



**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*

October 21, 2010

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

Re: United States v. GlaxoSmithKline LLC

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, SB Pharmco Puerto Rico, Inc. ("SB Pharmco"), a copy of which plea agreement is attached hereto as Exhibit One, and in exchange for certain other promises made herein between and among the United States and your client, GlaxoSmithKline LLC (GlaxoSmithKline LLC, its parent, GlaxoSmithKline plc, their direct and indirect subsidiaries and their successors will be referred to as "GlaxoSmithKline"), the United States and GlaxoSmithKline hereby agree as follows:

1. No Criminal Prosecution of GlaxoSmithKline

The United States hereby declines prosecution of GlaxoSmithKline LLC, GlaxoSmithKline plc or any of their direct or indirect subsidiaries (other than SB Pharmco as set forth in the Information) for conduct by or attributable to GlaxoSmithKline or any of its subsidiaries that:

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

October 21, 2010

Page 2

(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 Office of Consumer Litigation of the Department of Justice prior to the date of this agreement, relating to:

- (i) the production, manufacturing, processing, packing, and/or holding of drugs at SB Pharmco's Cidra, Puerto Rico manufacturing facility between the years 2001 and 2005; or
- (ii) conduct, communications and reporting regarding the Food and Drug Administration's oversight, regulatory inspections and actions regarding the Cidra, Puerto Rico manufacturing facility between the years 2001 and 2005.

The United States does not decline criminal prosecution of GlaxoSmithKline or any of GlaxoSmithKline's related entities for any other conduct beyond that set forth above. Without limitation, for the drugs manufactured at Cidra, this release expressly does not extend to any conduct relating to post-marketing studies or analyses; marketing or promotion; or conduct, communications and/or reporting to the FDA or physicians or customers regarding the safety, efficacy, and/or recommended uses of the drugs concerning issues other than manufacturing, processing, packing and/or holding of the drugs at Cidra.

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 is dependent upon and subject to SB Pharmco fulfilling its material obligations in the Plea Agreement and GlaxoSmithKline fulfilling its material obligations both herein and in the related Civil Settlement Agreement attached hereto as Exhibit Two. If SB Pharmco does not fulfill its material obligations in the Plea Agreement and/or GlaxoSmithKline does not fulfill its material obligations both herein and in the related Civil Settlement Agreement, GlaxoSmithKline 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. Cooperation of GlaxoSmithKline

GlaxoSmithKline shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing civil, criminal or administrative investigation of its current and former officers, agents, and employees and customers in connection with matters described

October 21, 2010

Page 3

in Paragraph One. GlaxoSmithKline shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, agents, and employees for interviews sought by law enforcement agents, upon request and reasonable notice in connection with the matters described in Paragraph One. GlaxoSmithKline shall also take reasonable measures to encourage its current and former officers, agents, and employees to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity in connection with matters described in Paragraph One.

In addition, GlaxoSmithKline shall, in connection with matters described in Paragraph One, promptly furnish to law enforcement agents, upon request, all documents and records in its possession, custody or control relating to the conduct that are within the scope of any ongoing federal investigation, trial or other criminal proceeding, and that are not covered by the attorney-client privilege or work product doctrine.

Provided, however, notwithstanding any provision of this Agreement, that: (1) GlaxoSmithKline is not required to request of its current or former officers, agents, or employees that they forego seeking the advice of an attorney or that they act contrary to that advice; (2) GlaxoSmithKline is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) GlaxoSmithKline is not required to waive any privilege or claim of work product protection except to the extent set forth in the succeeding paragraph.

GlaxoSmithKline acknowledges that SB Pharmco expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the Information and is in fact guilty of that offense. GlaxoSmithKline agrees that it will not make statements inconsistent with this explicit admission of guilt by SB Pharmco to the crime charged in the Information.

### 3. Who Is Bound By Agreement

This letter agreement is binding upon the Attorney General of the United States, the United States Department of Justice, including all United States Attorneys, except that this agreement does not bind the Tax Division of the United States Department of Justice or the Internal Revenue Service of the United States Department of the Treasury. This letter agreement is binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of GlaxoSmithKline 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's products to foreign customers. A copy of the letter to United States Attorney Carmen M. Ortiz on behalf of the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Side Letter Agreement is attached as Exhibit Three.


It is expressly understood that this Side Letter Agreement will have no effect on state or local prosecuting authorities, except as set forth in the civil settlement agreements between GlaxoSmithKline and the various states.


4. Complete Agreement

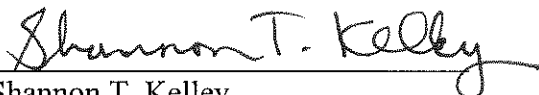
This Side Letter Agreement, the Plea Agreement with SB Pharmco, the Civil Settlement Agreement, and the Tolling Agreement between GlaxoSmithKline and the United States Attorney dated May 3, 2010, are the complete and only agreements between the parties. No promises, agreements or conditions have been 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 LLC and if you are authorized to enter into this agreement on behalf of GlaxoSmithKline LLC, please sign below and return the original of this letter to Assistant U.S. Attorney Susan G. Winkler.

