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

November 7, 2011

Theodore V. Wells, Jr., Esq.
Paul, Weiss, Rifkind, Wharton and Garrison, LLP
1285 Avenue of the Americas
New York, New York 10019

R.J. Cinquegrana, Esq.
Choate Hall & Stewart, LLP
Two International Place
Boston, MA 02110

Re: United States v. Merck & Co., Inc.

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, Merck Sharp & Dohme Corp., 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, Merck & Co., Inc., its direct and indirect subsidiaries (other than Merck, Sharp & Dohme Corp.) and its successors, the United States and Merck & Co., Inc. hereby agree as follows:

1. No Criminal Prosecution of Merck & Co., Inc.

The United States hereby declines prosecution of Merck & Co., Inc. or any of its direct or indirect subsidiaries (other than Merck Sharp & Dohme Corp. as set forth in the Information) for conduct by or attributable to Merck & Co., Inc. or any of its subsidiaries that:

(a) falls within the scope of the Information to which Merck Sharp & Dohme Corp. 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 Merck Sharp & Dohme Corp.'s:

(i) sales, marketing and promotion of Vioxx before it was withdrawn from the market in September 2004; and

(ii) communications with and reporting to the Food and Drug Administration in connection with the marketing and labeling of Vioxx.

The United States does not decline criminal prosecution of Merck & Co., Inc. or any of Merck & Co., Inc.'s related entities for any other conduct beyond that set forth above.

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

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

2. Who Is Bound By Agreement

With respect to matters set forth in Paragraph 1, this Agreement is binding upon Merck & Co., Inc. 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 Office of Consumer Litigation of the Department of Justice. The non-prosecution provisions in Paragraph 1 are also binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of Merck & Co, Inc. or any of its subsidiaries that are or may be conducted in the future by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses

in connection with the sales and marketing of Merck & Co., Inc.'s or any of its subsidiaries' products to foreign customers, which investigations are specifically excluded from the release in Paragraph 1. A copy of the letter to United States Attorney Carmen M. Ortiz from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Agreement is attached as Exhibit Three. Merck & Co., Inc. understands that this Agreement does not bind any state or local prosecutive authorities, the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury.

3. Complete Agreement

This Side Letter Agreement, the Plea Agreement and the Civil Settlement Agreement with Merck Sharp & Dohme Corp., and the September 23, 2011 modification of the Tolling Agreement between Merck & Co., Inc. and the United States Attorney dated February 24, 2006, 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 Merck & Co., Inc. and if you are authorized to enter into this agreement on behalf of Merck & Co., Inc., please sign below and return the original of this letter to Assistant U.S. Attorney Susan G. Winkler.

Very truly yours,

Carmen M. Ortiz

CARMEN M. ORTIZ
United States Attorney
District of Massachusetts

Susan Winkler

Susan G. Winkler

Jeremy M. Sternberg

Zachary A. Cunha
Assistant U.S. Attorneys
District of Massachusetts

in connection with the sales and marketing of Merck & Co., Inc.'s or any of its subsidiaries' products to foreign customers, which investigations are specifically excluded from the release in Paragraph 1. A copy of the letter to United States Attorney Carmen M. Ortiz from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Agreement is attached as Exhibit Three. Merck & Co., Inc. understands that this Agreement does not bind any state or local prosecutive authorities, the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury.

3. Complete Agreement

This Side Letter Agreement, the Plea Agreement and the Civil Settlement Agreement with Merck Sharp & Dohme Corp., and the September 23, 2011 modification of the Tolling Agreement between Merck & Co., Inc. and the United States Attorney dated February 24, 2006, 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 Merck & Co., Inc. and if you are authorized to enter into this agreement on behalf of Merck & Co., Inc., 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

Jeremy M. Sternberg

Zachary A. Cunha
Assistant U.S. Attorneys
District of Massachusetts

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

By: 
Jill P. Furman
Assistant Director
Consumer Protection Branch
U.S. Department of Justice

ACKNOWLEDGMENT OF AGREEMENT

I am authorized to execute this Side Letter Agreement on behalf of Merck & Co., Inc.. Merck & Co., Inc. has been advised of the contents of this Side Letter Agreement, the Plea Agreement and Civil Settlement Agreement with Merck Sharp & Dohme Corp. and the criminal Information charging Merck Sharp & Dohme Corp., and has discussed them fully with its counsel. I am further authorized to acknowledge on behalf of Merck & Co., Inc. that these documents fully set forth the agreements made between Merck & Co., Inc. and the United States, and that no additional promises or representations have been made to Merck & Co., Inc. 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: 11-22-11

Bruce N. Kuhlik
Executive Vice President and General Counsel
Merck & Co., Inc.

