAP article with physicians.

62. The call notes written by GSK sales representatives repeatedly reflect their off-label promotion of Paxil, including the following:

> "Left water fountain. Reviewed [article on] Paxil adolescent MDD. Emphasized significance vs. placebo, study size. . . . Had reviewed article. Cited data to help underscore to parents/patients Paxil's utility here. Also important if liability an issue." *6/27/01 Milwaukee, WI*

> "Astros game. Discussed Paxil placebo and imipramine study in adolescents." *7/13/01 Houston, TX*

> "Detailed doctor on Paxil for major depression in adolescents and he agreed to use Paxil there." *6/1/01 Newark, OH*

> "Dinner and Yankee game with family. Talked about Paxil studies in children." *8/1/01 Westport, CT*

63. It was not until August 2003, after Great Britain contraindicated Paxil for children and the FDA warned doctors about possible suicide risks, that GSK for the first time asked its sales representatives to identify doctors on their call lists who treated patients under 18. As of May 2005, GSK had identified 5,800 child psychiatrists on the lists of physicians for Paxil representatives to target for Paxil promotions, including by providing samples. Of these, GSK confirmed that 1,324 were child-only prescribers.

**4. GSK Promoted Paxil for Children by Giving Samples to Child Psychiatrists.**

64. GSK also promoted Paxil for off-label uses by providing free Paxil samples to doctors who primarily or exclusively treated children.

65. GSK policies encouraged its sales representatives to provide samples to all doctors on their call lists. Because the Paxil call lists included doctors who primarily or exclusively treated children, GSK caused its sales representatives to give Paxil samples to doctors who were likely or certain to use the samples for unapproved uses.

66. GSK knew that its samples were being used in this manner, as illustrated by a survey of sales representatives which showed that the representatives wanted more smaller-dose Paxil pills, "which were used for children, elderly, and anxiety patients."

**5. GSK Promoted Paxil for Children During Paxil Forum Meetings.**

67. In 2000 and 2001, GSK also promoted Paxil for unapproved uses by bringing top-prescribing psychiatrists to lavish resorts for Paxil Forum meetings. There were four Forum meetings each year. Each representative attended two per year, and got to invite two psychiatrists to each meeting.

68. The meetings were held at expensive resorts such as the El Conquistador Resort & Golden Door Spa in Puerto Rico, the Rio Mar Beach Resort in Hawaii, and the Renaissance Esmeralda Resort & Spa in Palm Springs, California. GSK paid for the psychiatrists' lodging, air fare, and a $750 honorarium. GSK paid speakers a $2,500 honorarium. GSK also paid spouses' airfare if two cheaper tickets were available for the cost of one full-coach fare.

69. The psychiatrists typically arrived on a Friday morning. Presentations took place on Friday afternoon and Saturday morning. GSK hosted nice dinners on Friday and Saturday evenings and paid for entertainment including sailing, snorkeling, tours (e.g. the Bacardi rum distillery), golf, deep sea fishing, rafting, glass-bottomed boat rides, and balloon rides.

70. The actor/comedian GSK hired to emcee one of the meetings told the attendees "we have a wonderful and unforgettable night planned. Without giving it all away, I can tell you—you'll be experiencing a taste of luxury." One psychiatrist complained, "the style of the

conference would have been suitable for a convention of cosmetic sales reps; this is supposed to be a scientific meeting. To me, the music, lights, videos, emcees are offputting and a distraction (even demeaning)."

71. For many other psychiatrists, however, the Forum meetings seem to have had the intended effect. After the May 2000 Forum meeting in Hawaii, one psychiatrist wrote: "A beautiful location, enjoyable and fun-filled activities, an exciting, cutting edge, informative educational program, well-presented and organized, all add up to a most valuable and helpful experience – exhilarating!" Another doctor wrote after the Forum 2001 meeting in Palm Springs: "Both my wife and I enjoyed the extra care our drug rep gave to us all weekend."

72. Dr. Wagner spoke and recommended the use of Paxil for children and adolescents at one Forum meeting in 2000, three in 2001, and two in 2002. Before one meeting at which she spoke, a sales representative wrote to his supervisor that both of the psychiatrists he had invited "have high volume and are child specialists, which the program is devoted to."

73. GSK also used the meetings to relay its incorrect and misleading claims in the JACAAP article. GSK added Dr. Wagner to the agenda of a Paxil Forum meeting in June 2001 to "capitalize" on the impending JAACAP publication. Dr. Wagner's presentations during the Forum meetings were similar to the one she gave to the sale force. Dr. Wagner said adolescent patients who received Paxil in the 329 study showed "significantly greater improvement."

74. A GSK report of the 2000 meetings said that 12% of the attending psychiatrists said they would be more comfortable prescribing Paxil for children and adolescents as a result of the meeting. In written evaluations, numerous psychiatrists wrote that they would increase their Paxil prescriptions for children as a result of the meeting.

75. GSK tracked the Paxil prescription by doctors who attended the 2000 Forum meetings. "Results suggest that the Paxil Forum had a significant impact on Paxil market share

in the months after attendance," said a November 2000 memo for the Paxil marketing director. "Physicians grew actual market share versus their forecasted share immediately after Forum attendance. Test physicians grew market share significantly relative to Control physicians." The memo concluded that increased Paxil prescriptions due to the Forum 2000 meetings resulted in at least $900,000 in additional revenue in 2000 alone.

## IV. GSK'S OFF-LABEL MARKETING OF WELLBUTRIN SR

76. WBSR is an antidepressant that has been approved by the FDA for only one use: the treatment of Major Depressive Disorder in adults eighteen years of age or older.

77. From 1999 through at least 2003, GSK engaged in a nationwide scheme to promote the sale and use of WBSR as safe and effective for indications, doses and populations that the FDA never approved as safe and effective, and that were not medically accepted indications. For example, GSK promoted WBSR for:

(1) weight loss and obesity;
(2) sexual dysfunction;
(3) Attention Deficit Hyperactivity Disorder (ADHD), Attention Deficit Disorder (ADD), bipolar disease and anxiety;
(4) addictions, including to drugs, alcohol and gambling;
(5) patients under age 18, including children;
(6) use as an add-on or in combination with other drugs;
(7) use as an antidote for the side effects of other antidepressant medications; and
(8) use in dosages contrary to that recommended in the label, with safety claims greater than those justified in the label.

78. GSK targeted the promotion of WBSR for unapproved uses especially in quality of life areas, e.g., enhancing sex life, losing weight, addressing substance addictions and attention issues. GSK promoted WBSR as what some sales representatives referred to as "the happy, horny, skinny pill." GSK did so knowing that much of the cost of the unapproved, non-medically accepted and/or inappropriate uses would be borne by federal health care programs.

79. GSK used the following tactics to achieve its marketing goals for WBSR:

(1) **Publicity Strategies:** GSK hired a public relations firm to hype small preliminary studies of WBSR for weight loss, obesity and sexual dysfunction in consumer and general news media to encourage WBSR sales for unapproved uses;

(2) **Speaker Programs:** GSK hired physicians to speak to other health care professionals and recommend unapproved uses for WBSR;

(3) **Details and Samples:** GSK encouraged sales representatives to provide one-on-one sales pitches ("details") to physicians about off-label uses of WBSR and distributed samples for uses not approved as safe and effective, such as samples to child psychiatrists and pediatricians for use in children;

(4) **"CME":** GSK sponsored ostensibly independent "medical education" events and/or medical society and grand rounds presentations on off-label WBSR uses where GSK effectively controlled topics, speakers, content, and participants; and

(5) **Inducements: Sham Advisory Boards, Trainings and Entertainment:** GSK used sham advisory boards, sham sales representative trainings and other forms of entertainment and remuneration to promote off-label usage of WBSR and induce doctors to prescribe WBSR.

80. While GSK promoted WBSR for unapproved, non-medically necessary and/or inappropriate uses, GSK also took steps to evade detection by government agencies and conceal the real purpose and nature of activities, including making repeated false statements to the FDA about the conduct and concealing the documents that demonstrated the conduct.

A. GSK's Corporate Plans Set Forth Its Intent to Promote WBSR for Unapproved Uses

81. In a variety of national and regional strategy documents, GSK reflected its corporate strategy to promote the use of WBSR for unapproved uses.

**1. GSK Hired A Public Relations Firm to Create Buzz and Drive Sales of WBSR for Off-Label Uses.**

82. In 1998 and 1999 and through at least 2002, GSK used media plans as part of its marketing strategy to promote WBSR. These media plans were designed to "create [a] buzz" and to publicize off-label uses of WBSR, such as for weight loss or sexual dysfunction in non-depressed patients. Exh. 5.

83. For example, GSK hired the Cooney/Waters Group ("Cooney/Waters"), a public

relations firm, to promote and publicize a GSK-funded pilot study by Dr. Kishore Gadde of Duke University on the use of WBSR in non-depressed obese patients. Although the pilot study included only 25 patients who were on the drug for only eight weeks, GSK and Cooney/Waters promoted the study in the mainstream media and fostered the coverage of WBSR as a diet pill. This promotion included preparing and distributing a press release about the study to general consumer magazines (such as Allure and Redbook), providing Dr. Gadde with media training, and coordinating with the media "to make sure reporters and editors have the new data and understand its significance." Given the limitations of the study and preliminary nature of the data, its "significance" should only have been to researchers considering further research, not to the general public.

84. Cooney/Waters and GSK's efforts generated stories from CNN and Dateline, as well as tabloids. Exh. 6. It resulted in articles with headlines such as "Bigger than Viagra? It sounds too good to be true: a drug to help you stop smoking, stay happy and lose weight" and "Now *That* is a Wonder Drug." As Cooney/Waters itself touted in a September 1999 report to GSK (Exh. 7), its efforts to promote Gadde's "weight study has been carried by: [ ] More than 70 local television stations [ ] More than 50 local newspapers and consumer magazines nationwide and in the United Kingdom [ ] More than 9 Internet outlets nationwide [ ] 12 trade publications in the United States [and] Media impressions exceed[ed] 15 million (not including wire and Internet impressions)."

85. One example of the media pick up included the following article in the tabloid "The Sun":

# The pill doctors say will help you to slim

## ... AND THEY DISCOVERED IT BY ACCIDENT

**DOCTORS have found a new pill to help you lose weight — purely by accident.**

Researchers discovered that a pill used for depression had the unexpected side effect of making patients shed their flab.

*There is even evidence it can help people stop smoking!*

Now the British company who developed the drug — Bupropion — is considering [illegible] will become the world's most effective weight-loss treatment, though it may be some time before it gets a licence here.

Some of the women who have taken it have lost more weight than patients on the much-hyped new anti-obesity drug Xenical, which was launched last year.

### Amazed

Bupropion is said to be entirely safe and can be taken for life to prevent weight gain.

The drug has also been discovered to be as effective as the nicotine patch in helping smokers to quit and is due to be launched for that use in Britain later this year.

Though it isn't yet licensed to treat the overweight, Dr Kishore Gadde, a psychiatrist at Duke University Medical Centre, North Carolina, expects doctors round the world to try it experimentally.

Dr Gadde prescribed the drug for mild depression while helping women to lose weight at the university fitness centre.

"I was amazed by what

By MARTIN HALLE

happened because there had been nothing published about this drug having the ability to help weight loss," he says.

"The patients were pleasantly surprised because they had not been expecting such an effect. They had been given the drug because they were down about their weight."

Dr Gadde persuaded Bupropion's British manufacturers, Glaxo-Wellcome, to support a trial. He says: "I wanted to see if the drug would work under possible what I had observed may have been a fluke."

But the results of a two-month study involving 18 women with an average weight of 15st proved the original reports were no mistake.

The women lost up to a stone — six per cent of their body weight — while on a diet of 1,600 calories a day.

Dr Gadde is convinced Bupropion will take off as an obesity treatment.

He says: "These were overweight women who were able to achieve a good weight loss over a short period of time.

"We still need to carry out further trials with a larger group of patients but it looks as if we have discovered a new use for this drug.

"The results appear as good as those achieved for Xenical and in some cases better.

"Some of the women on the trial have been taking the drug for up to a year and are continuing to lose weight."

Women on the trial reported that the drug did not suppress their appetite but helped them feel more satisfied more easily.

Dr Gadde says: "A lot of the patients have said that while on the drug they can eat a fattening food like a small piece of pie and feel satisfied though not necessarily full."

Bupropion works in a different way to other anti-depressants. It acts on two brain chemicals, norephinephrine and dopamine, which are both implicated in the brain's reward and pleasure pathways.

Dr Gadde adds: "This probably explains why patients say the drug helps them feel more satisfied while not suppressing [illegible] by *suppressing the desire to eat. This drug acts in a more sophisticated way, by allowing you to eat but reducing your desire to overeat.*"

Specialists treating the obese have been short of drug treatments since the banning of popular diet pills phentermine and fenfluramine after they were blamed for causing heart disease in patients.

### Dry

He says: "News of my study is spreading and people are bound to experiment because there are not that many drugs available for obesity.

"The important thing is that there are no significant side effects apart from a feeling of a dry mouth."

But Glaxo advises GPs NOT to use it to treat patients suffering from a history of seizures, anorexia or bulimia.

British doctors will be able to prescribe Bupropion for obesity once it gains a licence for treating smoking.

But it could be some time before it gets official approval as a slimming pill.

LOOKING GOOD... *the drug Bupropion could give people with weight problems a whole new image*

CASE STUDY: Jan Luces

NEW LOOK...

86. GSK also hired Cooney/Waters to publicize results of other off-label studies to general and consumer media, including a small study of WBSR to treat sexual dysfunction, and a later study of WBSR for weight loss in patients with depressive symptoms but not depression.

87. GSK also hired Dr. Drew Pinsky from MTV and Loveline as a spokesperson to deliver messages about WBSR in settings where it did not appear that Dr. Pinsky was speaking for GSK. GSK indirectly paid Dr. Pinsky $100,000 in March 1999 and $175,000 in April 1999.

Exh. 8. In about June 1999, Dr. Pinsky spoke on a national radio program and communicated key GSK WBSR campaign messages. The "Highlights" included: "Switching to or adding Wellbutrin is recommended for people experiencing a loss of libido." During the program, among other things, Dr. Pinsky noted that the drug in WBSR, bupropion, could explain a woman suddenly having 60 orgasms in one night. Dr. Pinsky explained that one of the things he advocates for people experiencing diminished libido or arousal is WBSR. Exh. 9.