Very truly yours,

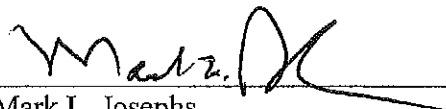
  
CARMEN M. ORTIZ  
United States Attorney  
District of Massachusetts

  
Susan G. Winkler

  
Shannon T. Kelley  
Assistant U.S. Attorneys  
District of Massachusetts

October 21, 2010  
Page 5

TONY WEST  
ASSISTANT ATTORNEY GENERAL  
CIVIL DIVISION  
U.S. DEPARTMENT OF JUSTICE

By:   
Mark L. Josephs  
Trial Attorney  
Office of Consumer Litigation  
U.S. Department of Justice

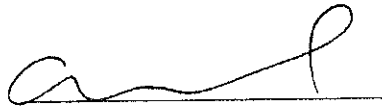
October 21, 2010

Page 6

**ACKNOWLEDGMENT OF AGREEMENT**

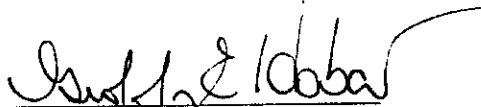
I am authorized to execute this Side Letter Agreement and the Civil Settlement Agreement on behalf of GlaxoSmithKline LLC. GlaxoSmithKline LLC has been advised of the contents of this Side Letter Agreement, the Civil Settlement Agreement, the Plea Agreement with SB Pharmco, Inc., and the criminal information charging SB Pharmco, Inc., and has discussed them fully with its counsel. I acknowledge on behalf of GlaxoSmithKline LLC that these documents fully set forth the agreements made between GlaxoSmithKline and the United States, and that no additional promises or representations have been made to GlaxoSmithKline, 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: 10/26/10



Elpidio Villarreal  
Senior Vice President, Global Litigation  
GlaxoSmithKline LLC

Dated: 10/26/10



Geoffrey E. Hebart, Esq.  
Matthew J. Connor, Esq.  
Covington & Burling LLP  
Counsel for Defendant



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*

October 21, 2010

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

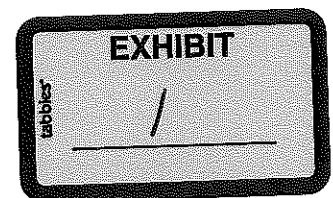
Re: United States v. SB Pharmco Puerto Rico, Inc.

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, SB Pharmco Puerto Rico, Inc. (hereinafter "SB Pharmco"), in the above-referenced case. The Agreement is as follows:

1. Change of Plea

At the earliest practicable date SB Pharmco shall waive indictment and plead guilty to the one-count Information attached hereto as Exhibit A. Count One of the Information charges that from in or about March 2003 to October 2004, SB Pharmco introduced for delivery into interstate commerce various quantities of adulterated drugs Paxil CR, Avandamet, Kytril, and Bactroban in violation of 21 U.S.C. §§ 331(a), 333(a)(2) and 351(a)(2)(B). SB Pharmco expressly and unequivocally admits that it committed these offenses and further admits that it acted with the intent to defraud or mislead. Defendant expressly and unequivocally further admits that it is in fact guilty of this offense, and agrees that it will not make any statements inconsistent with this explicit admission. SB Pharmco agrees to waive venue, to waive any applicable statutes of limitations, and to waive any legal or procedural defects in the Information.



2. Penalties

SB Pharmco faces the following maximum penalties on Count One of the Information:

- a. A fine of \$500,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greatest. *See* 18 U.S.C. §§ 3571(c)(5) and (d). Given SB Pharmco's gross gain from its sales of Paxil CR, Avandamet, Kytril and Bactroban that were deemed adulterated between March 2003 and October 2004 totaled \$98,834,224, the maximum possible fine in connection with this count is \$197,668,448.
- b. A term of probation of not more than five (5) years. *See* 18 U.S.C. § 3561(c)(2);
- c. Restitution to any victims of the offense. *See* 18 U.S.C. §§ 3556 and 3663; and
- d. A mandatory special assessment of \$400. *See* 18 U.S.C. § 3013..

3. Sentencing Guidelines

The parties agree that the fine provisions of the United States Sentencing Guidelines ("U.S.S.G.") applicable to organizational defendants for felony violations of the Food, Drug, and Cosmetic Act, see U.S.S.G. § 8C2.1, are calculated as follows, and that this calculation takes into account SB Pharmco's conduct under 18 U.S.C. §§ 3553 and 3572:

- a. The parties agree that the base fine is \$98,834,224, which is the pecuniary gain to the organization from the offense. *See* U.S.S.G. §§ 8C2.4(a), 8C2.3.
- b. Pursuant to U.S.S.G. § 8C2.5, the culpability score is six (6), which is determined as follows:
  - i. Base culpability score is five (5) pursuant to U.S.S.G. § 8C2.5(a);
  - ii. Add three (3) points pursuant to U.S.S.G. § 8C2.5(b)(2) in that the organization had 200 or more employees and an individual within high-level personnel of organization participated in, condoned, or was willfully ignorant of the offense; and
  - iii. Deduct two (2) points pursuant to U.S.S.G. § 8C2.5(g)(2) in recognition of SB Pharmco's full cooperation and clearly



demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct.

- iv. Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of six (6) is 1.20 to 2.40.
- v. Thus, the advisory Guideline Fine Range is \$118,601,069 to \$197,668,448. *See* U.S.S.G. §§ 8C2.7(a), (b); 18 U.S.C. §§ 3571(c), (d).

