U.S. Department of Justice

Carmen M. Ortiz
United States Attorney
District of Massachusetts

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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
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Jill Furman
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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 annual 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.