Dated: _____

Theodore V. Wells, Jr., Esq.
Paul, Weiss, Rifkind, Wharton and Garrison, LLP
Counsel for Merck & Co., Inc.

Dated: _____

R.J. Cinquegrana, Esq.
Choate Hall & Stewart, LLP
Counsel for Merck & Co., Inc.

ACKNOWLEDGMENT OF AGREEMENT

I am authorized to execute this Side Letter Agreement on behalf of Merck & Co., Inc.. Merck & Co., Inc. has been advised of the contents of this Side Letter Agreement, the Plea Agreement and Civil Settlement Agreement with Merck Sharp & Dohme Corp. and the criminal Information charging Merck Sharp & Dohme Corp., and has discussed them fully with its counsel. I am further authorized to acknowledge on behalf of Merck & Co., Inc. that these documents fully set forth the agreements made between Merck & Co., Inc. and the United States, and that no additional promises or representations have been made to Merck & Co., Inc. 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: _____

_____
Bruce N. Kuhlik
Executive Vice President and General Counsel
Merck & Co., Inc.

Dated: 11.22.11

Theodore V. Wells, Jr.
Theodore V. Wells, Jr., Esq.
Paul, Weiss, Rifkind, Wharton and Garrison, LLP
Counsel for Merck & Co., Inc.

Dated: 11.22.11

_____
R.J. Cinquegrana, Esq.
Choate Hall & Stewart, LLP
Counsel for Merck & Co., Inc.

Exhibit One

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

November 7, 2011

Theodore V. Wells, Jr., Esq.
Paul, Weiss, Rifkind, Wharton and Garrison, LLP
1285 Avenue of the Americas
New York, New York 10019

R.J. Cinquegrana, Esq.
Choate Hall & Stewart, LLP
Two International Place
Boston, MA 02110

Re: United States v. Merck Sharp & Dohme Corp.

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, Merck Sharp & Dohme Corp. ("Merck"), in the above-referenced case. The Agreement is as follows:

1. Change of Plea

At the earliest practicable date Merck 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 May 1999 to April 2002, Merck introduced for delivery into interstate commerce a misbranded drug, Vioxx, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1). Merck expressly and unequivocally admits that it committed this offense. Merck 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. Merck agrees to waive venue, to waive any applicable statutes of limitations, and to waive any legal or procedural defects in the Information.

2. Penalties

Merck faces the following maximum penalties on Count One of the Information:

a. 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 greatest. *See* 18 U.S.C. §§ 3571(c)(5) and (d). Merck's gross gain from its sales from misbranded Vioxx between May 1999 and April 2002 totaled $536,060,000, and thus the maximum possible fine in connection with this count is $1,072,120,000;

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. § 3563; and

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

3. 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 Merck's conduct under 18 U.S.C. §§ 3553 and 3572, as follows:

a. The parties agree that the base fine is $536,060,000, 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 three (3), which is determined as follows:

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

ii. There is no basis for any addition to the base culpability score under U.S.S.G. § 8C2.5(b);

iii. Deduct two (2) points pursuant to U.S.S.G. § 8C2.5(g)(2) in recognition of Merck'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 three (3) is .6 to 1.2; and

v. Thus, the advisory Guideline Fine Range is $321,636,000 to $643,272,000. *See* U.S.S.G. §§ 8C2.7(a), (b); 18 U.S.C. §§ 3571(c), (d).

4. Agreed Disposition

The United States and Merck 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 all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572:

a. A criminal fine of $321,636,000 to be paid within one week of the date of sentencing;

b. A mandatory special assessment of $125 pursuant to 18 U.S.C. § 3013;

c. In light of the Civil Settlement Agreement between Merck and the United States (which is being signed contemporaneously with this Plea Agreement, and is attached hereto as Exhibit B) which, subject to its terms, requires the payment of $628,364,000, plus interest from September 8, 2010, 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 in this case given that numerous unknown individuals and insurance companies purchased Vioxx, 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 product at issue would be extraordinarily difficult, if not impossible. *Cf.* 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 Merck 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; and

d. The United States agrees that it will not seek a term of probation in light of the Corporate Integrity Agreement entered into between Merck and the Office of Inspector General of the Department of Health and Human Services, attached as Exhibit C.

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, Merck:

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 Merck 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 Merck is accountable under U.S.S.G. § 1B1.3;

e. Engages in acts which form a basis for finding that Merck 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.