#### 4. Agreed Disposition

The United States and SB Pharmco agree pursuant to Fed. R. Crim. P. 11(c)(1)(C) 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 of all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572:

- a. A criminal fine of \$140,000,000 - to be paid within one week of the date of sentencing.
- b. Mandatory special assessments totaling \$400 pursuant to 18 U.S.C. § 3013, to be imposed as follows:
- c. Criminal Forfeiture in the amount of \$10,000,000.
- d. In light of the pending civil action, United States of America ex rel. Cheryl Eckard v. GlaxoSmithKline, et al., Civil Action No. 04-10375 (D. Mass.), and the Civil Settlement Agreement between SmithKline Beecham Corporation d/b/a/ GlaxoSmithKline and the United States (which is being signed contemporaneously with this Plea Agreement, and is attached hereto as Exhibit B) which requires the payment of \$600,000,000, plus interest, the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a proper restitution order outweighs the need to provide restitution to any non-federal victims in this case given that numerous unknown individuals and insurance companies purchased or reimbursed for the drug products in question, 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)(1)(B)(ii). Accordingly, the United States agrees that it will not seek a separate restitution order as to SB Pharmco as part of the resolution of the Information and the Parties agree that the appropriate disposition of this case does not include a restitution order.

The United States may, at its sole option, be released from its commitments under this Agreement, including, but not limited to, its agreement that this paragraph constitutes the appropriate disposition of this case, if at any time between Defendant's execution of this Agreement and sentencing, SB Pharmco:

- 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 SB Pharmco 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 SB Pharmco is accountable under U.S.S.G. § 1B1.3;
- e. Engages in acts which form a basis for finding that SB Pharmco 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.

SB Pharmco 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).

5. No Further Prosecution of SB Pharmco

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 SB Pharmco for any additional federal criminal charges or charges under the Food Drug and Cosmetic Act against Defendant with respect to the conduct that:

- (a) falls within the scope of the Information to which SB Pharmco 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 Office of Consumer Litigation of the Department of Justice prior to the date of this Agreement relating to:

- (i) the production, manufacturing, processing, packing and/or holding of drugs at SB Pharmco's Cidra, Puerto Rico manufacturing facility between the years 2001 and 2005; or
- (ii) conduct, communications and reporting regarding the Food and Drug Administration's oversight, regulatory inspections and actions regarding the Cidra, Puerto Rico manufacturing facility between the years 2001 and 2005.

The United States does not decline criminal prosecution of SB Pharmco for any other conduct beyond that set forth above. Without limitation, for the drugs manufactured at Cidra, this release expressly does not extend to any conduct relating to post-marketing studies or analyses; marketing or promotion; or conduct, communications and/or reporting to the FDA or physicians or customers regarding the safety, efficacy, and/or recommended uses of the drugs concerning issues other than manufacturing, processing, packing and/or holding of the drugs at Cidra.

This declination is expressly contingent upon:

- a. the guilty plea of SB Pharmco to the Information attached hereto as Exhibit A being accepted by the Court and not withdrawn or otherwise challenged; and
- b. SB Pharmco's performance of all of its obligations as set forth in this Agreement and the attached Civil Settlement Agreement.

If SB Pharmco's guilty plea is not accepted by the Court or is withdrawn for any reason, or if SB Pharmco should fail to perform any obligation under this Agreement or the Civil Settlement Agreement, 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 SB Pharmco, in connection with the conduct encompassed by this plea agreement, within the scope of the grand jury investigation, or known to the United States.

6. Payment of Mandatory Special Assessment

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

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

- a. SB Pharmco has conferred with its attorney and understands that it has the right to challenge its convictions in the United States Court of Appeals for the First Circuit ("direct appeal"). SB Pharmco also understands that it

may, in some circumstances, be able to challenge its convictions in a future proceeding (such as, for example, in a collateral challenge pursuant to 28 U.S.C. § 2255 or 28 U.S.C. § 2241). SB Pharmco waives any right it has to challenge its conviction on direct appeal or in any future proceeding.

- b. SB Pharmco has conferred with its attorney and understands that defendants ordinarily have a right to appeal their sentences and may sometimes challenge their sentences in future proceedings. SB Pharmco 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. SB Pharmco 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 Defendant. Given that a defendant who agrees to a specific sentence cannot later challenge it, and also because SB Pharmco desires to obtain the benefits of this Agreement, SB Pharmco agrees that it will not challenge the sentence imposed in an appeal or other future proceeding. SB Pharmco 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.
- 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 4, even if the Court rejects one or more positions advocated by a party at sentencing.

#### 8. Cooperation

SB Pharmco shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing civil, criminal or administrative investigation of its current and former officers, agents, employees, and customers in connection with the matters described in the Information. SB Pharmco shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, agents, and employees for interviews sought by law enforcement agents, upon request and reasonable notice in connection with matters described in the Information. SB Pharmco shall also take reasonable measures to encourage its current and former officers, agents, and employees to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity in connection with matters described in the Information.

In addition, SB Pharmco shall furnish to law enforcement agents, upon request, all documents and records in its possession, custody or control relating to the conduct that is within the scope of any ongoing federal investigation, trial or other criminal proceeding in connection with matters described in the Information, and that are not covered by the attorney-client

privilege or work product doctrine.

Provided, however, notwithstanding any provision of this Agreement, that: (1) SB Pharmco is not required to request of its current or former officers, agents, or employees that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) SB Pharmco is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) SB Pharmco is not required to waive any privilege or claim of work product protection.

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

SB Pharmco 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.