88. According to a report prepared on behalf of GSK in 2002, the media campaigns surrounding use of WBSR for obesity, weight loss and sexual dysfunction reached a total audience of more 387 million, "[s]parked sales growth" and caused WBSR to be used increasingly as a first-line product, both alone and in combination with other therapies. Exh. 10

B. Follow-Up on Gadde Study

89. Following the pilot study by Dr. Gadde on the use of WBSR for obese non-depressed women, GSK hired Dr. Gadde and other weight loss specialists to give promotional talks on behalf of GSK to other physicians and to discuss the use of WBSR as a "weight-loss agent." In these talks, the speakers reviewed the use of WBSR for weight loss in non-depressed patients and advocated its use for weight loss, despite the lack of FDA approval or substantial evidence supporting this use. In such programs, Dr. Gadde, a consultant for the Duke Diet and Fitness Center, presented his study on the use of WBSR in non-depressed patients.

90. However, in the spring of 2000, when Dr. Gadde was preparing the manuscript about the study for publication, GSK had a falling out with him over his insistence on emphasizing certain safety warnings and his refusal to use Wellbutrin SR's trade name.

91. Dr. Gadde was informed by a chairperson at his university, also a GSK consultant, that GSK would not fund any more of Dr. Gadde's studies due to his refusal to remove some of the safety discussion from the article. GSK's Clinical Director for their Central

Nervous System program, Tim Kuhn, also informed Dr. Gadde in writing that Dr. Gadde should not have made the decision to submit his own article on the study to the journal Lancet rather than JAMA without consulting with GSK as GSK was his "partner in publishing decisions that consider both patient and brand issues." Kuhn explained to Dr. Gadde the consequences of such a failure to consult with GSK: "It is unlikely that additional support for other investigator-initiated projects will be embraced enthusiastically if there is no input from GW [GlaxoWellcome, GSK's predecessor] or if input from GW is not considered." Exh. 11.

92. After this falling out, GSK's national marketing team increasingly utilized other physicians, including Dr. Ken Fujioka, an endocrinologist specializing in weight loss treatments, as its spokespeople to present the Gadde study, rather than Dr. Gadde himself.

93. GSK hired Dr. Fujioka in September 2001 to train the WBSR sales force on using WBSR for weight loss. Dr. Fujioka is known as the "Fat Doctor" due to his focus on diet and weight loss. Dr. Fujioka does not treat depression and thus does not even utilize WBSR for its only on-label use. Dr. Fujioka's talk on the effects of WBSR on weight included slides claiming WBSR is associated with significantly more weight loss than placebo and that 77% of patients treated with WBSR 400 mg/day achieved more than 5% weight loss. This presentation also included claims about the effectiveness of WBSR to treat obesity in non-depressed patients.

94. GSK sales force members utilized Dr. Fujioka in programs and sales calls to discuss the weight loss effects of WBSR. Some examples of the call notes reflecting GSK's sales force use of Dr. Fujioka include:

> "SIB program with local KOL's and visiting KOL's (Ken Fujioka). Goodman presented on WSR in ADHD and Depression, outstanding job, Fujioka presented the weight data which sparked alot of participation from the audience as well as feedback . . . ." *11/3/01 Durham, NC*

> "Followed up on sib. Enjoyed. Liked Fu[j]ioka talk benef of lbs w/ wsr." *10/26/01 Hudson, FL*

"she loved fujioka..invited her to hear hudziak in january" *11/26/01 Brockton, MA*

"Dr Fujioka lecture on weight studies in Boston. Send him info on the use of methadone and WSR." *11/9/01 Lynn, MA*

"She came to the Fujioka program and I would expect to see her WSR numbers increase based on the weight loss data he presented tonight. . . . thought we should really spread the word about these studies" *3/21/02 Redwood City, CA*

"he says dr fujioka was great- he walked out of his office after the tele conf and implimented options he spoke about." *6/27/02 Bangor, MA*

C. Operation Hustle: National Campaign for WBSR to Treat "Co-Morbidities"

95. In 1999, GSK also instituted "Operation Hustle" - a national sales campaign. In meetings with national sales and marketing personnel in about 17 cities around the country, GSK introduced a new approach to selling WBSR by promoting WBSR for "co-morbid conditions" that were not FDA-approved uses for WBSR, but may also exist in depressed patients, such as weight gain, sexual dysfunction, and ADHD. GSK instructed its sales force to promote WBSR as increasing the neurochemical agents norepinephrine and dopamine, and thus effective in treating "co-morbid" disorders thought to be connected to levels of norepinephrine and dopamine, such as ADHD, addiction, and craving.

96. In April 2000, GSK's strategic plan for WBSR identified as sales opportunities off-label uses such as ADHD, anxiety, lethargy and bi-polar disorders and listed WBSR use in combination with other antidepressants to their treat side effects as a growth opportunity.

97. GSK's off-label marketing strategies worked. Less than a year later, GSK noted that WBSR's "use for treatment of antidepressant induced sexual dysfunction has increased due to product positioning," and that it was a "[p]roduct of choice for adding . . . patients who experience sexual dysfunction or efficacy poop-out." Sales increased approximately 34% from 2000 to 2001, far in excess of the market rate of growth for antidepressants.

98. Sharon Sharo, the Director of WBSR Marketing, presented to the management team the plans for WBSR for 2001 and included as WBSR "Growth Drivers for 2001":

- Completed 2 Obesity trials - results presented [at conferences] . . .
- Obesity study investigating the efficacy and tolerability for WBSR in overweight and obese women published in Obesity Research 9/01 (Gadde).
- WBSR was effective and well tolerated for weight loss at 8 weeks with sustained [sic] the weight loss through the continuation phase.

99. Sharo also explained that GSK's objectives of speaker training for WBSR included "Present and position Gadde and Anderson weight data" despite the fact that the weight data was both off-label and extremely preliminary. She also noted that the December 2001 Speaker Training in Fort Lauderdale, Florida would include a key talk by Dr. Fujioka.

100. In August 2001, GSK's Strategic Brand Plan for WBSR noted under "opportunities" an "increased awareness of sexual dysfunction and legitimacy of treatment of sexual dysfunction in non-depressed patients." The Brand Plan also stated that GSK will "[a]ggressively support the efficacy and utility of WBSR with new clinical data" and "[t]hrough non-promotional means (MI letters, publications etc.) optimize use of strong clinical data for prevalence of antidepressant induced sexual dysfunction, comparison vs. key competitors in depressed and non-depressed patients for weight loss and HSDD."

101. GSK also pushed throughout the company the message to promote WBSR as an "add-on" drug to treat co-morbidities (i.e., side effects of other drugs) and for combination therapy. For example, in a 2002 Business Plan forwarded by a Regional Sales Director in the New England Region, a manager set forth the following strategy to grow market share:

> Increased focus on Dl Medicaid High potential Prescribers: Target Medicaid areas with strong messages about the benefits associated with NE and DA (the components of WBSR) (i.e. LOW sexual dysfunction, impact on weight, cognition, lethargy and smoking cessation . . . Develop Medicaid Champions to

disseminate WBSR messages . . . increase the switching/adding for sexual dysfunction.

102. Other business plans also encouraged growing WBSR sales by utilizing "weight loss data" and promoting the product as "add-on therapy to SSRI." These plans also included a specific focus on physicians prescribing for Medicaid patients.

D. GSK Used Speaker Programs to Promote WBSR for Unapproved Uses.

103. GSK used speaker programs to spread off-label information about WBSR. GSK trained and paid physicians to speak to other physicians at thousands of promotional events per year that were organized by GSK's sales representatives and managers. Many of these events included false and/or misleading claims about WBSR's safety and efficacy for unapproved uses. In these talks on behalf of GSK, the speakers recommended WBSR for a wide variety of unapproved uses, including for weight loss, to treat sexual dysfunction, ADHD and other attention disorders, and even for patients with bulimia or who were abruptly discontinuing alcohol (both of which were specifically contraindicated in WBSR's labeling).

104. GSK paid physicians to attend lavish meetings, in places such as Jamaica, during which GSK promoted WBSR for off-label uses. These meetings were intended to reward physicians who were writing a large number of WBSR prescriptions and induce physicians to write more WBSR prescriptions, including for unapproved uses. Sales representatives' call notes reflect the off-label discussions and purpose of these meetings:

> "Jamacia Discussed role of WSR in treating depression, ADHD, and obesity" *1/27/01 NY, NY*

> ". . . Wellbutrin Speakers Training – Jamaica – Interacted several times. He was interested in meeting someone from Marketing about soft money – I told him to talk to [Marketing Director] Lafmin Morgan – which he did." *1/28/01 Durham, NC*

> "really enjoyed Jamaica – told of successfully using Welb in pt w/ADHD" *1/30/01 Minneapolis, MN*

". . . had a wonderful time in jamaica with well sr marketing. spent some time with tom and bill which was great. he is eager and ready to talk for us. numbers are reflecting a large increase in new rx's... i think he gets the picture. sched. a reprint mastery for the group in his office on the 16th . . ." *1/31/01 Quincy, MA*

105. In late 1999 or early 2000, GSK established a national WBSR speaker program known as PRIDE (Peer Review of Intimacy, Depression and Efficacy) that featured many off-label speakers. GSK determined that its PRIDE dinner programs yielded an approximate 280 percent "return on investment."

106. GSK representatives, including managers, attended every PRIDE program. GSK obtained copies of the presentations and invited to speak most frequently those speakers who effectively promoted off-label uses of WBSR. Sales representatives and managers invited the key speakers back to speak over and over again across the country and touted them to their colleagues, sometimes precisely because of the off-label messages and their ability to increase sales of WBSR.

107. GSK paid such speakers in the range of $1,000 to $2,500 for a one hour program. Because many of the speakers traveled the country making virtually identical presentations at each location, little or no additional preparation time was necessary. Moreover, the same speaker might be paid three times a day for making the same or similar presentation at breakfast, lunch and dinner in a single day. Some speakers would not even agree to come to a territory to speak unless they were guaranteed a "six pack" of speaking events at approximately $2,000 each, for a total of at least $12,000 for the two day trip. This amount far exceeded the amounts they were otherwise paid to practice medicine or lecture as university professors.

**1. Dr. James Pradko**

108. Dr. James Pradko was one of GSK's top WBSR speakers from 2001-2003. From 2001 to 2002, he was paid half a million dollars per year for speaker programs about WBSR and

nearly a million dollars in 2003 alone. Dr. Pradko was also hired by GSK to present at sales representative training sessions—both initial and advanced sales training—and was repeatedly a presenter at GSK's WBSR National Speaker Training Meetings. Dr. Pradko, whose specialty is family practice, was also appointed to GSK's National Advisory Board.

109. Dr. Pradko traveled to every GSK sales region to present his standard presentation, "The Neuroreceptor Basis of Initial Antidepressant Choice." In 2002, Dr. Pradko made this presentation at more than 300 promotional speaker events.

110. Dr. Pradko's presentation was permeated with off-label claims about WBSR. Among other claims, Dr. Pradko represented that WBSR could be used for weight loss, ADD in pediatric patients, chronic fatigue syndrome, marital dysfunction, erectile dysfunction, addictions and chemical dependencies, attention disorders, low energy in anxious patients, sleep disorders, restoring REM levels of sleep, restoring libido and a healthy sex life, and treatment of pregnant women. Dr. Pradko also told attendees that WBSR could be used as an "add-on" to treat SSRI side effects such as "poop out", sexual dysfunction and weight gain.

111. Many of Dr. Pradko's claims were contrary to WBSR's label. For example, Dr. Pradko asserted that he put all of his pregnant patients on WBSR and further claimed that the FDA said that it is safest antidepressant in pregnancy. WBSR's prescribing information, however, specifically cautioned that the drug "should be used during pregnancy only if clearly needed" and that "there are no adequate or controlled studies in pregnant women." Moreover, after animal studies were done, the FDA updated the label for WBSR in March 2007 to Pregnancy Category C because "it did appear to cause harm to the fetus in previous animal studies." According to the updated label, "[i]n these studies, there was an increased risk of birth defects and lower fetal weights when the medication was given to pregnant rabbits."

112. Dr. Pradko's recommendations to use WBSR use in treating sleep disorders are

likewise called into question by WBSR's label. The label cautions that in placebo-controlled trials, between 11 and 16 percent of patients receiving WBSR experienced insomnia. Even GSK's own marketing department recognized that "[i]nsomnia is a common concern/comorbid condition within the depressed patient population and bupropion [the operative molecule in WBSR] is associated with increased insomnia."

113. Similarly, Dr. Pradko's claims advocating WBSR use in pediatric patients contravene the drug's FDA approval, which was approved only for patients 18 and older. GSK's prescribing information warned that the safety and effectiveness of WBSR in pediatric patients has not been established. Moreover, as noted above, in October 2004, the FDA required all antidepressants including WBSR to carry a black box warning that describes the increased risk of suicide and suicidal thoughts and behavior in children and adolescents given antidepressants.

114. Despite its off-label content, GSK managers around the country and at headquarters enthusiastically embraced Dr. Pradko's messages and his standard talk using a baseball analogy known as the "baseball diamond talk." Sales representatives repeated and reinforced Dr. Pradko's off-label messages in their calls upon physicians. For example, in July 2000, a northeast marketing development manager emailed the national brand directors:

> First of all, congrats to you and your entire WSR team on a great WSR Univ.! Using Dr. Pradko's baseball graphic of neurotransmitters, you guys have hit a grand slam. The numbers, the incremental growth, what a success story. (Now I know why you called them "PRIDE" programs.)