Merck 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 Merck

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), the United States agrees that, other than the charge in the attached Information, it shall not further prosecute Merck 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) Merck's sales, marketing and promotion of Vioxx before it was withdrawn from the market in September 2004; and

(b) Merck's communications with and reporting to the Food and Drug Administration in connection with the marketing and labeling of Vioxx.

This declination is expressly contingent upon:

a. the guilty plea of Merck to the Information attached hereto as Exhibit A being accepted by the Court and not withdrawn or otherwise challenged; and

b. Merck's performance of all of its obligations as set forth in this Agreement and the attached Civil Settlement Agreement.

If Merck's guilty plea is not accepted by the Court or is withdrawn for any reason, or if Merck 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 Merck, 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

Merck 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. Merck 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"). Merck also understands that it may, in some circumstances, be able to challenge its convictions in a future proceeding. Merck waives any right it has to challenge its conviction on direct appeal or in any future proceeding;

b. Merck 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. Merck 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. Merck 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 Merck desires to obtain the benefits of this Agreement, Merck agrees that it will not challenge the sentence imposed in an appeal or other future proceeding. Merck 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 4, even if the Court rejects one or more positions advocated by a party at sentencing.

8. 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.

9. Fed. R. Crim. P. 11(c)(1)(C) Agreement

Merck's plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). Merck 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 Merck, with the exception of paragraph 11 (Waiver of Defenses) which shall remain in full effect.

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

10. 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 Merck may have incurred or may incur as a result of its conduct and its plea of guilty to the attached Information.

Merck'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, attached as Exhibit B, according to the terms set forth in the Civil Settlement Agreement.

11. Waiver of Defenses

If Merck's guilty plea is not accepted by the Court for whatever reason, if Merck's guilty plea is later withdrawn or otherwise successfully challenged by Merck for whatever reason, or if Merck breaches this Agreement, Merck 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 Merck may already have for conduct occurring before February 24, 2001, as further described in the parties' September 23, 2011 modification of the tolling agreement dated February 24, 2006, attached hereto as Exhibits D and E. 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.

12. Breach of Agreement

If the United States determines that Merck has failed to comply with any material provision of this Agreement, the United States may, at its sole option, be released from its commitments under

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

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

a. are wholly dependant upon Merck's timely compliance with the material provisions of the attached Civil Settlement Agreement, and that

b. failure by Merck 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 Merck at any time hereafter breaches any material provision of this Agreement, Merck 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 Merck as set forth in this Agreement; and (2) Merck 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 such a breach, Merck understands and agrees that the United States may pursue any and all charges that might otherwise have been brought but for this Agreement, and Merck 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 Merck may already have for conduct occurring before February 24, 2001.

13. Who Is Bound By Agreement

With respect to matters set forth in Paragraph 5, this Agreement is binding upon Merck 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 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 Merck 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 Merck'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 F. Merck 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.

14. Corporate Authorization

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

15. Complete Agreement

This Agreement and the attachments hereto, together with the Civil Settlement Agreement 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. 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, Merck, please have the authorized representative of Merck 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

CARMEN M. ORTIZ
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

By: Susan Winkler
Susan G. Winkler

Jeremy M. Sternberg

Zachary A. Cunha
Assistant U.S. Attorneys
District of Massachusetts

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

By: _____
Jill P. Furman
Assistant Director
Office of Consumer Litigation
U.S. Department of Justice

If this letter accurately reflects the Agreement between the United States and your client, Merck, please have the authorized representative of Merck 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

ORIGINAL

_____
emy M. Sternberg
Zachary A. Cunha
Assistant U.S. Attorneys
District of Massachusetts

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

By: _____
Jill P. Furman
Assistant Director
Office of Consumer Litigation
U.S. Department of Justice

If this letter accurately reflects the Agreement between the United States and your client, Merck, please have the authorized representative of Merck 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

_____
Jeremy M. Sternberg

_____
Zachary A. Cunha
Assistant U.S. Attorneys
District of Massachusetts

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

By: _____
Jill P. Furman
Assistant Director
Office of Consumer Litigation
U.S. Department of Justice

Exhibit A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
	)	CRIMINAL NO.
	)	
v.	)	
	)	
MERCK SHARP & DOHME CORP.	)	VIOLATION:
	)	
	)	21 U.S.C. §§ 331(a), 333(a)(1), 352(f)(1)
Defendant	)	(misbranding)
	)	

INFORMATION

The United States Attorney charges that:

PRELIMINARY ALLEGATIONS

At all times material hereto, unless otherwise alleged:

The Defendant

1. Between May 1999 and September 2004, Merck & Co., Inc. was a New Jersey corporation headquartered in Whitehouse Station, New Jersey, and was the operating company for Merck's pharmaceutical business in the United States. As a result of a reverse merger with another pharmaceutical company in 2009, Merck & Co., Inc. became a wholly-owned subsidiary of the acquiring company and was renamed **MERCK SHARP & DOHME CORP**. The acquiring company was renamed Merck & Co., Inc. The new Merck & Co., Inc. is a holding company for **MERCK SHARP & DOHME CORP**. and other corporate entities. Currently, **MERCK SHARP & DOHME CORP**. (**"MERCK"**) is the operating company in the United States for the pharmaceutical business formerly conducted by Merck & Co. Inc. **MERCK** was publicly traded (NYSE ticker symbol MRK).

2. **MERCK** was engaged in, among other things, the development, manufacture, promotion, sale and distribution of prescription drugs intended for human use nationwide and in the District of Massachusetts. **MERCK** sold billions of dollars of pharmaceutical products each year.

3. One prescription drug that was developed, manufactured, promoted, and sold by **MERCK** was Vioxx, a pain relief medication. Vioxx was distributed by **MERCK** into interstate commerce in the United States, including specifically into Massachusetts, from in or about May 1999 through in or about September 2004, when **MERCK** withdrew Vioxx from the market.

The FDA and the FDCA

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

5. The FDCA and its implementing regulations required that before a new drug was legally distributed in interstate commerce, the sponsor of a new drug was required to submit a New Drug Application ("NDA") to the FDA.

6. The FDCA required that the NDA include proposed labeling for the proposed intended uses of the drug which included, among other things, the conditions for therapeutic use. The NDA was required to provide, to the satisfaction of FDA, data generated in adequate and well-controlled clinical investigations that demonstrated that the drug was safe and effective when used in accordance with the proposed labeling.

7. An NDA sponsor was not permitted to promote or market the drug until the FDA had approved an NDA, including approval of the proposed labeling. Moreover, if approved by the FDA, the sponsor of the NDA was permitted to promote and market the drug only for the medical conditions of use specified in the approved labeling. Uses not approved by the FDA were known as "unapproved"or "off-label" uses.

8. The FDCA, and its implementing regulations, required the sponsor to file a new NDA, or amend the existing NDA, in order to label or promote a drug for uses different from the conditions for use specified in the approved labeling. The new or amended NDA was required to include a description of the newly proposed indications for use and evidence, in adequate and well-controlled clinical investigations, sufficient to demonstrate that the drug was safe and effective for the newly proposed therapeutic use or uses. Only upon approval of the new NDA, or supplement, could the sponsor promote the drug for the new intended use.

9. Under the FDCA, a drug was "misbranded" if its labeling did not contain "adequate directions for use." 21 U.S.C. § 352(f)(1). "Adequate directions for use" meant directions under which a layperson could use a drug safely and effectively for the purposes for which it was intended. 21 C.F.R § 201.5. A prescription drug, by definition, could not bear adequate directions for use by a layperson, but an FDA-approved prescription drug, bearing the FDA-approved labeling, could be exempt from the adequate directions for use requirement if it was sold for an FDA-approved use. A prescription drug that was marketed for non-approved, off-label uses, did not qualify for this exemption and therefore was misbranded. 21 C.F.R. § 201.100.

10. The FDCA prohibited, among other things, the distribution in interstate commerce of a misbranded drug.

The Vioxx Approval Process

11. On or about November 23, 1998, **MERCK** submitted an NDA for approval of a drug called Vioxx (chemical name: rofecoxib), which was a new drug within the meaning of 21 U.S.C. §321(p) and 21 C.F.R. §310.3(h)(4) and (5). In that application, **MERCK** sought to demonstrate the drug's safety and efficacy for, and sought approval for, use for relief of the signs and symptoms of osteoarthritis, management of pain, and treatment of primary dysmenorrhea (the "Approved Uses"). On or about May 20, 1999, the FDA approved Vioxx for those uses and approved a label on that same date. Vioxx was not then approved for any use or condition other than the Approved Uses.

12. From at least May of 1999 through in or about April 2002, unapproved or off-label uses for Vioxx included the treatment of the signs and symptoms of rheumatoid arthritis.

13. In 1999, **MERCK** initiated a clinical trial, known as Vioxx Gastrointestinal Outcomes Research ("VIGOR"), designed to determine whether Vioxx was safer for the gastrointestinal tract than traditional pain relievers. The VIGOR trial was a prospective, randomized, double blind comparison of 50 mg of Vioxx and 1000 mg of naproxen in over 8,000 patients with rheumatoid arthritis. The VIGOR results were made public by **MERCK** and provided to the FDA in March 2000.