SB Pharmco admits that the value of the quantities of Paxil CR and Avandamet that were adulterated and distributed in violation of 21 U.S.C. § 331, totaled at least \$10,000,000 in United States currency. SB Pharmco acknowledges and agrees that the quantities of Paxil CR and Avandamet which were adulterated 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, SB Pharmco agrees that the United States is entitled to forfeit as "substitute assets" any other assets of SB Pharmco up to the value of the now missing directly forfeitable assets.

SB Pharmco agrees that, no later than one week after sentencing, it shall remit the amount of \$10,000,000 in United States currency to the United States Marshals Service pursuant to wire instructions provided by the United States Attorney's Office. SB Pharmco and the United States agree that this payment shall satisfy any and all forfeiture obligations that SB Pharmco may have as a result of its guilty plea.

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

SB Pharmco agrees to consent to the entry of orders of forfeiture for the \$10,000,000 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. SB Pharmco 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, SB Pharmco 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. Fed. R. Crim. P. 11(c)(1)(C) Agreement

SB Pharmco's plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). SB Pharmco cannot withdraw its plea of guilty unless the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith. If the sentencing judge rejects this 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 SB Pharmco, with the exception of paragraph 13 (Waiver of Defenses) which shall remain in full effect.

SB Pharmco 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 SB Pharmco immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. SB Pharmco 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.

12. Civil and Administrative Liability

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

SB Pharmco's civil liability to the United States in connection with certain of the matters under investigation by the Government is resolved in the Civil Settlement Agreement with GlaxoSmithKline LLC, attached as Exhibit B, according to the terms set forth in that Agreement.

13. Waiver of Defenses

If SB Pharmco's guilty plea is not accepted by the Court for whatever reason, if SB Pharmco's guilty plea is later withdrawn or otherwise successfully challenged by SB Pharmco for whatever reason, or if SB Pharmco breaches this Agreement, SB Pharmco 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 SB Pharmco may already have for conduct occurring before August 27, 2002, as further described in the parties' tolling agreement dated May 3, 2010, attached hereto as Exhibit C. 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.

14. Breach of Agreement

If the United States determines that SB Pharmco has failed to comply with any provision of this Agreement, or has committed any crime following its execution of this Agreement, the United States may, at its sole option, be released from its commitments under this Agreement in its entirety by notifying SB Pharmco, 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. SB Pharmco recognizes that no such breach by it of an obligation under this Agreement shall give rise to grounds for withdrawal of its guilty plea. SB Pharmco understands that should it breach any provision of this Agreement, the United States will have the right to use against SB Pharmco before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by SB Pharmco, and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation.

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

- a. are wholly dependant upon SB Pharmco's timely compliance with the material provisions of the attached Civil Settlement Agreement, and that
- b. failure by SB Pharmco to comply fully with the material terms of this Agreement or the attached Civil Settlement Agreement will constitute a breach of this Agreement.

In the event SB Pharmco at any time hereafter breaches any material provision of this Agreement, SB Pharmco 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 Agreement, including but not limited to the promise not to further prosecute SB Pharmco as set forth in this Agreement; and (2) SB Pharmco will not be relieved of its obligation to make the payments set forth in this Agreement and the attached Civil Settlement Agreement, nor will it be

entitled to return of any monies already paid. Moreover, in the event of a breach, SB Pharmco understands and agrees that the United States may pursue any and all charges that might otherwise have been brought but for this Agreement, and SB Pharmco 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 SB Pharmco may already have for conduct occurring before April 27, 2002.

15. Who Is Bound By Agreement

With respect to matters set forth in Paragraph 5, this Agreement is binding upon SB Pharmco and the Office of the United States Attorney for the District of Massachusetts, the United States Attorney's Offices for each of the other 93 judicial districts of the United States, and the Office of Consumer Litigation of the Department of Justice. The non-prosecution provisions in Paragraph 5 are also binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of SB Pharmco 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 SB Pharmco's products to foreign customers, which investigations are specifically excluded from the release in Paragraph 5. 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 D. SB Pharmco 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.

16. Corporate Authorization

SB Pharmco's acknowledgment of this Agreement and execution of this Agreement on behalf of the corporation is attached as Exhibit E. SB Pharmco shall provide to the U.S. Attorney and the Court a certified copy of a resolution of the governing authority of SB Pharmco 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) agreed to enter into the proposed Plea Agreement; (4) agreed to authorize SB Pharmco to plead guilty to the charges specified in the Information; and (5) agreed to authorize 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 F. SB Pharmco agrees that either a duly authorized corporate officer or a duly authorized attorney for SB Pharmco, at the discretion of the Court, shall appear on behalf of SB Pharmco and enter the guilty plea and will also appear for the imposition of sentence.

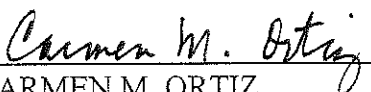


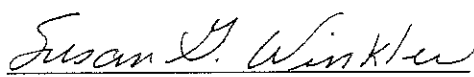
17. Complete Agreement

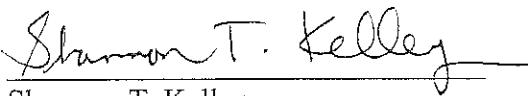
This Agreement and the attachments hereto, together with the Civil Settlement Agreement and attachments thereto, and the separate side letter with GlaxoSmithKline LLC and attachments thereto, set forth the complete and only agreement between the parties relating to the disposition of this case. No promises, representations or agreements have been made other than those set forth in this Agreement and its attachments, and the Civil Settlement Agreement and its attachments, and the separate side letter with GlaxoSmithKline LLC and its attachments. This Agreement supersedes prior understandings, if any, of the parties, whether written or oral. This Agreement can be modified or supplemented only 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, SB Pharmco, please have the authorized representative of SB Pharmco sign the Acknowledgment of Agreement below. Please also sign below as Witness. Return the original of this letter to Assistant U.S. Attorney Susan G. Winkler.