115. In addition to live speaker programs, GSK actively promoted Dr. Pradko's off-label messages with an audio cassette version of his lecture. From at least 2000 until into 2003, GSK purchased and distributed to physicians hundreds, if not thousands, of audiocassette tapes of Dr. Pradko's standard lecture with the off-label marketing messages (the "Pradko tape"). The sales force reflected this and the impact on sales in their call notes, including the following:

"Raved about Pradko (could hear better on tapes than at program in A.C.) and the fact that he has increased his WSR use EVEN MORE!!!! in certain types of pts." *4/25/01 Vineland, NJ*

"followed up w/ pradko tape, dr was so happy to have it, wants bubble sheets too, scheduled to speak to corporations in the area in march, reminder on wt loss data, adding sr, & first line therapy" *2/11/02 Bridgewater, NJ*

"Stressed the Pradko Tape and he said she will listen to it on the drive back home tonight and he liked the analogies and he said he had just written for the 150 for 13yr ld girl that was on adderall and becoming combative but doing better with the add. He said he is starting slower and lower and seeing better compliance to start it out." *10/29/02 Wellston, MI*

"told about morning program with pradko in march. has listened to half the pradko tape already and said he would come to the program." *1/28/03 Battle Creek, MI*

"She raved about the Pradko tape, has listened to it 3 times, much less commercial than the teleconference, loved the information, uses it daily now. I also gave her WSR bubble sheet tear-offs, which she likes and will use. Finally went over XL coming – very interested in this." *6/11/03 Grand Rapids, MI*

"went through all products and then went through all reasons to use well xl and 100% conversion. pradko tapes and he said he would go to the program." *10/22/03 Smyrna, GA*

116. In the spring of 2002, a GSK marketing development manager worked with Dr. Pradko to prepare a DVD of Dr. Pradko's standard talk. GSK paid for the development costs. Although the DVD purported to be independent medical education, it was in fact the promotional talk Dr. Pradko gave on behalf of GSK and developed into a DVD at GSK's request.

117. Dr. Pradko provided the DVD to the southeast region of GSK for a pilot project, with the hope that the company would purchase the rights to use the DVD nationally. The Regional Sales Director at the time, Anne Whitaker, supported the project and accompanied a sales representative to a physician's office to view the DVD. Although Whitaker observed the content of the DVD at that time, including the off-label messages it contained, her team continued to distribute and play the DVD for physicians around the region.

118. In one month, GSK sales representatives in the southeast played this DVD for

physicians approximately 900 times. The representatives raved about the "independent" CME DVD's effectiveness in persuading physicians to prescribe WBSR with comments such as "This DVD has been the best selling tool for me yet. It has not only helped me reach customers that would not attend programs but also teach myself and customers the best way to use [WBSR]."

**2. Dr. James Hudziak**

119. In standard presentations that were delivered hundreds of times at GSK PRIDE and local speaking events, Dr. James Hudziak, a child psychiatrist, advocated using WBSR for a wide range of off-label treatments including ADHD, addictions, sexual dysfunction, obesity, weight reduction, bi-polar disorders, addictions and bereavement. Dr. Hudziak's off-label messages were in slide presentations he provided to GSK prior to his talks on behalf of the company. Sales representatives were thrilled with the impact of Dr. Hudziak's off-label messages, as reflected in their call notes, including the following:

> "Lunch with the group today. we dsicussed the use of WSR to treat ped with ADD and ADHD problems. I used the Hudziak and Wilens articles to discuss WSR advantages. They all agreed." *5/10/01 Atlanta, GA*

> "Follow up on Hudziak SIB. He thought Hud was interesting and wanted to read everything Hud talked about. Need to follow with all the studies mentioned in the SIB, probably Sex Monograph, Rush, etc." *4/22/02 Marion, OH*

> "disc what hudziak says in regard to wsr and adhd." *9/9/02 Franklin, TN*

> "hudziak approp pt profile for obese/smokers adhd/weight loss potential, the higher the BMI, the more you'll lose – said he would try" *9/10/02 Clearwater, FL*

120. Not everyone was as impressed with Dr. Hudziak, however. According to one sales representative, one physician who attended "thought [Dr. Hudziak] was a drug whore."

121. Dr. Hudziak's talks and messages were well-known to senior managers at GSK. His slides were circulated among the members of the sales force, including to managers. He spoke at both speaker trainings and national advisory boards. Senior marketing managers

attended his talks. GSK managers around the country regularly booked Dr. Hudziak for speaker engagements and repeatedly encouraged others to book him in their regions, even though they knew his slides and presentation contained off-label information.

122. WBSR Brand Director Lafmin Morgan and Regional Sales Director Mike Delea attended Dr. Hudziak's GSK sponsored talk in connection with the arrival of the Tall Ships flotilla in Boston in the summer of 2000. Delea congratulated the team that organized the event noting that "Dr. Hudziak gave a solid presentation on the effectiveness of [WB]SR. The weather was perfect, along with the boat cruise and viewing of the Tall Ships." Exhs. 12-15.

123. Sales representative comments concerning this event include the following:

> "wants to go to the 4pm tall ships. ... - will get back to him if we decide agst kids. don't think we will.... numbers are way to imp. to us." *06/20/00 Boston*
>
> "confirmed 3 tix for tall ships for doc and kids." 07/07/00 Randolph, MA
>
> "Still talking about Bermuda trip. Wants to play golf at Ipswich CC. Setting it up for Sept. Looking forward to Tall Ships." *07/13/00 Salem, MA*
>
> " . . . r/t Hudziak program in Providence in Jan. Said she & Dr. had heard him at Tall Ships and Dr. loved him. Her prescribing in growth track show this!" *12/15/00 New Bedford, MA*

124. Dr. Hudziak was also a popular moderator for advisory boards. He was hired by GSK to lead numerous local and Special Issue Boards, where he presented off-label information and encouraged other physicians to use WBSR for on and off-label uses.

125. For example, Dr. Hudziak was a featured speaker at a Regional Advisory Board for the northeast region in August 2000 at the Fairmont Princess Hotel in Bermuda. Dr. Hudziak was paid $5,000 and he and his wife were treated to accommodations and entertainment for the weekend, which Dr. Hudziak described as a vacation. Exhs. 16-18.

126. The GSK manager who organized the event solicited input from the GSK sales force as to which doctors to invite in order to impact sales. He asked managers to nominate

attendees by providing information on their key "customers" (physicians), those customer's prescribing habits and what the sales manager would "wish to achieve with [the] customer . . . in an effort to obtain the greatest ROI [Return on Investment] . . . ." Exh. 19.

127. GSK then selected doctors to attend in order to impact their prescribing of GSK drugs. The organizers were provided instructions the sales team's goals for each physician, including ways to increase their use of WBSR off-label. For example, the sales team noted that one doctor "is very pleased with the use of WBSR especially with its effectiveness in ADHD. Please utilize his positive experience and enthusiasm of WBSR to influence other clinicians." For another: "Dr. [N] is a Child Psychiatrist and I would like the safety and efficacy of a first line antidepressant and treatment option for ADHD to be relayed to him." Exh. 20.

128. One physician was told that he was invited to "sit for 4 hours, share your thoughts around WSR, get paid at a nice place in Bermuda" and he was invited because he was "the number one potential doc in the entire state of Maine prescribing anti-depressants." The event included a four-hour meeting in three days in Bermuda. By noon Saturday, the "work" was done and GSK provided meals, activities and an evening dinner cruise. Exh. 21.

129. The Bermuda meeting presentations included numerous recommendations for off-label uses of WBSR by Dr. Hudziak. Moreover, sales force statements before and after the meeting demonstrate the purpose of the meeting was really to encourage prescribing of WBSR, and not to gather needed consulting about WBSR, including:

> "will be attending rabs program in Bermuda 8/11-8/13: low market share but high volume target. . ." *07/05/00 Westerly, RI*
>
> "She spoke highly of their trip to Bermuda and of riding around on a scooter! She like Hudziak's talk, and is incrcasing her usage of SR." *02/01/01 Greenland, NH*
>
> "He attended the Bermuda RAB this past August and he has increased his prescribing of WellSR" *12/13/2000 email re: Marlborough, MA physician*

130. Dr. Hudziak was also a speaker selected by GSK for ostensibly independent CME events relating to WBSR. In fact, in the summer of 2002, Dr. Hudziak expressed concern because a new Vermont law required him to report the large amount of compensation that GSK paid him to speak on its behalf. To avoid disclosing how much he was receiving from GSK, Dr. Hudziak informed GSK that he would only do CME events, not promotional events.

131. GSK therefore arranged a series of purportedly independent "CME" events where GSK scheduled the event and selected the speaker (Dr. Hudziak) but arranged for a CME vendor, Primary Care Network, to "accredit" the events.

**3. Other Physician Speakers**

132. Besides Dr. Pradko, Dr. Hudziak, Dr. Gadde and Dr. Fujioka, many other GSK physician speakers for WBSR also used presentations that promoted off-label uses. These doctors were paid by GSK for such speaking engagements and spoke at GSK-sponsored events.

133. For example, Dr. Norman Sussman's standard PRIDE presentation incorporated representations that WBSR promotes weight loss, including in non-depressed patients. Dr. Sussman also advocated using WBSR to treat ADHD, smoking cessation, SSRI side effects, chronic fatigue syndrome, restless sleep, and Parkinson's disease.

134. Dr. Sussman also made claims that improperly minimized or contradicted the drug's FDA-approved label. Dr. Sussman represented that WBSR's seizure rates were either equivalent to or less than the rates seen with SSRIs, even though no head-to-head trials studied comparative seizure rates and the seizure rate listed for WBSR in its label is higher than some other antidepressants. Likewise, Dr. Sussman suggested WBSR be used to treat patients with eating disorders, even though the label contraindication such use because of seizure risk.

135. GSK speakers Drs. Sarah Atkinson and Anita Clayton also recommended WBSR for weight loss in non-depressed patients, among other off-label uses. Dr. Jeffrey Green

presented WBSR as a treatment for cocaine and alcohol addictions and ADHD. In doing so, Dr. Green, also improperly minimized WBSR's FDA-required seizure risk. Dr. Croft recommended WBSR for the treatment of sexual dysfunction, for weight loss, ADD, chronic pain and children.

136. GSK representatives attended every PRIDE event and were well aware of the speakers' off-label claims. Leading speakers such as Drs. Pradko, Hudziak, Sussman, Clayton and Atkinson, Croft, and others spoke dozens of times a year and were highly sought after by GSK for such events. GSK used these speakers to promote off-label use of WBSR by frequently employing them as speakers, with full knowledge of the content of their presentations.

137. By at least October 2001, a GSK sales representative had notified senior GSK managers of the use of speaker programs to promote off-label uses, including to promote WBSR for children and ADHD and, in subsequent months, for weight loss. Exh. 22. The representative pointed out the evidence of the off-label speaker programs in his colleagues' call notes.

138. When this representative did not receive a response, he escalated his complaints to GSK's heads of human resources and compliance. In his complaint, the representative noted that he had "come forward with the truth, which could save the reputation of GSK, and millions of dollars in fines." Exh. 23. He later also wrote to GSK Chief Executives Robert Ingram and David Stout about his complaints. In early 2002, GSK initiated a compliance investigation that confirmed many of the representative's allegations, including the use of WBSR speaker programs to promote WBSR off-label and use of a spa program to entertain physicians.

139. The complaining sales representative was offered an unusually favorable severance package, including relocation payments and keeping the company car.

140. Although a manager admitted during GSK's internal investigation that he had been told by the sales representative that the speaker programs were off-label, and although another sales representative confirmed that the manager was aware of the off-label nature of the

programs, the manager received only a "verbal warning." Moreover, although the Chief Compliance Officer noted that off-label discussions by GSK speakers were "normal" (i.e. common) (Exh. 24), no action was taken to investigate further and the off-label promotion continued.

A. Sales Representatives Repeatedly Promoted Off-Label Uses of WBSR.

**1. GSK Immersed Its Sales Force in Information on WBSR's Off-Label Uses.**

141. GSK actively encouraged its sales force to promote WBSR for off-label uses. From the time of their introductory sales training and throughout their tenure with the company, sales representatives were bombarded with information about off-label uses of WBSR, including

Dr. Pradko's standard presentation at new representative sales training (every GSK sales representative who sold WBSR was also provided his or her own personal copy of Pradko's standard presentation, replete with off-label claims). Exh. 25.

142. Sales representatives were provided with multiple copies of the results of GSK-funded studies on weight loss in the non-depressed. For example, in June 2001, GSK distributed a memorandum to its WBSR sales force with new clinical data on the drug's impact on weight loss in non-depressed obese patients. GSK also distributed to its sales force the Gadde study and other studies of the use of WBSR in patients who did not have a diagnosis for depression.

143. GSK required the WBSR sales forces to take a home study course that included a review of studies on the off-label use of WBSR for weight loss. GSK required a mandatory written "knowledge certification" on the off-label weight loss data in non-depressed patients and other tests on off-label material about WBSR for ADHD.

144. Although representatives were "told" that they were not supposed to use this information affirmatively in promotion, they were required to "role-play" scenarios with their managers where they could use this off-label information. Moreover, their performance was

judged and their bonuses based on sales goals that reflected all sales, including off-label sales.

145. GSK sales representatives also proactively promoted the results of studies of non-depressed patients treated with WBSR for weight loss and sexual dysfunction despite the lack of any FDA-approval for these indications. Similarly, GSK directly promoted WBSR as an "add on" combination therapy to address SSRI-induced side effects, such as weight gain, sexual dysfunction, and so-called "poop out" or loss of energy. Thus, GSK's emphasis on various off-label uses translated into direct promotion to prescribing physicians by the company's sales representatives and was reflected year after year in the sales representatives' call notes. GSK took no action to correct the off-label marketing efforts documented in thousands of such call notes during the relevant time periods. The following are just a few of the many instances:

> "Killer detail today on SR. She wasn't seeming to know much about it but the line Happy Horny and Skinny was a good line for her today and we really got into the whole conversation" *2/1/01 Corvallis, OR*
>
> "…we talked about wsr in combo. with a ssri as well as using it in non depressed women for sexual dis" *2/16/01 Millstadt, IL*
>
> "Wants to golf; Reminder on Happy horny skinny pill;" *5/9/01 Bethel Park, PA*
>
> "Wellbutrin SR for the treatment of cocaine addiction." *8/9/01 Belle Mead, NJ*
>
> "Great conversation on WSR new wt loss study-augmenting for sex side affects-brought in rest of breakfast from NW health-loved it! Gave me more time to discuss the off label uses-ie Bipolar, ADD, Poop out." *8/20/01 Arlington Hghts., IL*
>
> "Nice follow up to last visit regarding use of WSR for anxiety, PTSD, ADD/ADHD, and social phobia." *9/26/01 Santa Fe, NM*
>
> "asked to prescribe in overweight pts also any pts with addictions need dopamine and wsr will give to them" *3/6/02 Trenton, NJ*
>
> "Quick positive points and talked about why I was there. Nondepressed women libido but he wouldn't bite." *3/11/02 Seattle, WA*
>
> "WBsr for your couch potatoes, happy, horny, skinny pill" *8/30/02 Folsom, CA*
>
> "Told him the "happy-horny-skinny" line which he loved. Makes it easier to

remember the se profile." *10/29/02 Grand Rapids, MI*

"quick hello and reminders – was in a hurry just reminded of the happy horny skinny pill great for over the holidays" *11/25/02 Yellow Springs, OH*

"talked to dr about using wsr for sexual dis. in his non depressed pat." *1/27/03 O Fallon, IL*

146. In addition, although WBSR is not FDA-approved for patients under the age of 18, GSK targeted child psychiatrists and pediatricians for promotion of WBSR. GSK required sales representatives to visit certain pediatricians and child psychiatrists repeatedly each quarter. On these visits, GSK representatives actively promoted WBSR for such off label indications as ADD/ADHD and pediatric depression.