14. In February 2001, **MERCK** submitted a supplemental NDA seeking FDA approval of rheumatoid arthritis as an indication for use for Vioxx.

15. On or about April 11, 2002, the FDA approved Vioxx for the treatment of rheumatoid arthritis.

16. Between May 1999 and April 11, 2002, **MERCK** promoted Vioxx to physicians for the treatment of rheumatoid arthritis, an unapproved use, before there was an FDA approved indication for rheumatoid arthritis.

17. On September 17, 2001, the FDA sent **MERCK** a Warning Letter regarding **MERCK's** improper promotional practices in connection with its marketing of Vioxx. In that Warning Letter, among other things, the FDA stated that **MERCK** was promoting Vioxx for unapproved uses, including rheumatoid arthritis. In particular, the FDA's Warning Letter stated:

> Your [**MERCK's**] audio conferences are misleading because they promote Vioxx for unapproved uses. For example, in your June 21, 2000, conference, you claim that in the VIGOR study ". . . the Vioxx 50 milligrams a day and the Naprosyn, a gram a day, were absolutely equally effective in terms of treating the patients with rheumatoid arthritis." Your claim is misleading because it suggests that Vioxx is effective for the treatment of rheumatoid arthritis when this has not been demonstrated.

18. Both before and after receipt of the Warning Letter, **MERCK** through its representatives promoted Vioxx for rheumatoid arthritis without any FDA approved indication for rheumatoid arthritis. For example, various **MERCK** sales representatives recorded in their call notes instances of promoting Vioxx for rheumatoid arthritis, including the following:

- March 20, 2000 – Representative A recorded as an "accomplishment" that he was able to "gain agreement on use of Vioxx for Ra [rheumatoid arthritis]" with Physician 1.
- March 24, 2000 – Representative B noted as a "strategy" with Physician 2 that he would "Continue to push Vioxx past Celebrex. Build on story of RA pat[ient]

given 12.5 mg Vioxx."

- September 5, 2000 - Representative C noted as a "next call strategy" that she urged that Physician 3 "use [Vioxx] first line in OA and RA pts."
- September 15, 2000 – Representative D noted as an accomplishment in his interaction with Physician 4 that he had an "in depth talk on RA and OA and how Vioxx helps during a lunch tutorial."
- October 16, 2000 – Representative E noted as a "strategy" with Physician 5 that he would "reinforce efficacy of Vioxx vs Celebrex for RA and pain."
- June 27, 2001 – Representative F noted as an "accomplishment" that "v[ioxx] is eff[ective] in ra" in conversation with Physician 6.
- June 28, 2001 – Representative G noted as an "accomplishment" that she had "discussed" with Physician 7 "additional uses/benefits of V[ioxx]" which included rheumatoid arthritis.
- September 25, 2001 – Representative H noted as an "accomplishment" in a conversation with Physician 8 that he had "discussed Vioxx excellent efficacy and off-label use in RA."
- November 15, 2001 – Representative I noted as a "strategy" for his interaction with Physician 9 that he would "gain agreement that Vioxx can be used for RA."

COUNT ONE

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

19. The allegations in paragraphs 1 through 18 are realleged and incorporated by reference herein.

20. Beginning as early as May 1999, and continuing thereafter until on or about April 11, 2002, in the District of Massachusetts and elsewhere, the defendant,

MERCK SHARP & DOHME CORP.

did introduce and cause the introduction, and did deliver for introduction and cause for delivery for introduction into interstate commerce, quantities of Vioxx, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321(g), for an unapproved use, namely the treatment of rheumatoid arthritis, which drug was misbranded within the meaning of 21 U.S.C. §352(f)(1), in that Vioxx's labeling lacked adequate direction for such use.

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

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

By: Susan Winkler
JEREMY M. STERNBERG
SUSAN G. WINKLER
ZACHARY A. CUNHA
ASSISTANT U.S. ATTORNEYS

JILL P. FURMAN
ASSISTANT DIRECTOR
OFFICE OF CONSUMER LITIGATION

Exhibit Two

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"), the TRICARE Management Activity ("TMA"), through its General Counsel; the Office of Personnel Management ("OPM"), which administers the Federal Employees Health Benefits Program; and the United States Department of Veteran Affairs ("VA") (collectively the "United States"), and Merck Sharp & Dohme Corp. ("Merck") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. At all relevant times, Merck & Co., Inc. was a New Jersey corporation headquartered in Whitehouse Station, New Jersey, and was the operating company for Merck's pharmaceutical business in the United States. As a result of a reverse merger with another pharmaceutical company in 2009, Merck & Co., Inc. became a wholly-owned subsidiary of the acquiring company and was renamed Merck Sharp & Dohme Corp. The acquiring company was renamed Merck & Co., Inc. The new Merck & Co., Inc. is a holding company for Merck Sharp & Dohme Corp. and other corporate entities. Currently, Merck Sharp & Dohme Corp. is the operating company in the United States for the pharmaceutical business formerly conducted by Merck & Co., Inc.