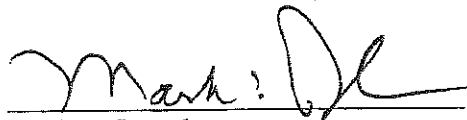
Very truly yours,

  
CARMEN M. ORTIZ  
UNITED STATES ATTORNEY  
DISTRICT OF MASSACHUSETTS

By:   
Susan G. Winkler

  
Shannon T. Kelley  
Assistant U.S. Attorneys  
District of Massachusetts

TONY WEST  
ASSISTANT ATTORNEY GENERAL  
CIVIL DIVISION  
U.S. DEPARTMENT OF JUSTICE

By: 

Mark L. Josephs  
Trial Attorney  
Office of Consumer Litigation  
U.S. Department of Justice



U.S. Department of Justice

Criminal Division

---

Office of the Assistant Attorney General

Washington, D.C. 20530

October 6, 2010

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

Attention: Susan Winkler  
Assistant United States Attorney

Re: Global Non-Prosecution Agreement for SB Pharmco Puerto Rico, Inc. and  
GlaxoSmithKline LLC

Dear Ms. Ortiz:

This is in response to your request for authorization to enter into a global case disposition agreement with the business entities known as SB Pharmco Puerto Rico, Inc and GlaxoSmithKline LLC.

I hereby approve the terms of the plea agreement with SB Pharmco Puerto Rico, Inc., including Paragraphs 5 and 15, and the Side Letter Agreement with GlaxoSmithKline LLC including Paragraphs 1 and 3, in which the United States Attorney's Offices and, with the exception of the Fraud Section, the Criminal Division of the Department of Justice agree not to initiate further criminal prosecutions as set out therein.

You are authorized to make this approval a matter of record in this proceeding.

Sincerely,

*Greg D. Andres / MR*

Greg D. Andres  
Deputy Assistant Attorney General  
Criminal Division

NOW THEREFORE, BE IT RESOLVED, that the Company is hereby authorized and directed to enter into the Plea Agreement and Settlement Agreements;

FURTHER RESOLVED, that the Company is authorized and directed to plead guilty to the charges specified in the Information related to the Company;

FURTHER RESOLVED, that pursuant to Section 5.1 of the Plan of Dissolution, the Trustee and/or his duly authorized representatives or attorneys, shall take all actions and deliver any agreements, certificates and documents and instruments with respect to or contemplated by the matters set forth above, including, without limitation, the payment of all amounts, fees, costs and other expenses, necessary or appropriate to effectuate the purpose and intent of the foregoing resolutions and to effectuate and implement the resolutions contemplated hereby;

FURTHER RESOLVED, that any actions taken by Trustee or his duly authorized representatives or attorneys, prior to the adoption of this resolution, that are within the authority conferred hereby, are fully ratified, confirmed and approved as the act and deed of the Company.

IN WITNESS WHEREOF, the undersigned has executed this Consent as of the 26 of October, 2010.

Signed for and on behalf of  
SB Pharmco Puerto Rico, Inc.

By:

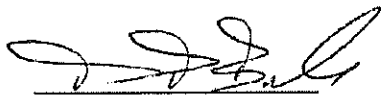


Desmond P. Burke, Trustee

**ACKNOWLEDGMENT OF AGREEMENT**

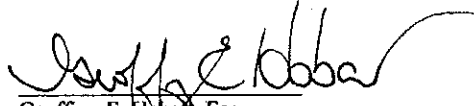
The Trustee of SB Pharmco Puerto Rico, Inc. (the "Trustee") is authorized to execute this Plea Agreement on behalf of SB Pharmco, Puerto Rico, Inc. and to take all such actions as may be necessary to effectuate this Plea Agreement. The Trustee has read this Plea Agreement, the attached criminal information, and the Civil Settlement Agreement, including all attachments, in their entirety and has discussed them fully in consultation with SB Pharmco's attorney. The Trustee acknowledges that these documents fully set forth SB Pharmco's agreement with the United States. The Trustee further states that no additional promises or representations have been made to SB Pharmco by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement and the attached Civil Settlement Agreement.

Dated: October 26<sup>th</sup> 2010



Desmond P. Burke  
Trustee  
SB Pharmco Puerto Rico, Inc.

Dated: 10/26/10



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

## SETTLEMENT AGREEMENT

### I. PARTIES

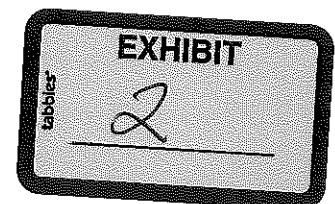
This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice, Civil Division, and the United States Attorney’s Office for the District of Massachusetts, and on behalf of, the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”), TRICARE Management Activity (“TMA”), the Department of Veterans Affairs (“VA”), and the United States Office of Personnel Management (“OPM”) (collectively the “United States”); the Relator Cheryl Eckard as identified in Paragraph C of the Preamble to this Agreement (“Relator”); and GlaxoSmithKline LLC, formerly known as SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, and SB Pharmco, Puerto Rico, Inc. (collectively “GSK”). Collectively, all of the above will be referred to as “the Parties.”