147. In these sales calls to child psychiatrists and pediatricians, GSK representatives also routinely gave out samples of WBSR, knowing and intending that the samples would be used for patients under 18, for whom the drug was not approved. GSK headquarters kept a database of all sample deliveries and was thus well aware that its employees were giving samples of WBSR to physicians who primarily or solely treated patients under 18.

148. This fact was also amply reflected in the call notes sales representatives made of their visits to pediatricians and child psychiatrists. The following are a few examples of GSK's internal reports of off-label promotion of WBSR to pediatricians and child psychiatrists.

"discussed use of wellbutrin in children for depression" *1/26/01 Reno, NV*

"good lunch. hit wsr with wilens and adhd. he says that it is effective and helps in disruptive kids alot. led him to hudziak article to show improvement in aggressiveness." *4/20/01 Gainesville, GA*

"apt today. Discussed W for ADD/ADHD. seems to be writing for these to indications the most. see primarily children [] OK on samples" *1/4/02 Aurora, IL*

"Even though he is a pediatrician, I talked with him about my products, because all have data in children. (adhd-wbsr; imitrex nasal spray-adolescent migraine). Had a good talk about kids." *5/14/02 Abbeville, SC*

"talked of baseball/told of well in adhd adolesence" *6/14/02 Chattanooga, TN*

149. GSK also knew from its own market research from at least 2000 to 2003 that the main messages being delivered by its sales force in promoting WBSR included repeated off-label claims for the use of WBSR as add-on, to treat sexual dysfunction and weight gain, for bipolar disease, for children and the treatment of ADHD. Reports from physicians of the main messages they received from GSK sales representatives included off-label messages such as the following:

- "Wellbutrin is indicated for anxiety…"
- "…effective against ADHD symptoms."
- "…good in children who have attention span problems…"
- "…in pregnant patients."
- "A useful medication in conjunction with the SSRIs to deal with sexual dysfunction induced by SSRIs"
- "Very good as an add-on medication to other SSRIs"
- "Very effective in add-on therapy in conjunction with other antidepressants"
- "People suffering from addiction such as smoking, overeating, or illegal drugs"
- "To prescribe Wellbutrin for anxiety disorder…also discussed using…it in children and adults for attention deficit."
- "It was now indicated for weight loss, as well as the treatment of depression, and smoking cessation."
- "Wellbutrin SR is indicated for generalized anxiety disorder…"
- "That it's safe, effective for treating depression, and also bipolar illness."

## V. GSK'S OFF-LABEL MARKETING OF ADVAIR

150. Advair is a combination drug that is approved by the FDA for the treatment of certain respiratory ailments under certain conditions. From the time of its launch in 2001 through at least 2010, GSK promoted the asthma drug Advair for first-line therapy for patients and uses that were neither FDA-approved nor medically appropriate. Among other things, GSK illegally promoted Advair for "all persistent" asthma patients, including specifically mild persistent asthma patients and patients who had not yet tried using just one component of the drug. GSK also at times promoted Advair for all asthma patients, including even mild intermittent asthma patients. GSK's promotion dramatically increased medication costs for patients who did not need the combination of two drugs provided by Advair. It also exposed patients to significant safety

risks without demonstrated treatment benefits.

151. GSK made false and misleading statements about Advair to health care providers, causing them to consider Advair safer and more effective than it was and thus to prescribe Advair to patients for whom it was not medically accepted and potentially unsafe and dangerous. This marketing also caused physicians to use Advair for other unapproved uses beyond asthma. GSK also made false and misleading statements directly to state and federal health care programs to cause them to pay for Advair and persuade them not to place what would have been medically appropriate restrictions on the reimbursement of Advair.

A. NIH Guidelines Do Not Recommend First-Line Use of Advair for Mild Asthma.

152. The prevailing guidelines for the diagnosis and treatment of asthma are the Guidelines for the Diagnosis and Treatment of Asthma. They were first published by the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH Guidelines) in 1991 and were updated in 1997, 2002 and 2007.

153. Under the NIH Guidelines, patients are categorized into mild, moderate and severe asthma. Patients with occasional asthma symptoms are categorized as mild "intermittent" asthma patients. The recommended treatment for mild intermittent asthma is a "rescue inhaler" (short-acting-beta-agonist (SABA) or albuterol) on an as-needed basis in response to symptoms.

154. Patients who regularly suffer asthma symptoms are categorized as having "persistent" asthma. The NIH Guidelines further categorize persistent asthma patients along a spectrum from "mild" to "severe." For mild persistent asthma, the Guidelines recommend treatment with a maintenance therapy, such as low-dose inhaled corticosteroid (ICS). The NIH Guidelines recommend that persistent asthma patients also use SABA on an as-needed basis.

155. For treatment of moderate persistent asthma, the 2007 NIH Guidelines recommend either increasing the dose of ICS or adding another controller medication, a long-

acting-beta-agonist (LABA), to the low-dose ICS. A "controller" or "maintenance therapy" refers to medication used every day, long-term, to control asthma symptoms

156. Under the NIH Guidelines, ICS is the recommended first-line maintenance treatment for persistent asthma patients. The 2007 NIH Guidelines state that "ICSs are the preferred treatment option for initiating long-term control therapy."

157. Advair, GSK's best-selling drug, is a combination of two other GSK-owned, FDA-approved drugs: Flovent (an ICS) and Serevent (a LABA). Advair is predominantly administered through a proprietary inhaler device called the "Diskus."

158. In the asthma context, "first-line" use refers to the first controller medication a patient is prescribed. First-line use of Advair in mild asthma patients is not supported by the NIH Guidelines.

B. Advair's Initial Approval and Label Limited Its First-Line Use.

159. Advair was approved by the FDA in August 2000 for the "long-term, twice-daily maintenance treatment of asthma." The label's Dosing and Administration section stated:

> The recommended starting doses for ADVAIR DISKUS are based upon patients' current asthma therapy. . . For patients who are not currently on an inhaled corticosteroid, **whose disease severity warrants treatment with 2 maintenance therapies**, including patients on non-corticosteroid maintenance therapy, the recommended starting dose is ADVAIR DISKUS 100/50 twice daily. [Emphasis added].

160. The language in Advair's label on disease severity and initiation of treatment was extensively negotiated by the FDA and GSK. GSK understood and agreed that the label restricted first-line use of Advair for "mild" asthma patients. These were patients for whom "long-term, twice-daily" use of Advair was non- medically accepted and potentially unsafe.

161. None of the pivotal trials submitted to the FDA in GSK's New Drug Application (NDA) for Advair studied the safety and efficacy of Advair for mild asthma patients. Moreover,

prior to the launch of the drug, GSK agreed with the FDA that Advair was not medically appropriate for such patients and represented to the FDA that it would promote Advair only for those for whom the combination of ICS and LABA was medically appropriate.

162. At the FDA's November 1999 Advisory Committee meeting to discuss GSK's NDA for Advair, Dr. Tushar Shah, GSK's Director of Respiratory Clinical Research, stated "In [mild] patients, combination therapy would be inappropriate" and "I think the label that we provided actually would exclude mild patients, because what we're saying is that this product is appropriate for patients in whom combination therapy is appropriate."

163. After that meeting, the FDA and GSK negotiated language in the Dosage and Administration section of the label to restrict Advair's first-line use by mild persistent patients.

164. GSK agreed and understood the effect of the restrictions in the Dosing and Administration section. Internally, just prior to the approval of the Advair label, GSK wrote:

> Despite the implication that Advair Diskus is indicated for all asthma, FDA is not comfortable that Advair be used or promoted for mild disease. They propose to describe the appropriate patient populations in the "Dosage and Administration" section of the label. This section now contains language that allows Advair to be used in patients currently taking non-corticosteroid maintenance therapy (salmeterol, LTMs etc), as well as inhaled corticosteroids. In addition, FDA appear comfortable in allowing Advair to be used in patients currently taking albuterol if we qualify they have moderate or severe disease. We are submitting proposed wording to include this patient population.
>
> . . .
>
> In summary, it now looks like we have a broad indication with specific dosage recommendations for patients on any maintenance therapy, as well as a subset of patients taking albuterol only. [Exh. 26].

C. The FDA Rejected GSK's Application to Include First-Line Dosing Instructions for Mild or All Asthma Patients.

165. In addition, on April 27, 2001, GSK submitted a supplemental NDA (sNDA) to the FDA seeking a broader first-line dosing instruction by providing additional clinical data. GSK specifically sought the removal of the language in the Dosage and Administration section

that reflected the limitation on Advair's first-line indication to patients "whose disease severity warrants treatment with 2 maintenance therapies . . . ."

166. In February 2002, the FDA rejected GSK's sNDA, and explained:

> We do not believe that you have provided sufficient evidence of efficacy to support this broadened indication for Advair Diskus. . . . In addition, this supplement did not provide adequate assurance of the relative safety of the combination product compared to the single component fluticasone [ICS] for the proposed population.

167. Notably, the FDA told GSK that Advair had not been shown to be superior to ICS — the recommended treatment for first-line use for mild (and later all) asthma patients. In its non-approvable letter to GSK, the FDA stated that the pivotal trial of the application, SAS30017, "failed to demonstrate the superiority of the combination product Advair Diskus to the single component fluticasone propionate using the protocol-specified analysis." Exh. 27.

168. In its "non-approvable" letter regarding the 2001 sNDA, the FDA warned GSK that marketing Advair with these claims could cause the drug to be considered "misbranded" under the United States Food, Drug and Cosmetic Act ("FDCA").

169. In March 2002, GSK wrote to the FDA and withdrew its sNDA "[as] there are currently no additional efficacy and safety data with which to amend this supplement."

D. The FDA Increased Warnings About Advair as GSK Studies Revealed Increased Risks.

170. In early 2003, GSK halted a clinical trial on the safety and efficacy of LABAs—the Salmeterol Multicenter Asthma Research Trial (or SMART study)—because a statistically significant number patients on LABAs died from asthma-related causes. As a result, the FDA added a "black-box" warning to Advair's label in 2003 that the data "showed a small but significant increase in asthma-related deaths in patients receiving [LABAs] . . . ." The boxed warning on the current version of the label states: "Long-acting beta2-adrenergic agonists (LABA), such as salmeterol, one of the active ingredients in ADVAIR DISKUS, increase the

risk of asthma-related death."

171. In November 2005, after analyzing the data from the terminated SMART study, the FDA issued an advisory warning against first-line use of LABA-containing products, such as Advair. The FDA stated:

> FDA is issuing this public health advisory to highlight recommendations about use of a LABA medicine for asthma: LABAs should not be the first medicine used to treat asthma. LABAs should be added to the asthma treatment plan only if other medicines do not control asthma, including the use of low-or-medium dose corticosteroids.

172. The FDA required revisions to Advair's label again in March 2006 to clarify the first-line restriction and further restrict first-line use to only severe asthma patients—those for whom a doctor determined ICS and SABA could not control asthma symptoms. The revised black box warning and Indications and Usage section of the label restricted first-line use of Advair to asthma patients whose "disease severity **clearly** warrants initiation with two maintenance therapies . . . ." (Emphasis added). The FDA also added to the Indication statement an "Important limitation of use" that "ADVAIR DISKUS is not indicated in patients whose asthma can be successfully managed by inhaled corticosteroids along with occasional use of inhaled, short-acting beta2-agonists." Accordingly, Advair was not approved for patients whose asthma could be controlled with medium or high dose ICS.

173. The day after the label revision, GSK noted internally that Dr. Badrul Chowdhury, Director of Pulmonary and Allergy Products at the FDA's Office of New Drugs, confirmed that the word "clearly" limited the first-line exception only to severe patients.

174. In February 2010, the FDA announced that it had conducted "a meta-analysis" of studies evaluating the use of LABAs which "suggested an increased risk for severe exacerbation of asthma symptoms in patients using LABAs compared to those not using LABAs." In June 2010, the FDA restated that "LABAs should only be used as additional therapy for patients with

asthma who are currently taking but are not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid."

175. Despite FDA's warnings, GSK downplayed Advair's safety risks to physicians both before and after the March 2006 label revision and promoted Advair with claims of superiority, safety and recommended use inconsistent with the safety risks and label revisions.

E. From the Launch of Advair, GSK Promoted Advair for First-line Use by Mild Patients Despite the FDA's Rejection of this Use.

176. Despite the FDA's restrictions, the lack of supporting clinical evidence and the fact that GSK told the FDA it would not promote for such use, GSK promoted Advair for first-line use in mild persistent and intermittent asthma patients from the time of Advair's product launch in April 2001.

177. GSK's product launch for Advair was a lavish event attended by thousands of sales representatives. The event was held in Las Vegas, Nevada, and attended and led by individuals at the highest levels of GSK management.

178. Advair's launch trained sales representatives to promote Advair for first-line use for all asthma patients, including mild persistent and mild intermittent asthma patients. The sales message was delivered by top GSK executives speaking to the sales force from the stage at the launch of Advair in Las Vegas, Nevada:

(a) Jim Daly, Advair's Product Manager, known as "Mr. Advair," presented the company's sales pitch to the entire sales force: "Advair is the complete, simple solution for persistent asthma. The proof - proof is everywhere. The proof is in the package insert. Our label is big, broad and beautiful. The proof is in the clinical data. We have superiority claims over virtually everything that physicians are prescribing today."