B. Merck developed, marketed, sold, and distributed pharmaceutical products throughout the United States, including the drug Rofecoxib, which was sold and marketed under the brand name Vioxx® from May 1999 until September 30, 2004, when Merck withdrew Vioxx from the market.

C. On such date as may be determined by the Court, Merck has agreed to plead guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the "Plea Agreement") to an Information to be filed in United States of America v. Merck Sharp & Dohme Corp., Criminal Action No. [to be assigned] (District of Massachusetts) (the "Criminal Action"), that will allege a violation of Title 21, United States Code Sections 331(a), 333 (a)(1), 352(f)(1), to wit, that Merck introduced and caused the delivery for introduction into interstate commerce of quantities of Vioxx® for an unapproved use, namely the treatment of rheumatoid arthritis, which drug was misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDCA").

D. Certain states have filed civil actions against Merck that are now consolidated in *In re VIOXX Products Liability Litigation*, MDL No. 1657, a federal multi-district litigation venued in the United States District Court for the Eastern District of Louisiana (the "MDL Action") that allege that Merck caused false claims for Vioxx to be submitted to the Medicaid program ("Medicaid"), Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-1 (the "State Alleged Medicaid Conduct"). The state civil actions allege other, non-Medicaid claims and such claims are not a subject of this Agreement.

E. The United States contends that it has certain civil claims against Merck, as specified in Paragraph 2 below, for engaging in the following conduct concerning the marketing and sale of Vioxx®:

> (i) from May 20, 1999 through April 11, 2002, Merck promoted Vioxx® for rheumatoid arthritis, an indication for use not approved by the federal Food and Drug Administration ("FDA") in violation of the FDCA, 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1); and which, during the period May 20, 1999 through February 28, 2000, was not a medically accepted indication, as defined by 42 U.S.C. § 1396r-8(k)(6), covered by state Medicaid programs;

(ii) from April 2000 through September 30, 2004, when Merck withdrew Vioxx® from the market, Merck promoted the cardiovascular safety of Vioxx® with certain statements by representatives and promotional speakers in written materials that were inaccurate, misleading, and inconsistent with the approved labeling for the drug, in violation of the FDCA, 21 U.S.C. §§ 331(k), 333(a)(1); and 352(f)(1); and that through the sale and distribution of a misbranded product, Merck obtained proceeds and profits to which it was not entitled; and

(iii) from April 2000 through September 30, 2004, when Merck withdrew Vioxx from the market, Merck made false representations concerning the safety of Vioxx to state Medicaid agencies on which state Medicaid agencies relied to their detriment in making formulary and prior authorization decisions.

Merck's conduct as described in this Preamble Paragraph will hereafter be referred to as the "Covered Conduct."

F. The United States alleges that, as a result of the Covered Conduct, Merck knowingly caused false or fraudulent claims to be submitted for payment for Vioxx® to Medicaid; the TRICARE Program (formerly known as the Civilian Health and Medical Program of the Uniformed Services); the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901-8914; and caused purchases of Vioxx® by the Department of Veterans' Affairs ("DVA") (collectively, "the Federal Health Care Programs"). The United States contends that engaging in the Covered Conduct and causing the submission of false or fraudulent claims to the Federal Health Care Programs gives rise to civil liability under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq.; or common law.

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

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

I. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by Merck nor a concession by the United States that its claims are not well-founded. Merck expressly denies the contentions and allegations of the United States as set forth herein and denies that it engaged in any wrongful conduct, except as to such admissions that Merck makes in connection with the Plea Agreement. Neither this Agreement or 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 any party to this Agreement.