### II. PREAMBLE

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

A. At all relevant times, GlaxoSmithKline LLC, a Delaware Limited Liability Company, had business operations in Philadelphia, Pennsylvania and Research Triangle Park, North Carolina. SB Pharmco Puerto Rico, Inc. (“SB Pharmco”) was a corporation organized under the laws of the Commonwealth of Puerto Rico with a principal place of business in Cidra, Puerto Rico. SB Pharmco was an indirect subsidiary of GlaxoSmithKline LLC’s UK-based parent corporation, GlaxoSmithKline, plc.

B. At all relevant times, GSK manufactured, distributed, and sold pharmaceutical



products in the United States, including drug products sold under the trade names of Paxil CR, Avandamet, Kytril and Bactroban that were manufactured at SB Pharmco's Cidra, Puerto Rico facility. (the "Covered Drugs")

C. On or about February 25, 2004, Cheryl Eckard ("Eckard") ("Relator") filed a qui tam action in the United States District Court for the District of Massachusetts captioned United States of America ex rel. Cheryl Eckard v. GlaxoSmithKline, et al., Civil Action No. 04-10375 (D. Mass.). On or about October 17, 2008, Eckard filed a Third Amended Complaint in the District of Massachusetts under the same case number and captioned United States of America, et al. ex rel. Cheryl Eckard v. SmithKline Beecham d/b/a GlaxoSmithKline, et al., and this Third Amended Complaint sets forth the current allegations in the qui tam action ("the Civil Action");

D. On such date as may be determined by the Court, SB Pharmco 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 v. GlaxoSmithKline, Criminal Action No. [to be assigned] (District of Massachusetts) (the "Federal Criminal Action") that will allege a violation of Title 21, United States Code, Sections 331(a), 333(a)(2), and 351(a)(2)(B), namely, the introduction into interstate commerce, of adulterated drugs Avandamet, Paxil CR, Bactroban and Kytril, in violation of the Food, Drug and Cosmetic Act ("FDCA").

E. 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, shall be defined as “Medicaid Participating States.”

F. The United States alleges that GSK caused to be submitted claims for payment for the Covered Drugs to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (“the Medicaid Program”).

G. The United States further alleges that GSK caused claims for payment for the Covered Drugs to be submitted to the TRICARE program (formerly known as the Civilian Health and Medical Program of the Uniformed Services), 10 U.S.C. §§ 1071-1109; the Federal Employees Health Benefits Program (“FEHBP”), 5 U.S.C. §§ 8901-8914; and caused purchases of the Covered Drugs by the Department of Veterans Affairs (“VA”) (collectively, the “other Federal health care programs”).

H. The United States contends that it and the Medicaid Participating States have certain civil claims against GSK, as specified in Paragraph 2 below, for engaging in the following conduct concerning the manufacture, distribution, and sale of the Covered Drugs that were manufactured at SB Pharmco’s Cidra, Puerto Rico facility, at various points during the time period January 1, 2001 through April 1, 2005 (hereinafter referred to as the “Covered Conduct”):

GSK knowingly manufactured, distributed and sold in interstate commerce certain batches, lots, or portions of lots of the Covered Drugs during the period referenced above, the strength of which differed from, or the purity or quality of which fell below, the strength, purity, or quality specified in the drugs’ FDA-approved New Drug Applications (“NDAs”) or documents related to the drugs’ NDAs, the drugs’ labels and/or the standards set forth in the United States Pharmacopeia, in violation of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 351(b) and (c), which deems such products to be “adulterated,” and 21 U.S.C. § 331(a).

More specifically, GSK knowingly manufactured, distributed and sold certain batches,



lots, or portions of lots of: (1) Paxil CR that contained some split tablets causing some consumers to receive either product with no active ingredient and/or product with only the active ingredient layer and no controlled release mechanism; (2) Avandamet that contained some tablets with higher or lower amounts of rosiglitazone than specified; (3) Kytril that was labeled as sterile but was, in some vials, non-sterile; and (4) Bactroban ointments and creams that, in some packages, contained microorganisms.

As a result of the foregoing alleged conduct, the United States contends that GSK sold certain batches, lots, or portions of lots of the Covered Drugs, the strength of which materially differed from, or the purity or quality of which materially fell below, the strength, purity, or quality specified in the drugs' NDAs or related documents as described above, and thereby knowingly caused false and/or fraudulent claims to be submitted to, or caused purchases by, the Medicaid Program and the other Federal health care programs.

I. The United States also contends that it has certain administrative claims against GSK as specified in Paragraphs 3 through 5 below, for engaging in the Covered Conduct;

J. This Settlement Agreement is made in compromise of disputed claims. This Settlement Agreement is neither an admission of facts or liability by GSK, nor a concession by the United States or the Relator that their claims are not well-founded. GSK expressly denies the contentions and allegations of the United States and Relator as set forth herein and in the Civil Action and denies that it engaged in any wrongful conduct, except as to such admissions that SB Pharmco is required to make under the terms of the plea agreement, into which SB Pharmco is entering simultaneously with the execution of this Settlement Agreement. Neither this Settlement Agreement, its execution, 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 by GSK.

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

forth below.