(b) Stan Hull, a Senior Vice President, rhetorically asked the Advair sales representatives: "The clinical data that supports Advair—you know you gotta just ask the simple question: What patient with asthma is not appropriate for Advair?"

(c) GSK President David Stout told the sales force: "You've got to make Advair the 1st choice, 1st line, for the treatment of asthma."

(d) GlaxoSmithKline plc's Chief Executive Officer J.P. Garnier instructed the entire Advair sales force that they could promote Advair as necessary for all asthma patients by purporting to quote a conversation he had with a doctor as follows: "[H]e said, and you can quote him everywhere you want in the [United States], 'He said it would be criminal not to put an asthmatic patient on Advair.' It would be criminal."

Exh. 28 (launch presentation DVDs) & 28A (selected portions of launch DVDs).

179. Thus, from the time of Advair's launch, GSK at the highest levels encouraged and caused GSK sales representatives to make false and misleading statements about Advair's indication and clinical support. GSK's "superiority claims" over other drugs, including ICS, were not only unfounded—they were specifically rejected by the FDA.

180. GSK provided large financial incentives to sales representatives to promote Advair for unapproved, off-label uses. GSK executives took to the stage in the Las Vegas product launch and, using images of a slot machine to illustrate the potential for the sales force to make money by selling Advair, outlined the bonuses available to sales representatives as follows:

(a) Daly: "There are people in this room who are going to make an ungodly sum of money selling Advair. . . . That's the way it should be. When GSK makes money you make money. The more you sell the more you make. God bless America."

(b) Stout: "But I know it takes a little bit more than just good luck a little hard work, you need what? Extra incentives! ... Let's spin the big [launch bonus] jackpot here. . . . [Jackpot spins on screen] $5 for every rep for every 100[/50 Advair] script. I think we can make some millionaires out there."

(c) Garnier: "What is the #1 reason why you should love to be a GSK sales rep? ... ADVAIR'S BONUS PLAN! Yeah!"

Exh. 28 & 28A (DVDs).

181. By spinning the jackpot wheel, Stout demonstrated GSK's lucrative launch bonus plan for Advair that, in addition to all other bonuses, would pay each sales representative $5 per prescription of Advair 100/50 written in their territory. Advair 100/50 was the lowest dose of

Advair, and GSK used this incentive to push its representatives to promote Advair for mild asthma patients.

F. High Level GSK Executives Implemented the Off-Label Promotion of Advair

182. The direction to target mild and newly diagnosed patients for first-line Advair use came from the highest level of the company and was reiterated by the company's senior management, including in presentations to investors.

183. For example, in a June 2002 presentation to investors, Stan Hull, GSK's Senior Vice President of United States Pharmaceuticals, explained:

> So, to summarize . . . we have cannibalized the majority of the Serevent and Flovent business and we are really dominating our efforts now into getting patients who are inadequately treated on short-acting beta-agonists onto Advair.

184. Hull went on to note that GSK was promoting for all patients on SABA, despite the physicians' reluctance. He asserted: "It's potentially a fatal mistake to manage a patient only with a short-acting beta agonist because of the perception that the disease is mild." To the contrary, the FDA had concluded that there were potential increased safety risks from putting mild patients who did not need the combination product on Advair.

185. In a presentation to investors in March 2004, Hull, accompanied by President of United States Pharmaceuticals Chris Viehbacher, was even more explicit about GSK's intent to pursue the mild asthma population for Advair, stating: "One of our strategies this year, or objectives, will be focusing on this category the mild asthmatic. . . . So our objective in simple terms this year is to persuade a physician to start their patients on Advair."

186. Hull admitted that many physicians do not agree with such an approach as medically appropriate. He stated: "the biggest objection we get back is, Advair is my medicine of choice for many patients who have moderate to severe asthma. However, not everybody needs Advair." Hull explains GSK's response, which is essentially that Advair is the best patient care

for all asthmatics, as reflected in the company's false and misleading marketing: "[I]f I am a physician I want my asthmatic patients to get the best care possible, so why would you . . . not be giving a patient with asthma Advair."

187. Hull even bragged to investors about GSK's success in promoting Advair for first-line use in the mild population to investors. He stated:

> You may ask yourself how we are doing in this mild segment. We started this overall approach in 2003 and we started with a share of about 18% and now we are approaching 34% in this segment, so we are seeing this initiative is working, not as fast as I would like it to, but definitely working.

188. In 2004, Viehbacher, in an investor presentation in London, England, with the Chairman of the Board of GlaxoSmithKline plc Sir Christopher Hogg present, emphasized that it was GSK's strategy to push Advair for all asthmatics. He stated: "The real opportunity for us with Advair is that we can now convince physicians that there is no such thing as mild or severe asthma: you have asthma, and you can achieve better control."

189. At the same meeting, Hull explained: "So with Advair we want to help physicians think simply: if the patient is asthmatic, what do I do? We want them to prescribe Advair 100/50 as their first choice for managing these patients."

190. In January 2006, GSK's CEO J.P. Garnier, told investors that the FDA warning about the safety of Advair should not affect GSK's stock price because it is "not meaningful and it is not going to have a big effect." He stated: "I think products such as Advair are phenomenal for the treatment of asthma, and they should be used for mild to moderate and severe asthmatics." Garnier also explained: "Physicians are not going to listen to the FDA."

191. These top executives drove the off-label strategies for Advair to keep Advair sales growing because Advair sales were critical to GSK's stock price and investor ratings. For example, when, in April 2003 Advair sales declined for just three weeks, David Stout, then Chief

Operating Officer of GlaxoSmithKline plc, sent an email to Viehbacher, President of U.S. Pharmaceuticals, asking "What is happening with Advair? . . . I think we better light a fire under the team . . . sooner rather than later."

192. In June 2004, when investment analysts noticed a decline in Advair's growth, they downgraded their rating of GSK stock. The analysts noted that GSK was seeking to grow Advair in the category of mild persistent asthma "despite the drug not being recommended in the guidelines for this level of disease severity." Exh. 33.

193. In response, GSK's Advair brand team was asked to prepare a response for GSK's senior management, including Garnier, Stout, Viehbacher, Hull, and set forth a plan to increase Advair's growth. Exh. 34. The response quoted the Deutsche Bank statement that "Strict adherence to the US guidelines would imply that Advair usage should be confined to patients with moderate and severe persistent asthma." The response also noted that much of the recent sales of Advair had been for patients who had neither asthma nor COPD. The GSK marketing team nonetheless stated: "We are confident that the changes that we have made to the selling [Plan of Action] and the promotional message will drive growth in Q3 and Q4. The changes include: . . . Focus on earlier use of Advair, specifically in patients who have uncontrolled asthma but are typically thought of as 'mild' by primary care physicians." Exh. 34.

**1. GSK's False and Misleading Promotion of Advair for First-Line Use.**

194. From 2000-2010, GSK promoted Advair for unapproved and non-medically accepted first-line use in asthma by making false and misleading statements about Advair's indication and the NIH Guidelines, as well as false claims that Advair was superior to other asthma drugs, including ICS, for first-line use.

195. From immediately following the Advair launch in April 2001, GSK inundated the market with its improper marketing messages, sending nearly 2,300 sales representatives to

70,000 physicians in the first five days alone. From the beginning, GSK's senior managers in the field also instructed the sales force to promote Advair for first-line use and all asthma patients, including mild asthma patients. For example, on or about March 2001, a GSK Regional Sales Director manager forwarded a message to train sales representatives with the leading line: "Doctor, three benefits of treating your mild asthma patients with Advair are: ..."

196. GSK aggressively pursued a national strategy to "Establish ADVAIR Diskus as the Physician's First Choice for the Treatment of ALL Persistent Asthma." GSK created and distributed to its sales force for sharing with physicians all around the country glossy sales aids that told physicians to "Prescribe Advair for your persistent asthma patients."

197. GSK's promotion of Advair for all asthma patients and all persistent asthma patients directly contradicted the NIH Guidelines and the FDA-approved label.

198. GSK's promotion of Advair as superior for first-line use was false and misleading because GSK did not inform health care providers that the FDA specifically rejected the company's sNDA for first-line use of Advair by mild persistent asthma patients. Nor did GSK disclose that the FDA had reviewed the data and analysis and concluded that the available evidence did not support Advair's safety and efficacy, let alone its superiority, for patients on SABA alone, including intermittent and mild persistent asthma patients.

199. The FDA specifically rejected the pivotal trial in GSK's sNDA application—study SAS30017—for failure to meet its protocol defined endpoints. GSK had submitted a modified statistical analysis for study SAS30017 to the FDA to claim statistical significance, but the FDA's explicitly concluded that the study failed to meet its protocol-defined endpoints and did not demonstrate superiority of Advair over ICS for asthma patients taking SABA alone. The FDA also noted certain safety signals from the study in this population. Exh. 35.

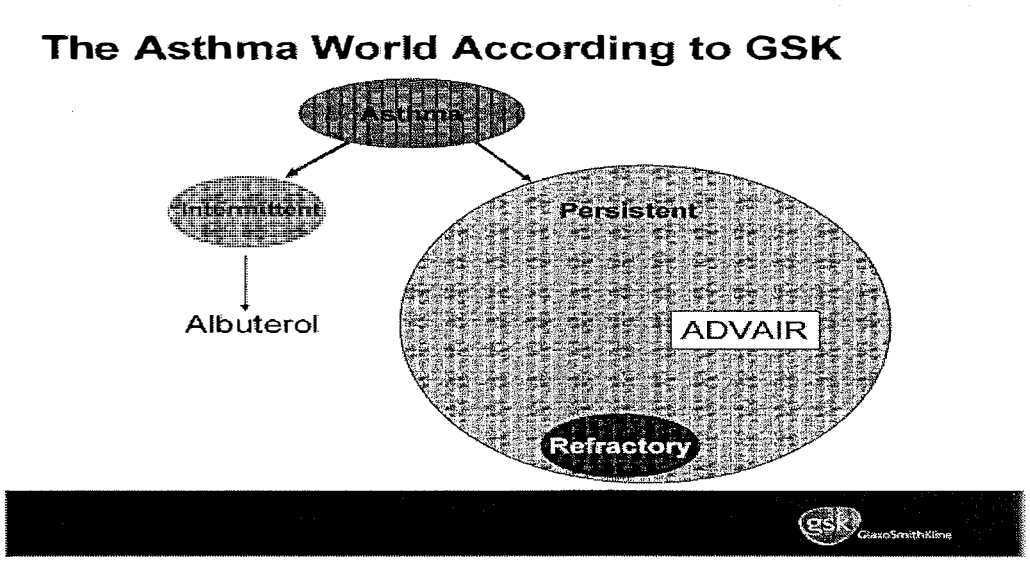
200. Without informing health care providers of the FDA's rejection of the sNDA or

study or the concerns raised by the FDA, GSK used SAS30017 to construct its core marketing messages that Advair "delivers superior symptom control" compared to ICS alone and that Advair provides "more symptom free-days" than ICS alone. GSK disseminated this false claim of superiority to ICS for patients previously on SABA alone in GSK's written marketing materials for Advair and in advertising campaigns for Advair, including in nationally broadcast pre-recorded teleconferences across the country.

201. Moreover, although the SAS30017 study was limited to moderate to severe patients, GSK used the study to claim superiority to ICS alone for all asthma patients uncontrolled on SABA alone. This claim directly contradicted the FDA's conclusions when it reviewed SAS30017. In addition, after the March 2006 FDA-required label change, this promotional claim directly contradicted the "Important Limitation of Use" in GSK's label for Advair, which stated that Advair should not be used for patients who could be adequately controlled on ICS alone.

202. GSK also misled prescribers with its "Myth of Mild" asthma campaign. GSK trained sales representatives to promote Advair based on the false assertion that mild asthma does not exist or that patients do not go to a doctor for "mild" asthma. GSK told physicians that all of their patients deserve the most effective asthma treatment, i.e., Advair. One GSK manager explained to her team that the portion of asthmatics with mild asthma was essentially non-existent or "infinitesimally small." The same regional manager signed communications to the regional sales team and outside physicians with the tag line "If it's asthma, its Advair."

203. GSK depicted its view of the asthma market as follows:




204. GSK sales representatives widely used the "myth of mild" arguments to convince physicians to treat their mild asthma patients as though they were moderate or severe, in contradiction of the NIH Guidelines' recommendations and the FDA-approved label.

**2. GSK Deliberately Sought to Convert ICS/Flovent Sales to Advair, Without Regard to Safety or Medical Appropriateness.**

205. GSK promoted Advair, the most expensive of its asthma products, even against Flovent—its own (cheaper) ICS product. Internal training documents refer to Flovent as the Advair sales representative's "#1 Competition." GSK also instructed portions of the sales force to promote Advair based on claims that the physicians could save time and earn more money by prescribing Advair and with the phrase "Advair is easy to use for all asthma patients." Exh. 29. Although Flovent/ICS was the medically appropriate medication for many asthma patients, GSK promoted Advair for these patients because it was more profitable. GSK internally stated that "Advair is now the engine that drives GSK."