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

TERMS AND CONDITIONS

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

1. Merck shall pay to the United States and the Medicaid Participating States the sum of six hundred twenty eight million three hundred sixty four thousand dollars and 0/100 ($628,364,000.00) (the "Settlement Amount") and interest on the Settlement Amount at a rate of 2.125% from September 8, 2010, continuing until and including the day before payment is made. The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

a. Merck shall pay to the United States the sum of four hundred twenty six million three hundred eighty nine thousand dollars and 0/100 ($426,389,000), plus accrued interest on this amount at the rate of 2.125% per annum from September 8, 2010, continuing until and including the day before payment is made (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than seven (7) business days after (i) this Agreement is fully executed by the Parties and delivered to Merck's attorneys; or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as described in Preamble Paragraph C in connection with the Criminal Action and imposes the agreed upon sentence, whichever occurs later.

b. Subject to the terms and procedures referenced below, including the implementation of the individual Medicaid State Settlement Agreements, Merck shall pay to each of the Medicaid Participating States its respective allocated share of the sum of two hundred one million nine hundred seventy five thousand dollars and 0/100 ($201,975,000) plus accrued interest on this amount at the rate of 2.125% per annum from September 8, 2010, continuing until and

including the day before such payment is made (the "Medicaid State Settlement Amount"). The Medicaid State Settlement Amount shall be deposited by electronic funds transfer pursuant to written instructions from the NAMFCU Negotiating Team into one or more interest-bearing money market or bank accounts held in the name of Merck but segregated from other Merck accounts (the "State Settlement Accounts") no later than seven (7) business days after (i) this Agreement is fully executed by the Parties and delivered to Merck's attorneys; or (ii) the Court accepts a Fed. Crim. P. 11(c)(1)(C) guilty plea as described in Preamble Paragraph C in connection with the Criminal Action and imposes the agreed upon sentence, whichever occurs later. Funds from the State Settlement Accounts shall be administered pursuant to terms and conditions to be agreed upon by Merck and the NAMFCU Negotiating Team as set forth in the individual Medicaid State Settlement Agreements that Merck will enter into with the Medicaid Participating States.

c. If Merck's agreed-upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph C is not accepted by the Court or the Court does not impose the agreed-upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or Merck. If either the United States or Merck exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five (5) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Merck will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims, actions or proceedings arising from the Covered Conduct that are brought by the United States within 90 calendar days of rescission.

2. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, in consideration of the obligations of Merck set forth in this Agreement, and conditioned upon Merck"s payment in full of the Settlement Amount, the United States (on behalf of itself, its officers, agencies, and departments) agrees to release Merck, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees, assigns, and their current and former directors, officers, employees or agents, individually and collectively, from any civil or administrative monetary claim the United States has or may have for the Covered Conduct and the State Alleged Medicaid Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812, the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et. seq., any statutory provision creating a cause of action for civil damages or civil penalties 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 O, Subpart I, 0.45(d), and common law claims for fraud, payment by mistake, breach of contract, disgorgement and unjust enrichment.

3. In consideration of the obligations of Merck set forth in this Agreement and the Corporate Integrity Agreement ("CIA") entered into between OIG-HHS and Merck, and conditioned upon Merck's full payment of the Settlement Amount, OIG-HHS agrees to refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Merck under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activity) for the Covered Conduct and the State Alleged Medicaid Conduct, or under 42 U.S.C. § 1320a-7(b)(1)

based on Merck's agreement to plead guilty to the Criminal Action referenced in Paragraph C above, except as reserved in Paragraph 6 (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Merck from the Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct and the State Alleged Medicaid Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

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

5. In consideration of the obligations of Merck in this Agreement, conditioned upon Merck's full payment of the Settlement Amount, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking debarment from the FEHBP against Merck under 5 U.S.C. § 8902a or 5 C.F.R. Part 970 for the Covered Conduct and

the State Alleged Medicaid Conduct, except as reserved in Paragraph 6 (concerning excluded claims), below, and except if excluded by the OIG-HHS pursuant to 42 U.S.C. § 1320a-7(a) or required by 5 U.S.C. § 8902a(b), or 5 C.F.R. Part 970. Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

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

a. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct and the State Alleged Medicaid Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct or the State Alleged Medicaid Conduct; or

g. Any liability of individuals (including current or former directors, officers, employees, or agents of Merck) who receive written notification that they are the target of a criminal investigation, are criminally indicted or

charged, or are convicted, or who enter into a criminal plea agreement arising from the Covered Conduct or the State Alleged Medicaid Conduct.

7. Merck waives and shall not assert any defenses Merck 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, and Merck acknowledges that no characterization or opinion with respect to characterization of the Settlement Amount for purposes of the Internal Revenue laws has been made by the United States in connection with the resolution of the matters covered by this Agreement.