### III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations set forth below in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. GSK agrees to pay to the United States and the Medicaid Participating States the sum of Six Hundred Million Dollars (\$600,000,000) plus accrued interest in an amount of 3.25% per annum from June 18, 2010 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. The debt shall be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) The Federal Settlement Amount of Four Hundred Thirty Six Million Four Hundred Forty Thousand Dollars (\$436,440,000) plus accrued interest in an amount of 3.25% per annum from June 18, 2010, and continuing until and including the day before payment is made under this Agreement, 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 in connection with

the Federal Criminal Action and imposes the agreed-upon sentence, whichever occurs later.

(b) GSK shall pay to the Medicaid Participating States the Medicaid State Settlement Amount of One Hundred Sixty-Three Million Five Hundred and Sixty Thousand Dollars (\$163,560,000), plus interest accrued on this amount at the rate of 3.25 percent per annum from June 18, 2010, 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 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) Contingent upon the United States receiving the Federal Settlement Amount from GSK, the United States agrees to pay, as soon as feasible after receipt, to Relator Eckard a Relator's Share of 22% of the Federal Settlement Amount referred to in subparagraph (a) of this paragraph equal to \$96,016,800 plus the pro rata share of the actual accrued interest paid to the United States by GSK on the amount set forth in Paragraph 1 above (“Relator’s Share”).

2. Subject to the exceptions in Paragraph 6 (concerning excluded claims), below, 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, agents, agencies, and departments) agrees to release GSK, together with its predecessors, current and former parents, direct and indirect affiliates, 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; 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 of payment by mistake, fraud, disgorgement, unjust enrichment and, if applicable, breach of contract.

3. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against GSK and/or its officers, directors, and employees from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7(b) or 42 U.S.C. § 1320a-7a (permissive exclusion).

4. OPM expressly reserves all rights to institute, direct, or to maintain any administrative action seeking debarment against GSK from the FEHBP under 5 U.S.C. § 8902(b) (mandatory debarment), or (c) and (d) (permissive debarment).

5. TMA expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against GSK and/or its officers, directors, and employees from the TRICARE Program under 32 C.F.R. §§ 199.9.

6. Notwithstanding any term of this Agreement, specifically removed and excluded from the scope and terms of this Agreement as to any entity or person (including GSK and the Relator) 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 or permissive exclusion from Federal health care programs and debarment.
- (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 deficient 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 services due; and
- (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 a criminal plea agreement arising from the Covered Conduct.

7. The Relator, and her respective heirs, successors, attorneys, agents, and assigns, agrees not to object to this Agreement and agrees and confirms that this Agreement is fair, adequate and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B), and expressly waives the opportunity to request a hearing on any objection to this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon payment by the United States of the amounts set forth in Paragraph 1(c) above, the Relator for herself individually, and for her heirs, successors, agents, and assigns, fully and finally releases, waives, and forever discharges the United States, its officers, agents, and employees, from any claims arising from or relating to 31 U.S.C. § 3730; from any claims arising from the Covered Conduct and/or the filing of her Civil Action; and from any other claims for a share of the Federal Settlement Amount; and in full settlement of any claims the Relator may have under this Agreement. This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relator arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement. Relator does not release the Medicaid Participating States from any claims that Relator has for a share of any settlement or judgment obtained by the Medicaid Participating States concerning the Covered Conduct.

8. In consideration of the obligations of GSK set forth in this Agreement, and conditioned upon receipt of the payments described in Paragraph 1(c) above, the Relator, for herself, and her heirs, successors, attorneys, agents, assigns, and any other person or entity acting on her behalf or asserting her rights, hereby fully and finally releases, waives and forever discharges GSK, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and

former directors, officers and employees, individually and collectively from any and all liability, claims, allegations, demands, actions or causes of action whatsoever, known or unknown, fixed or contingent, in law or in equity, in contract or tort, under any federal or state statute or regulation, or under common law or that the Relator otherwise would have standing to bring, arising from or relating to the Covered Conduct and that the Relator asserted or could have asserted in, or arising from or relating to, the Civil Action. Provided, however, that the Relator does not release GSK for any claims for attorneys' fees, expenses and costs under 31 U.S.C. § 3730(d).

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, waives and discharges the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expense 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 United States' investigation and prosecution of civil claims arising out of or in connection with the Civil Action.

11. In consideration of the obligations of the Relator 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 releases, waives, and forever discharges the Relator and her respective heirs, successors, assigns, agents, and attorneys from any claims or allegations GSK has asserted or could have asserted arising from the Covered Conduct or related to the initiation, investigation, and/or prosecution of the Civil Action by Relator and her attorneys. Provided, however, that GSK expressly reserves any defenses or claims with respect to Relator's claim for attorneys' fees, expenses, and costs under 31 U.S.C. § 3730(d), which is reserved pursuant to Paragraph 8 above.

12. Neither the Federal Settlement Amount nor the Medicaid State Settlement Amount shall be decreased as a result of the denial of claims for payment now being withheld from payment by any state or federal 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 (or cause the appeal of) any such denial of claims.

13. 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. §§ 1395-1395ggg and 1396-1396v, 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 Program, Medicaid Program, and TRICARE Program:

- (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 the Relator; and

All costs described or set forth in this Paragraph 13(a) are hereafter “Unallowable Costs.”

- (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 parents, subsidiaries or affiliates to the Medicare,

Medicaid, or TRICARE 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 VA 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 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.

14. GSK agrees to cooperate fully and truthfully with the United States' investigation relating to the Covered Conduct of individuals and entities not released in this Agreement. Upon reasonable notice, GSK shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. GSK agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by its counsel or agent.