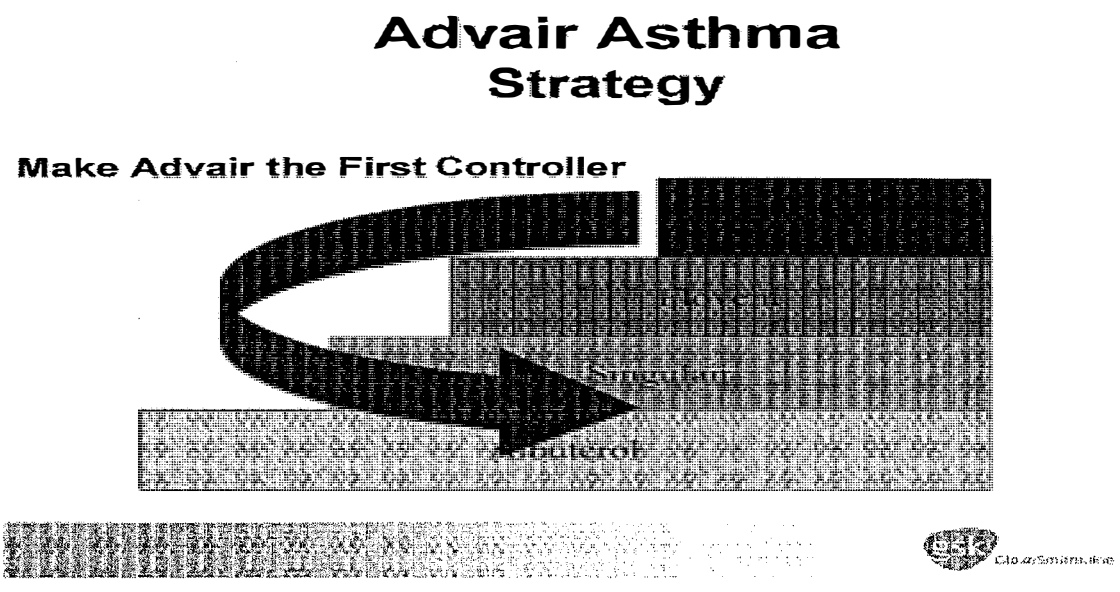
206. GSK emphasized to its sales force that a high percentage of patients stay on the drug that they are initially prescribed, and thus they needed to promote Advair for use earlier in the treatment paradigm. GSK instructed its sales force to "please remember to deliver the

message 'Make Advair the First Controller' on each and every sales call." Exhs. 30-32.

207. GSK national marketing managers also explained to the sales force that in order to realize the opportunity of Advair, they needed to "Realize that one opportunity is in patients new to asthma therapy," who had not even used SABA, and "Understand that getting your product on first is the most important thing to do." Thus, contrary to the general medical principle of treating patients with only as much medication as they need, GSK's sales force promoted non-medically necessary and off-label use of Advair for all asthma patients with false arguments of safety and efficacy. Exh. 31.

208. Thus, using the diagram below, GSK taught its sales teams "It is all about Getting ADVAIR on First!!!" and "Advair is superior to Flovent and Singulair." The selling line GSK gave the sales force was "Make Advair 100/50 your first choice for patients symptomatic on rescue medication" despite the lack of evidence for superiority in this group, the FDA's explicit rejection of such initial Advair use and the safety risk associated with Advair. Exh. 31.








209. As part of this effort, the GSK central marketing team also incorrectly informed the sales force that the SAS30017 study showed that Advair was superior to Flovent on every

efficacy measure for patients symptomatic on albuterol alone. Exhs. 31-32.

210. Throughout this time period, GSK heavily rewarded Advair sales in its sales force compensation, but did not reward Flovent sales, despite its medical appropriateness. For years, GSK refused to provide Flovent samples, despite complaints from doctors. Instead, GSK explained to physicians that the patients the physicians wanted to prescribe Flovent should be prescribed Advair—with one sales representative saying GSK could not "ethically" provide samples of Flovent.

### 3. From 2006-2010, GSK Continued to Misleadingly Promote Advair for First-Line Use Despite Additional Warnings and Restrictions by the FDA.

211. Despite the additional restrictions on first-line use in the Advair label placed in March 2006, GSK continued to promote Advair for first-line use by falsely claiming the NIH Guidelines supported such use and by using the FDA-rejected study SAS30017 to falsely claim that Advair was superior to ICS for first-line use.

212. One of GSK's anchor strategies for promoting Advair for inappropriate first-line use after the March 2006 label revisions was based on the number of SABA refills a patient filled. GSK promoted Advair for patients who refilled their SABA a certain number of times (two to four) in the last year. GSK did this by falsely claiming that these patients must be using their inhaler daily. GSK told physicians that these patients were therefore "Step 3" [moderate asthma] patients under the NIH Guidelines.

213. GSK then falsely told physicians that Advair was "preferred" or "a preferred" treatment for these patients under the NIH Guidelines, even though the 2007 NIH Guidelines did not recommend initiation of treatment with Advair for these patients GSK's promotion was therefore contrary to the first-line restriction in Advair's approved label to patients "whose disease severity clearly warrants" initiation with combination treatment and also contrary to the

Important Limitation of Use in Advair's label, which stated that Advair was not indicated if a patient could be controlled on ICS plus occasional SABA.

214. GSK's claim as to SABA refills reflecting a lack of controlled asthma was faulty for several reasons. First, it is common for patients to keep spare SABA canisters in multiple locations (e.g. home, work and car), and thus the use of several canisters does not necessarily reflect how often patients use the drug. Also, NIH Guidelines caution that "[b]efore increasing therapy . . . the clinician should review the patient's inhaler technique and adherence" because often patients who overuse albuterol are not using their inhaler properly.

215. GSK's false and misleading promotion of Advair was reflected by the sales representatives in their call notes including the following:

> "Advair appro. for ALL persistent asthmatics, inc. mild/start-ups." 07/26/2001 Doylestown, PA
>
> "Advair for all persistent asthmatics... mild moderate or severe." 05/16/2001 Kenosha, WA
>
> "Emphasized Advair not just for severe asthmatics but also mild intermittent." 10/31/2001 Milwaukee, WI
>
> "advair diskus for mild intermittent." 02/05/2002 Trenton, NJ
>
> "Discussed benefit of offering to all intermittent asthma patients." 03/26/2003 Oakdale, CA
>
> "...advair diskus for mild intermittent. . . ." 02/05/2002 Trenton, NJ
>
> "...ADVAIR GOALS OF THERAPY. ASKED FOR MILD PATIENTS AS INITIAL THERAPY" 03/27/2002 Fort Wayne, IN
>
> "...Advair first-line, even mild asthma, superior to singulair and FP alone..." 03/25/2002 Henrietta, TX
>
> "... Used NIH to close hard that there are NO mild asthma pts. Advair IS the solution." 03/04/2003 San Antonio, TX
>
> "...discussed stressing myth of mild asthma. If there in your office, never mild..." 03/04/2003 Garden City, MI

"…he laughed and said "you want me to use Advair for every patient?" I said yes, anyone that is "persistent" by nih criteria…" 03/06/2003 Alexandria, VA

"…She said that she had heard that the mild asthma cme program was a Advair advertisement…" 03/06/2003 Madera, CA

"Dr. says that she is going to start writing more Advair since she attended the Myths of Mild Asthma CME in Beverly Hills awhile back. Said the talk was excellent and Advair was spoken very highly of, which has influenced her to begin writing more of it." 03/12/2003 Torrance, CA

"Remind her of the new indication/usage of Advair 100/50 for her patients suffering from mild to severe cases of asthma." 06/24/2004 Long Beach, CA

"Asked docs to try Advair 1rst line rather than Flovent" 09/7/2004 Revere, MA

"…discussed no reason not to put pts on Advair more effective in reducing albuterol use and increase in symptom free days." 03/31/2005 Weston, FL

216. GSK's promotion convinced doctors that Advair was safer and more effective than it really was and thereby caused them to use Advair not only for non-medically accepted, off-label uses in asthma patients, but also for other off-label respiratory conditions, such as bronchitis, coughs, common colds and wheezing.

217. GSK also did not train its sales representatives to relay the contrary "important limitation of use" in Advair's label, which restricted Advair use by those who could not be controlled on ICS even with occasional use of SABAs.

218. In 2006, GSK, knowing that it was under federal investigation and that the government investigators were looking at call notes as a source of evidence, modified its call note system to use a drop-down menu of approved core messages and anticipated and desired responses from the physicians. Sometimes there was also a small space for additional comments. Nonetheless, even in this pre-scripted system, GSK included as one of its approved core messages that Advair delivered "more symptom free days" than other asthma products, including ICS, even though it had not proven such superiority for most patients. Furthermore, in the

section for desired physician responses, GSK listed the response "will use first line."

219. Following the implementation of this system, in thousands of call notes, GSK sales representatives reflected that they delivered the approved core message of "Advair Diskus delivers more symptom free days" and in many instances reflected that the physician gave the response agreeing to use Advair "first line." Below are a few examples of this pattern:

> "ADVAIR DISKUS ASTHMA: Approved Core Message(s) Delivered: Physician's Response: Will use first line uncontr mild persis." 06/5/2006 Boca Raton, FL

> "ADVAIR DISKUS ASTHMA: Approved Core Message(s) Delivered: ADVAIR DISKUS? delivers more symptom free days. Physician's Response: . . . Will use first line for persistent asthma." 06/13/2006 Schwenksville, PA

> "ADVAIR DISKUS ASTHMA: Approved Core Message(s) Delivered: ADVAIR DIKUS 100/50 delivers superior symptom control. Physician's Response: Challenge/issue for physician Guidelines + ICS 1st . . . Will use first line." 06/04/2007 Teleford, PA

> "ADVAIR DISKUS ASTHMA: Approved Core Message(s) Delivered: Advair Diskus 100/50 delivers superior symptom control. Physician's Response: Will use first line keep smoke pts on it." 06/20/2007 Orlando, FL

220. In 2009, the Executive Director of Advair Marketing emailed "innovative ideas" from a senior manager including once again recommending Advair for all patients: "[M]y favorite thing to say is 'Step 3 [for moderate asthma patients under the NIH guidelines] with ADVAIR is just a starting place'. Why wouldn't you give it to everyone. Guidelines are just that – guidelines. . . . I am just being honest with what works. You can't argue with our success."

G. GSK Made Additional False and Misleading Statements about Advair.

221. GSK also promoted Advair with other false and misleading claims, including:

(1) purporting to quote the NIH Guidelines' recommendation that physicians aggressively treat asthma to "gain control quickly" of symptoms, while ignoring—and omitting from quotes in printed materials—the second half of the sentence that states patients should be frequently reevaluated to see if they can be "stepped-down" to less medication;

(2) advising physicians that they should not step patients down from Advair because doing so could result in a loss of control over the patients' asthma, even though this advice is directly contrary to the NIH Guidelines and good medical practice;

(3) promoting Advair as a means to reduce steroid use, a claim rejected by the FDA in 2003. In just the last half of 2003, GSK budgeted over $5 million to train speakers and held thousands of "faculty led teleconferences" on topics including steroid sparing;

(4) promoting Advair to avoid "airway remodeling" in the lungs from asthma, despite a lack of substantial evidence or FDA approval for such a claim;

(5) promoting Advair with the unsubstantiated claim of "increased patient compliance" despite a lack of evidence or FDA approval for this claim;

(6) promoting Advair as more "cost-effective" despite a lack of evidence or approval for this claim, the fact that Advair cost nearly twice as much as ICS alone, the increased the risk of Advair-related exacerbations and death, and the fact that Advair was not approved or medically accepted for mild first line use;

(7) promoting Advair 500/50 ("Advair 500") for COPD patients, even though the FDA refused to approve Advair 500 for COPD, finding that it was not an approvable dose for safety and efficacy reasons. Studies showed that the COPD patients treated with Advair had a higher incidence of respiratory tract infections and pneumonia. COPD patients treated with Advair 500 also showed no documented benefit over those treated with the lower dose; and

(8) promoting Advair 500 for COPD and with misleading information regarding its efficacy. Even though the FDA denied the "mortality" claim and approval for the 500 dosage for COPD because Advair 500 continued to increase patients' risk of pneumonia, GSK nonetheless promoted Advair 500 for COPD patients.

222. To drive sales of Advair for COPD, GSK also engaged in an "only 1" campaign to promote Advair for COPD patients who had previously had only one exacerbation. In April 2008, the FDA approved Advair Diskus 250/50 for the reduction of exacerbations in patients with COPD with a history of exacerbations.

223. To support its "Only One" campaign, GSK made false and misleading statements about the American Thoracic Society Treatment Guidelines for COPD (the ATS Guidelines). The ATS Guidelines recommend an ICS/LABA combination for COPD patients with one prior exacerbation only if the patient also has a FEV (forced expiratory volume) of less than 50%,

which is categorized as severe COPD. GSK trained its representatives to omit this important requirement and instead state that ATS guidelines recommend Advair for COPD patients who had "only one" exacerbation, thereby promoting Advair for milder COPD patients, contrary to ATS guidelines. GSK gave sales representatives buttons to wear with the phrase "Only One."

224. Moreover, when a sales representative questioned this message as "not true," a GSK marketing manager nonetheless encouraged the use of the false message with primary care physicians who were unlikely to perform the FEV test. She thus acknowledged that GSK was promoting Advair for COPD to doctors who did not have the tools to diagnose COPD.

225. GSK continued to direct its sales force in sales training to deliver this false and misleading message to physicians through at least the spring of 2010.

H. GSK Made False and Misleading Statements to Medicaid Programs to Prevent Medically Appropriate Restrictions on Advair Reimbursement.

226. GSK presented false and misleading information directly to the Medicaid programs to block step edits and prior authorization requirements for Advair that would have restricted non-medically accepted off-label use—edits such as requiring a patient to try an ICS before a LABA-containing product, such as Advair, unless the physician diagnosed the patient as having moderate to severe asthma.

227. GSK made the false and misleading claims described above, including the statements regarding control, superiority to ICS, mortality, and albuterol refills, directly to Medicaid program representatives. GSK also made unfounded claims of Advair's cost-effectiveness compared to ICS, despite the fact that Advair is much more expensive than ICS.

228. GSK also tied the payment of state supplemental rebates and discounts to Medicare Part D drug plans to agreements by Medicaid programs and insurance plans not to "disadvantage" Advair with prior authorizations, step edits or requirements that patients first fail

to be treated sufficiently by other drugs. As a general matter, GSK paid certain supplemental rebates on its products only if Medicaid agreed not to place restrictions on its products. Here, however, the proposed restrictions would have only brought recommended usage in line with the FDA-approved indication and NIH Guidelines. Thus, GSK used its rebate payments to encourage off-label use of Advair by penalizing efforts to limit Advair's use for Medicaid patients to patients for whom it is indicated in its label.

229. GSK's State Government Affairs group closely monitored and attempted to defeat state efforts to restrict off-label use, including step edits, in order to pursue its promotion of unapproved first-line use and to ensure Medicaid programs paid for these uses. For example, in 2006, Arkansas Medicaid restricted first-line Advair use consistent with the March 2006 label. Arkansas Medicaid determined that this restriction increased appropriate use of Advair and decreased Advair utilization by 25% without adverse impact on patient care.