8. Merck fully and finally releases the United States, and its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Merck has asserted, could have asserted, or may assert in the future against the United States, and its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

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

previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

10. Merck agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Merck, 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 Medicaid Program and Federal Health Care Programs:

(1) the matters covered by this Agreement and the related Plea Agreement;

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

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

(4) the negotiation and performance of this Agreement and the related Plea Agreement;

(5) the payment Merck makes to the United States pursuant to this

Agreement; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to OIG-HHS. However, nothing in this paragraph 10.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Merck.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Merck, and Merck 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 Merck or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Merck further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph 10) 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 Merck 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. Merck agrees that the United States, at a minimum, shall be entitled to recoup from Merck 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 Merck or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph 10) on Merck or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Merck's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

11. Merck 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 Merck, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual

promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Merck was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

12. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 2 above or in Paragraph 13 (waiver for beneficiaries paragraph), below.

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

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

15. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

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

17. For purposes of construing this Agreement, this Agreement shall be deemed to

have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

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

19. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

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

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

22. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

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

/

/

/

/

/

THE UNITED STATES OF AMERICA

CARMEN M. ORTIZ
United States Attorney
District of Massachusetts

DATED:_____ **BY:** _____
Susan G. Winkler

DATED:_____ **BY:** _____
Jeremy M. Sternberg

DATED:_____ **BY:** _____
Zachary A. Cunha
Assistant United States Attorneys

THE UNITED STATES OF AMERICA

CARMEN M. ORTIZ
United States Attorney
District of Massachusetts

DATED:_____ **BY:** _____
Susan G. Winkler
Assistant United States Attorney

BY: _____
Jeremy M. Sternberg
Assistant United States Attorney

BY: _____
Zachary A. Cunha
Assistant United States Attorney

TONY WEST
Assistant Attorney General
Civil Division

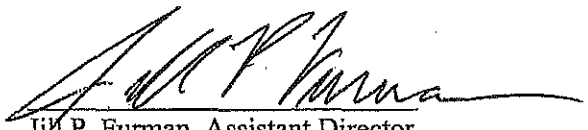
DATED: 11·17·11 **BY:** _____
Joyce R. Branda, Director
Jamie Ann Yavelberg, Assistant Director
Tracy Hilmer, Assistant Director
Commercial Litigation Branch, Civil Division
U.S. Department of Justice

BY: _____
Jill P. Furman, Assistant Director
Lauren Bell, Trial Attorney
James Nelson, Trial Attorney
Consumer Protection Branch, Civil Division
U.S. Department of Justice

TONY WEST
Assistant Attorney General
Civil Division

DATED:_____ **BY:** _____

Joyce R. Branda, Director
Jamie Ann Yavelberg, Assistant Director
Tracy Hilmer, Assistant Director
Commercial Litigation Branch, Civil Division
U.S. Department of Justice

BY: 

Jill P. Furman, Assistant Director
Lauren Bell, Trial Attorney
James Nelson, Trial Attorney
Consumer Protection Branch, Civil Division
U.S. Department of Justice

DATED: 11/21/11 BY: 

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

DATED: 11/17/11 BY: _____

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

DATED: 11/9/11 BY: Shirley R Patterson

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

DATED: 1/10/11

BY: _____

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

MERCK SHARP & DOHME CORP.

DATED: 11-22-11 **BY:** _____

Bruce N. Kuhlik
Executive Vice President & General Counsel
Merck & Co., Inc.

DATED:_____ **BY:** _____

Theodore V. Wells Jr., Esq.
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas, New York, NY 10019

DATED:_____ **BY:** _____

R.J. Cinquegrana, Esq.
Choate, Hall, & Stewart, LLP
Two International Place
Boston, MA 02210

MERCK SHARP & DOHME CORP.

DATED:_____ **BY:** _____

Bruce N. Kuhlik
Executive Vice President & General Counsel
Merck & Co., Inc.

DATED: 11.22.11 **BY:** Theodore V. Wells, Jr.

Theodore V. Wells Jr., Esq.
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas, New York, NY 10019

DATED: 11.22.11 **BY:** _____

R.J. Cinquegrana, Esq.
Choate, Hall, & Stewart, LLP
Two International Place
Boston, MA 02210

Exhibit Three

U.S. Department of Justice

Criminal Division

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

FEB 16 2011

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

Attention: Jack Pirozzolo
First Assistant United States Attorney

Re: Global Side Letter Agreement for Merck & Co, Inc.

Dear Ms. Ortiz:

This is in response to your request for authorization to enter into a Side Letter Agreement with the pharmaceutical company Merck & Co., Inc.

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

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

Sincerely,

Lanny A. Breuer
Assistant Attorney General

GREG D. ANDRES
DEPUTY ASSISTANT ATTORNEY GENERAL
CRIMINAL DIVISION