15. This Agreement is intended to be for the benefit of the Parties only. Other than as set forth in this Agreement, the Parties do not release any claims against any other person or entity.

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 payers based upon the claims defined in the Covered Conduct.

17. 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).

18. The United States shall intervene in the Civil Action as to the Covered Conduct and consent to the voluntary dismissal as to GSK and all other defendants and all other allegations set forth in the Civil Action. Within five (5) business days following payment of the Settlement Amount, the United States and Relator shall file a stipulation of dismissal in the Civil Action as follows:

- (a) the stipulation of dismissal shall be with prejudice as to the United States' and Relator's claims as to GSK and all other defendants as to the Covered Conduct in the Civil Action pursuant to and consistent with the terms and conditions of this Agreement;
- (b) the stipulation of dismissal shall be without prejudice as to the United States and with prejudice as to the Relator as to GSK and all other

defendants and as to all other claims in the Civil Action; and

- (c) provided, however, that the following claims shall not be dismissed, unless they are settled, any required United States consent is obtained, and the Court is so informed: (1) Relator's claims for a Relator's Share under the Medicaid State Settlement Agreements; and (2) Relator's claims for reasonable attorneys' fees, expenses and costs pursuant to 31 U.S.C. § 3730(d).

19. Except as expressly provided to the contrary in this Agreement, each party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

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 dispute regarding Relator's attorneys' fees, expenses and costs shall be the United States District Court for the District of Massachusetts.

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 subsequent dispute.

23. Except as expressly set forth herein, this Agreement constitutes the complete agreement between the Parties. 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 the Relator represent and warrant that they are authorized by the 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.

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

27. This Agreement is binding on the Relator's successors, transferees, heirs, attorneys and assigns.

28. All Parties consent to the disclosure of this Agreement, and information about this Agreement, to the public.

29. 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.

30. Notwithstanding any provision of this Agreement, if the guilty plea referenced in Paragraph II(D) 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 the Agreement is rescinded, the calculation of any statute of limitations period for any civil or

administrative claims brought by the United States arising from the Civil Action shall not include the period from the Effective Date through ninety (90) days after the date of the rescission.

[page intentionally left blank]



UNITED STATES OF AMERICA

CARMEN M. ORTIZ  
U.S. Attorney, District of Massachusetts

By: *Susan G. Winkler*  
*Shannon T. Kelley*

SHANNON T. KELLEY  
SUSAN G. WINKLER  
Assistant U.S. Attorneys  
United States Attorney's Office  
District of Massachusetts

Dated: 10/26/10

UNITED STATES OF AMERICA

TONY WEST  
Assistant Attorney General

By:




JOYCE R. BRANDA  
JAMIE ANN YAVELBERG  
Attorneys

Commercial Litigation Branch, Civil Division  
United States Department of Justice

Dated: 10/26/10


By:



**GREGORY E. DEMSKE**  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services

Dated: 10/25/10

By:



ROBERT D. SEAMAN  
General Counsel  
TRICARE Management Activity  
United States Department of Defense  
On Behalf of the TRICARE Program

Dated: *October 25, 2010*


By: *Shirley R. Patterson*  
SHIRLEY R. PATTERSON  
Acting Deputy Associate Director  
Insurance Operations  
United States Office of Personnel Management

Dated: *10/24/10*

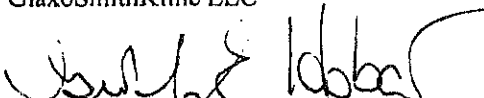
By: *J. David Cope*  
J. DAVID COPE  
Assistant Inspector General for Legal Affairs  
United States Office of Personnel Management

Dated: *10/25/2010*

GLAXOSMITHKLINE LLC

By:   
\_\_\_\_\_  
Elpidio Villarreal  
Senior Vice President  
Global Litigation  
GlaxoSmithKline LLC

Dated: 10/26/10

By:   
\_\_\_\_\_  
Geoffrey E. Hobart, Esq.  
Matthew J. O'Connor, Esq.  
Covington & Burling LLP  
Counsel for GlaxoSmithKline LLC

Dated: 10/26/10

THE RELATOR

By: Cheryl Eckard  
Cheryl Eckard  
Relator

Dated: Oct 26, 2010

By: Neil V. Getnick  
Neil V. Getnick  
Lesley Ann Skillen  
Getnick & Getnick, LLP  
Counsel for Relator

Dated: 10/26/10



U.S. Department of Justice

Criminal Division

Office of the Assistant Attorney General

Washington, D.C. 20530

October 6, 2010

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

Attention: Susan Winkler  
Assistant United States Attorney

Re: Global Non-Prosecution Agreement for SB Pharmco Puerto Rico, Inc. and  
GlaxoSmithKline LLC

Dear Ms. Ortiz:

This is in response to your request for authorization to enter into a global case disposition agreement with the business entities known as SB Pharmco Puerto Rico, Inc and GlaxoSmithKline LLC.

I hereby approve the terms of the plea agreement with SB Pharmco Puerto Rico, Inc., including Paragraphs 5 and 15, and the Side Letter Agreement with GlaxoSmithKline LLC including Paragraphs 1 and 3, in which the United States Attorney's Offices and, with the exception of the Fraud Section, the Criminal Division of the Department of Justice agree not to initiate further criminal prosecutions as set out therein.

You are authorized to make this approval a matter of record in this proceeding.

Sincerely,

*Greg D. Andres / MR*

Greg D. Andres  
Deputy Assistant Attorney General  
Criminal Division