230. GSK internally called Arkansas' efforts to promote appropriate use of Advair as an "infestation" and fought to remove Arkansas' step-edit because "these people [the state Medicaid employees] talk" to each other. GSK internal documents stated: "We are facing a Medicaid step edit in Arkansas. All levels of GSK are involved including [Senior Vice President] Stan Hull." In 2008, it appears that GSK provided campaign donations to an Arkansas legislator who introduced a bill to remove the step edit. One GSK employee wrote to Stan Hull regarding GSK's Arkansas strategy: "Thanks for your time today and 'God save political donations'." Exh. 36.

231. GSK viewed such restrictions on Advair as "not acceptable" from a business perspective even though they encouraged more appropriate use of Advair and only would have restricted unapproved uses of Advair. GSK implemented a "hold the line" strategy to prevent other states from adopting step edits like Arkansas'. For example, Hull flew directly to an Ohio

Medicaid meeting in an attempt to defeat a proposed step edit that was entirely consistent with appropriate Advair use. GSK falsely argued that Advair "help[ed] the State avoid costs associated with asthma visits to emergency rooms across the State by Medicaid's asthmatic patients." GSK's proposed alternative step edit (for any patient who had been prescribed a SABA in the past year) was inconsistent with the FDA-approved label and recommendations of the NIH Guidelines. Even though Ohio implemented its step edit, reducing off-label use of Advair, GSK nominated the team that fought the step edit for a "Spirit Award" for delaying the implementation of the step-edit by three months. Exh. 37.

I. GSK's False and Misleading Marketing Caused Massive Overutilization of Advair.

232. GSK's promotion of Advair was both fraudulent and effective.

233. Numerous studies have confirmed Advair's overutilization. Some studies have shown that 50-90% of Advair asthma use is not justified by patients' medical history based on national treatment guidelines and the Advair label.

234. GSK's claims that Advair is more cost-effective than other medications were not only unapproved or unproven — they appear to be false. A 2010 Medco Health Solutions study of initial maintenance therapies for asthma "found that the group on a combination ICS/LABA had asthma-related pharmacy costs that were $215 more per patient per year than the ICS monotherapy group." The study also states: "These findings confirm that ICS/LABA combination use is prevalent in mild asthma patients and is associated with increased asthma-related pharmacy and total healthcare costs with no observed clinical benefit."

235. A 2010 meta-analysis of studies on initial maintenance therapy by the Cochrane Collaboration also found that such first-line use of Advair is not justified from a safety or efficacy perspective: "In patients with asthma who require daily anti-inflammatory therapy, there is insufficient evidence to support initiating therapy with a combination of inhaled

corticosteroids (ICS) and long-acting ß2-agonist (LABA) rather than with inhaled corticosteroids alone." The analysis showed that "the combination of ICS and LABA does not significantly reduce the risk of patients with exacerbations requiring rescue oral corticosteroids over that achieved with a similar dose of ICS alone."

## VI. GSK PAID KICKBACKS TO PHYSICIANS AND OTHERS TO INDUCE THEM TO PRESCRIBE AND RECOMMEND GSK DRUGS

236. In order to induce physicians to prescribe and recommend its drugs, GSK paid kickbacks to health care professionals in various forms, including speaking or consulting fees, travel, entertainment, gifts, grants, and sham advisory boards, trainings and continuing medical education (CME) programs. These payments induced physicians to prescribe GSK's products, including specifically Paxil, Wellbutrin and Advair, for both on and off-label uses. GSK provided budgets to the sales teams to entertain and pay physicians to induce them to prescribe and promote GSK's drugs. The allocation of "customer focus funds" for each sales district ranged from $600,000 in 2002 to $300,000 in 2008. Of these funds, each GSK sales representatives received between $15,000 to $30,000 per year to spend on speaker programs, including breakfasts and lunches at physician offices. In a New England regional marketing plan, GSK instructed its sales force on how to use entertainment as follows:

> Extra entertainment is highly recommended to reach as many ADVAIR targets as possible. Any form of entertainment should be utilized (in accordance with the AMA guidelines) and a speaker is not required. (Lunches, Clinic Round Tables and Speaker Programs are not considered extra entertainment. Extra entertainment is defined as taking a customer to dinner or a venue after business hours E.G. attending the Circuit with a large ADVAIR target). This type of activity will help you increase your business and total number of scripts for the national incentive program. [picture of dollars] On a regional basis any representative that does more than 2 entertainment programs in one week will receive a $100 American Express Gift Cheque from their manager. We will track these programs in the regional score card.

237. In some instances, GSK required sales representatives to track prescribing of

attendees after the entertainment events in order to demonstrate return on investment ("ROI") from the event. For example, the Northeast region purchased tickets to Fleet Center events such as Celtics and Bruins games at a cost of approximately $350 per premium seat. The managers instructed the representatives that "[f]or ROI it's imperative only KEY Customers attend these valuable venues," and required the representatives to complete a prescription tracking form four months after the event "to ensure ROI and continued funding . . . ." Exhs. 38-39.

238. For each drug, GSK also created a group of national "key opinion leaders" ("KOLs") who were paid generous consulting fees. GSK selected many of these physicians based on their prescribing habits and influence within the community and used the speaker fees paid to these physicians to induce and reward prescribing of GSK's products. GSK used these individuals to communicate marketing messages focused on the drugs' marketing campaigns at the time, including off-label uses. Some physicians on GSK's speaker's board have been paid more than a million dollars for speaking on behalf of the company and recommending its drugs.

239. GSK's sales representatives reflected in their call notes their use of money, gifts, entertainment and other kickbacks to induce doctors to prescribe GSK drugs, including:

> "invited to sib at clearwater will come doc very into QUID PRO QUO wants to be taken care of for his business. said not into food but likes sports and programs even into li ducks baseball. using wb sr for add on mostly not 1 line use said that will come as relationship grows" *2/20/01 Central Islip, NY*
>
> "I took him to a Cardinals ball game. We had a great time. He is a Cub fan and his wife is a Cards fan. The Cards won but he still had a great time. He is detail sensitive but I did what I could, When I asked for the business he laughed. I didnt really see the humor in it. How could he think I wouldn't ask for the business when I've treated his family to a day at the ball park. Oh well. I'll see what else I can do to try to influence him." *9/17/00 Decatur, IL*
>
> "Tkts to Crosby Still Nash. Asked for business in return..." *3/30/00 Oakland Gardens, NY*
>
> "...told him no gol[f] unless we se more scripts for sr I need to see a better roi from him he agreed..." *4/7/00 Mansfield, OH*

"took him to lunch and golf lesson…gained commitment to increase his use. will do this every three weeks, great ROI, very cheap." *5/9/01 Quinton, VA*

*One doctor in Rockledge, Florida during 2000 and 2001:*

"gave dr. his Nascar tickets…I will be going back at dr. for a return on investment"

"followed up from sending dr. to the race, he was very appreciative, I asked that he thank me w/ wsr scripts…"

"promised to use more wsr since we sent him to the races…"

"told him he's going to the pepsi 400 on WSR…asked him to rx w/ both hands…"

"attended Rockies game. asked him to prefer GSK products in return, said he will." *4/10/01 Aurora, CO*

"…will attend knicks-nets game. asked him to help us out in return" *2/4/02 North Bergen, NJ*

". . . Came out and asked me if I would still be interested in taking him fishing w/Dr. Fazal, Kahn, etc. . . HOW BOUT WRITING SOME SCRIPTS AND WE'LL GO FISHING ALL YOU WANT." *8/10/01 Escanaba, MI*

"discussed fishing when the $ comes back – asked for the business point blank" *7/10/01 Clearwater, FL*

"…He said he has been writing tons of SR with good results. He isn't kidding. His new scripts are almost 20%. That's almost 3000. That's a big change. . . . I have spent a lot of money on him and it has paid off." *5/3/01 Decatur, IL*

"Great call with Dr. J He enjoyed the pheasant hunt and would like to go again also he likes to fish leverage imitrex wellbutrin and valtrex business to get him to write more to go on our activity program trips he will help us" *3/8/01 Dothan, AL*

"Dr.[ ] now has a 15.5% MS for WBSR. I guess the tennis lessons helped." *1/28/02 Glen Cove, NY*

"Need to get his mkt shr up, all he wants to talk about is money and where we can send him. Asked to him to use more wsr." *5/15/02 Shreveport, LA*

"he wants to go to dinner programs and out of town meeting if can. he really can be bought. said he is using more well 100 in the peds which is mainly what he sees. didn't need any samples" *2/28/01 Knoxville, TN*

"always wants money. was giving wsr to a patient when I walked in..showed me the script." *2/12/02 Fort Walton Beach, FL*

"Asked me about any upcoming programs--he said he could take care of us if we take care of him. wants to go somewhere for advisory boards or something like that)" *6/4/03 Gonzales, Louisiana*

"Wanted WXL for herself. Told her that I need scripts and switches in return." *12/10/03 Fort Pierce, Florida*

A. GSK Promoted Off-Label Uses Through "Special Issue Boards" Which Paid High-Prescribing Physicians To Listen To Improper Promotional Claims

240. During 2000 and 2001 at least, GSK also utilized events termed "advisory boards" or consultant meetings and forums to disseminate its promotional messages. Although these boards were purportedly comprised of "thought leaders" for the purpose of obtaining advice from the physician, in fact, the "advisory" boards were little more than promotional events coupled with financial inducements to prescribing and influential physicians.

241. GSK invited and paid high-prescribing physicians at these events to listen to off-label promotion and/or to influence their prescribing practices. GSK held hundreds of "Special Issue Boards" or "SIBS" across the country. Indeed, in the first six months of 2001, for example, GSK held twenty WBSR "advisory" boards in and around the Philadelphia area alone.

242. GSK typically paid the physician between $250 and $750 each to attend a local "advisory" meeting. The payments did not reflect the value of services. The physician was not required to do anything but show up. GSK had no legitimate business reason to hire thousands of "advisors" to "consult" with the company about a single drug. GSK used these events as a reward or kickback to induce the attendees to prescribe and recommend GSK drugs.

243. The "advisory" meetings were often conducted over dinner at top local restaurants or hotels or in weekend retreats. At a typical "advisory board" meeting, physicians would listen to presentations about GSK's drugs, including their off-label uses. The "advisory" board

speakers—Drs. Pradko, Hudziak, Green and others—were often paid $2,000 to $3,000 to moderate the events with their standard presentation.

244. GSK records before and after such advisory boards demonstrate the plan to use these and other entertainment to influence the physicians, rather than to gain advice. For example, the following are comments of the sales representatives about the attendees of a Special Issue Board held on July 14, 2001 in Philadelphia moderated by Dr. James Hudziak.

As to one doctor in the Philadelphia area:

- "Flyers game. Will carbon every well sr script to prove to me how much he is using. Said he will now have to start writing more..." *02/27/2001*
- "Admits to using a lot of samples for some indigent patients, or until they patients receive script in mail. I still am curious as to where all well sr rxs are going because we are not seeing them." *05/02/2001*
- "well sr-he attended dr hudziak prog. He wrote 92 well sr scripts . . . " *07/20/2001*

As to another doctor in Philadelphia, PA:

- "...uses it in combo and first line, for ADD, etc...has heard Hudziak speak at SIB...invited him to RAB [Regional Advisory Board] but need to confirm that there is no conflict due to the fact that he's heard Hudziak before...is only interested in attending programs where he gets paid . . geee, go figure!" *06/28/2001*
- "quick stop in to let dr know he is confirmed for RAB . . . no conflict w/ his prior participation at SIB" *06/29/2001*
- "gaining good access to dr's...talked about prior auth . . . annot make dave s program. maybe next yr if we do one." *11/21/2001*

245. GSK representatives around the country also reflected in their call notes their use of sham consulting arrangements like SIBs to promote their products, including:

"Had good discussion with Dr. [ ] on all products. Wants to plan a fishing trip...Dr. [ ] will research places and costs, and we'll do it as a program or sib." *5/30/01 Spencer, IN*

"...He certainly doesn't like to be talked to about products. I need to be more

sneaky. Such as the SIBS program." *1/30/01 Bend, OR*

"loved the sib. leaned a lot of new info about migraine and exercise. told me he wrote two new imitrex scripts this week. It is all about the one hand washes the other with this guy. I am totally fine with this because that is why we have a budget!!..." *3/16/01 Danville, IN*

"She has received her honorarium for the Pride program and she said she has used a lot of WSR recently. uses it as add on and also in obese pts. Said SIB changed her rx habits...." *12/4/01 Saxonburg, PA*

"Gave him his SIB check. He said I made his day. I requested him to make my days by giving me just 10% more pf his Imitrex & Wellburtin prescriptions." *11/16/01 Huntington, NY*

"Spoke at SIB. did a fantastic job. Should see big ROI" *2/15/01 Hackensack, NJ*

246. Not all doctors, however, were susceptible to this tactic. One representative bemoaned: "he is killing me, wont come to SIB, thinks of it as a bribe." *4/16/01 Alton, IL*

B. GSK Paid Kickbacks Through CME and Other Sham Trainings

247. GSK also used so-called CME and CME Express programs and other sham trainings for marketing purposes, and to promote off-label uses for the GSK prescription drugs.

248. For example, in or about 2000 and 2001, GSK used "Reprint Mastery Training Programs" or "RMTS" to further promote its drugs by purporting to pay physicians to train sales representatives on clinical reprints. To do an RMT, a GSK representative set up "training sessions" with physicians to review reprints of studies. Although the training was purportedly for the representatives, in fact, the sales force was already familiar with the materials. GSK typically paid physicians $250 to $500 to review the reprints.

249. GSK representatives used these presentations to pay the physicians to review off-label articles. For example, in the case of WBSR, reprint training covered such materials as the Gadde weight loss study and a study of WBSR to treat sexual dysfunction.

250. Sales representatives also touted their use of these reprint programs to disseminate

off-label information and induce doctors to prescribe, with comments such as:

> "both sib and rmt has increased his scripts, uses wellsr much more and anxiety is not a concern..." *7/17/01 Union, NJ*
>
> "RMT with doc – went over ADHD and weight loss data." *8/27/01 Metuchen, NJ*
>
> "Confirmation of wellsr rmt check, planted seed with Madonna tickets that he is probably getting 2, therefore needed more support" *7/16/01 Iselin, NJ*
>
> "reinforced everything we had done for him and we need his business now" *2/23/01*
>
> "gave him reprint check told him we need a good roi for our efforts and need him to write our products exclusively agreed and said he would" 3/9/01 *Orrville, OH*

251. These CME programs purported to be independent education free of company influence, but in fact functioned as GSK promotional programs disguised as medical education. GSK maintained control and influence over the purportedly independent CME programs through speaker selection, and influence over content and audience, among other things. Although third party vendors were usually also involved, they served only as artificial "firewalls" that did not insulate the program from GSK's influence.

252. GSK also used the "speaker" payments for CME programs to reward physician loyalty and induce increased prescriptions. Physicians trained at GSK "speaker training" programs often doubled as CME presenters, giving substantially the same presentation as they did for the GSK speaking events. For example, Dr. Pradko's standard lecture at GSK sponsored talks was essentially the same presentation that he made at GSK-funded CME programs.

253. In or about 2001, GSK initiated a "CME Express" program, funded by GSK's Marketing Department, which offered CME credits for attendance at GSK-sponsored events. CME Express was not independent of GSK's influence. The content was often reviewed and approved by GSK representatives. GSK sales representatives selected the speaker, chose the

date and venue, and targeted potential attendees for invitation.

254. GSK used CME Express honoraria as a way to reward physicians and to induce prescriptions. For example, a GSK representative noted that he would "work on setting [a doctor in Knoxville] up to speak for us possibly as CME express speaker on roundtable presentation to his own group over lunch. $'s may be the way to his business." Another representative noted about a doctor in Maryville, Tennessee: "he wants money in his pocket. scheduled lunch. [] see if he wants to do a wellbutrin cme express for his office."

## VII. THE FEDERAL HEALTH CARE PROGRAMS

### A. The Medicaid Program

255. The Medicaid program is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a state Medicaid program and receives funding from the federal government, known as federal financial participation, based upon a formula set forth in the federal Medicaid statute.

256. Before the beginning of each quarter, each state submits to CMS an estimate of its Medicaid funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding the state will be permitted to draw down as the state actually incurs expenditures during the quarter (for example, as provider claims are presented for payment). After the end of each quarter, the state submits to CMS a final expenditure report, which provides the basis for adjustment to quarterly federal funding.

257. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a. It also requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396b, 1396a(a)(13), 1396a(a)(30)(A).

258. While federal drug coverage is an optional benefit available to the states, most

states provide coverage for prescription drugs that meet the definition of a covered outpatient drug, which is defined in the federal Medicaid Rebate Statute, 42 U.S.C. § 1396r-8(k)(2).

259. The Medicaid Rebate Statute generally prohibits federal payment for a covered outpatient drug unless the manufacturer enters into a rebate agreement with HHS. Once a manufacturer has entered into a drug rebate agreement, a state is generally required to cover the covered outpatient drugs of that manufacturer under the state plan unless "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i).

260. With certain limited exceptions not pertinent here, a prescription drug cannot be distributed legally in interstate commerce without first being approved by the FDA as safe and effective for a particular use. To gain FDA approval for a particular use, data from adequate and well-controlled clinical studies must demonstrate that the drug is safe and effective for the proposed use. As part of the approval process, the FDA also must approve the drug's labeling, which sets forth detailed information about the drug, including the approved conditions of use, dosages, and patient population(s). The drug's manufacturer cannot lawfully distribute or cause the distribution in interstate commerce of a drug that it intends to be used for an unapproved purpose or in a manner inconsistent with the drug's approved labeling, and cannot make or cause to be made false or misleading claims about the drug.

261. The Medicaid Rebate Statute defines "medically accepted indication" as any FDA approved use or a use that is "supported by one or more citations included or approved for inclusion in any of the compendia" set forth in the statute (i.e., Drugdex, American Hospital Formulary Service, and U.S. Pharmacopeia-Drug Information). 42 U.S.C. § 1396r-8(k)(6).

262. Thus, even if a drug is FDA-approved, Medicaid ordinarily does not cover off-label uses of the drug that are not supported by one or more citations included or approved for inclusion in the specified compendia.

263. The Federal Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS") prohibits any person or entity from offering, making, or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made in whole or in part by a federal health care program.

264. Medicaid does not cover claims for services or products where there has been a kickback relating to the underlying transaction. Any provider who submits claims to Medicaid must sign a provider agreement with each Medicaid program to which it submits claims. Massachusetts regulations, for example, provide that: "All pharmacies participating in MassHealth must comply with the regulations governing MassHealth, including but not limited to MassHealth regulations set forth in 130 CMR 406.000 and 450.000." The Massachusetts regulation at 130 CMR 450.261 provides: "All members and providers must comply with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, specifically including but not limited to 42 U.S.C. 1320a-7b [the federal anti-kickback statute]."

B. The Medicare Program

265. The Medicare program pays for the costs of certain healthcare services and items for eligible beneficiaries based on age, disability or affliction with end-stage renal disease. Generally, no payments may be made under Medicare for expenses incurred for items and services that are not "reasonable and necessary" for the diagnosis and treatment of an illness. 42 U.S.C. § 1395y(a)(1)(A).

266. In 2003, Congress amended the relevant statutes to create Medicare Part D, which provides additional optional drug coverage for Medicare beneficiaries. Under the Part D benefit, a "covered part D drug" means, in relevant part a drug that is approved by the FDA and is used for a "medically accepted indication." 42 U.S.C. § 1395w-102(d)(1) & (e)(4)(A)(ii) (citing 42 U.S.C. § 1396r-8(k)(6)). A medically accepted indication is defined as any use which is FDA-

approved or which is supported by one or more citations included or approved for inclusion in one of three specified drug compendia. Generally, Part D coverage is provided by sponsors who contract with CMS to provide such coverage and are responsible for making coverage determinations in accordance with the statutes and regulations.

267. Medicare does not cover claims for drugs and/or physician services where there is a kickback involved in the underlying transaction. Claims submitted to federal health care programs where a kickback paid or accepted relating to the transaction are false under the FCA.

268. Providers that seek to bill Medicare must sign a Provider Agreement that states:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me] . . . . I understand that payment of a claim by Medicare is conditioned upon the claims and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

C. GSK's False, Misleading and Illegal Marketing Caused the Submission of False and Fraudulent Claims to Federal Health Care Programs

269. GSK's promotion of its drugs described above was both fraudulent and effective, utilizing false and misleading statements and claims and kickbacks to cause doctors to prescribe GSK's drugs and federal health care programs to pay millions of dollars in false and fraudulent claims. Exhibit 39 is a sample of the claims submitted to federal health care programs for reimbursement of Paxil for patients under 18. Exhibit 40 is a sample of claims for WBSR for patients under 18 and for other off-label and non-medically accepted uses. Exhibit 41 is a sample of the claims submitted to federal health care programs for reimbursement of Advair for asthma patients who did not have a demonstrated need for Advair. These patients had no claims for an ICS in the past year, no diagnosis code for COPD and no markers of moderate to severe asthma i.e. no asthma-related hospital or ER visits in the previous month and either A) only 1 or 2 claims for SABA in the past year or B) no prior asthma medications in the past year. Exhibit

42 is a sample of claims submitted to federal health care programs for reimbursement of Advair for patients who did not even have a diagnosis of asthma or COPD. Through the false and misleading marketing schemes and kickbacks detailed herein, GSK caused these drugs to be prescribed for these uses.

270. Through payment of kickbacks described above to prescribers of WBSR, Advair and Paxil, GSK also caused the claims to federal health care programs for reimbursement of the GSK drugs subsequently written by those prescribers and for the prescribers' services connected with the selection of the GSK drugs to be false and fraudulent claims.

**COUNT I: FALSE CLAIMS ACT (PRESENTMENT OF FALSE CLAIMS)**

271. The United States hereby incorporates by reference the documents and exhibits attached, recited or referenced in the Relators' Complaints in these four consolidated matters.

272. The United States realleges the preceding paragraphs as if fully set forth herein.

273. GSK's false and fraudulent statements, including with respect to the safety and efficacy, superiority, and medical necessity and appropriateness of its drugs, to the public, to patients, to physicians and directly to Medicaid and other federal health care programs, were material to the physician's decisions to prescribe these drugs and the United States' decision to pay claims for these drugs and related services.

274. GSK knowingly caused to be presented false or fraudulent claims for payment or approval to the United States in violation of 31 U.S.C. § 3729(a)(1)(A), including

(a) claims for drugs caused by GSK's illegal promotion of its products as set forth above, samples of which are set forth in Exhs. 40-43; and

(b) claims for physician services by physicians who had received the improper inducements from GSK alleged above.

275. By virtue of the false or fraudulent claims that GSK caused to be made, the United States suffered damages in an amount to be determined at trial.

## COUNT II: FALSE CLAIMS ACT (FALSE STATEMENTS)

276. The United States realleges the preceding paragraphs as if fully set forth herein.

277. As set forth above, GSK knowingly made and caused to be made or used false and/or fraudulent statements or records material to false and/or fraudulent claims and/or to get these claims paid or approved by the United States, in violation of 31 U.S.C. § 3729(a)(1)(B) and former 31 U.S.C. § 3729(a)(2)[1], including

(a) claims for drugs caused by GSK's illegal promotion of its products as set forth above, samples of which are set forth in Exhs. 40-43;

(b) claims for physician services by physicians who had received the improper inducements from GSK alleged above.

278. By reason of these payments, the United States has been damaged in an amount to be determined at trial.

## COUNT III: UNJUST ENRICHMENT/DISGORGEMENT

279. The United States realleges the preceding paragraphs as if fully set forth herein.

280. As a consequence of the acts set forth above, GSK was unjustly enriched and received illegal profits. The United States conferred benefits upon GSK, GSK knew of and appreciated these benefits, and GSK's retention of these benefits under the circumstances would be unjust as a result of its conduct.

281. The United States therefore claims the recovery of all monies by which GSK has been unjustly enriched and has illegally profited, in an amount to be determined, which in equity

---

1 The Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21, 123 Stat. 1617 (May 20, 2009), modified and renumbered the subsections of 31 U.S.C. § 3729(a) of the False Claims Act, "to reflect the original intent of the law." Id. § 4, 123 Stat. 1621. Among other things, FERA modified former section 3729(a)(2) to impose civil liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Id. (recodifying section 3729(a)(2) as 3729(a)(1)(B)). Although FERA generally applies only to conduct occurring on or after the date of its enactment, Congress specified that Section 3729(a)(1)(B) "shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act. . . that are pending on or after that date." 123 Stat. 1625.

should be paid to the United States.

## PRAYER FOR RELIEF

WHEREFORE, the United States seeks against GSK the following:

1. On Counts One and Two under the False Claims Act, the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On Count Three for unjust enrichment/disgorgement, the damages sustained and/or amounts by which GSK was unjustly enriched or obtained illegally, plus interest, costs, and expenses, and all such further relief as may be just and proper.

## DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

TONY WEST
ASSISTANT ATTORNEY GENERAL

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

Dated: October 26, 2011 By: 

SARA MIRON BLOOM
Assistant United States Attorney
United States Attorney's Office
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3366

JOYCE R. BRANDA
JAMIE ANN YAVELBERG
ANDY J. MAO
DOUGLAS J. ROSENTHAL
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
(202) 616-0539

## 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."

D. The United States alleges that GSK caused claims for payment for the Covered Drugs to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk ("Medicare"); the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C.§§ 1396-1396w-5 ("Medicaid"); 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, et. seq.; and caused purchases of the Covered Drugs by the Veterans Affairs Program, 38 U.S.C. § 1701-1743 (collectively, the "Government Health Care Programs").

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-7b(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. §§ 1395-1395kkk 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 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: (i) retain an independent 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 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**

**CARMEN M. ORTIZ**
United States Attorney

By: Susan Winkler
SUSAN G. WINKLER
SHANNON T. KELLEY
BRIAN PEREZ-DAPLE
Assistant United States Attorneys
District of Massachusetts

Dated: 7/2/2012

STUART F. DELERY
Acting Assistant Attorney General

By: _____
JOYCE R. BRANDA
JAMIE ANN YAVELBERG
CHARLES J. BIRO
NATALIE A. PRIDDY
Attorneys
Commercial Litigation Branch, Civil Division
United States Department of Justice

Dated: 7/2/2012

By: _____
JILL FURMAN
MARK L. JOSEPHS
TIMOTHY T. FINLEY
Attorneys
Consumer Protection Branch, Civil Division
United States Department of Justice

Dated:

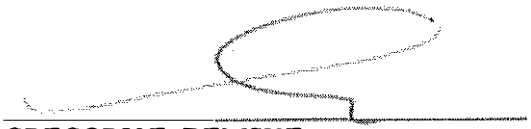
STUART F. DELERY
Acting Assistant Attorney General

By: _____
JOYCE R. BRANDA
JAMIE ANN YAVELBERG
CHARLES J. BIRO
NATALIE A. PRIDDY
Attorneys
Commercial Litigation Branch, Civil Division
United States Department of Justice

Dated:

By: 
JILL FURMAN
MARK L. JOSEPHS
TIMOTHY T. FINLEY
Attorneys
Consumer Protection Branch, Civil Division
United States Department of Justice

Dated: 7/2/2012

By: 

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

Dated: 6/22/12

By: 

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

Dated: 6/26/12

By: Shirley R. Patterson

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

Dated: 6/22/12

By: J. David Cope by Timothy C. Watkins Counsel to the Inspector General By Direction

J. DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

Dated: 6/26/12

**GLAXOSMITHKLINE LLC**

By: _____ Dated: 6-28-12

ELPIDIO VILLARREAL
Senior Vice President, Global Litigation
GlaxoSmithKline LLC

By: _____ Dated: 6.28.12

NINA M. GUSSACK
SEAN P. FAHEY
Pepper Hamilton LLP
3000 Two Logan Square
18th & Arch Streets
Philadelphia, PA 19103-2799
(215) 981-4000
Counsel to GlaxoSmithKline LLC

By: _____ Dated: 6/28/12

GEOFFREY HOBART
MATTHEW O'CONNOR
Covington & Burling LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2401
(202) 662-6000
Counsel to GlaxoSmithKline LLC