U.S. Department of Justice

Carmen M. Ortiz
United States Attorney
District of Massachusetts

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

April 26, 2010

Christopher A. Wray
Mark A. Jensen
King & Spalding LLP
1700 Pennsylvania Ave., N.W.
Washington, D.C. 20006

Robert L. Ullmann
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Blvd.
Boston, MA 02210

Re: United States v. Ortho-McNeil Pharmaceutical, LLC

Dear Counsel:

This letter sets forth the Agreement between the United States Attorney for the District of Massachusetts (the "U.S. Attorney") and the Department of Justice (collectively, the United States Department of Justice and the U.S. Attorney will be referred to as "the United States") and Ortho-McNeil Pharmaceutical, LLC, formerly known as Ortho-McNeil Pharmaceutical, Inc. ("OMP"):

1. Change of Plea

At the earliest practicable date, OMP shall plead guilty to the Information attached hereto as Exhibit A. The Information charges one count of misdemeanor misbranding a drug in violation of 21 U.S.C. §§331(a), 333(a)(1) and 352(f)(1). OMP expressly and unequivocally admits that it committed the crime charged in the attached Information and is in fact guilty of the offense. OMP agrees to waive venue, to waive any applicable statutes of limitations, and to waive any defects in the Information.

2. Penalties

OMP is subject to 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), (d). The gross gain resulting from the offense is $3,839,629. Thus the maximum fine is $7,679,258.

With respect to the count of conviction, OMP may be sentenced to a term of probation of not more than five (5) years. *See* 18 U.S.C. §3561(c)(2).

With respect to the count of conviction, OMP shall pay a special assessment of $125.00. *See* 18 U.S.C. §3013(a)(1)(B).

3. Criminal Fine/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 OMP's conduct under 18 U.S.C. §§3553 and 3572, as follows:

a. The pecuniary gain to OMP from the offense is $3,839,629.

b. Taking into account the nature and circumstances of the offense, among other factors, the appropriate multiplier is 1.6.

c. The resulting criminal fine is $6,143,407.

d. This agreed upon fine falls within the statutory maximum set forth in 18 U.S.C. §3571(d)(twice the gross gain or loss). The parties further agree that disgorgement is not necessary and that this fine amount will result in a reasonable sentence taking into consideration all of the factors set forth in 18 U.S.C. §§3553(a) and 3572.

4. Agreed Disposition

The United States and OMP agree pursuant to Fed. R. Crim. P. 11(c)(1)(C) that the following sentence is the appropriate disposition of the Information:

a. a criminal fine in the amount of $6,143,407 to be paid within two business days of the date of sentencing; and

b. a mandatory special assessment of $125 pursuant to 18 U.S.C. §3013, which shall be paid to the Clerk of Court on or before the date of sentencing; and

c. in light of the pending civil actions, including *United States ex rel. Maher, et al. v. Ortho-McNeil Pharmaceutical, Inc.*, C.A. No. 03-11445-WGY, and the Civil Settlement Agreement between OMP and others and the United States relating to the civil action which is being signed contemporaneously with this plea agreement, and attached hereto as Exhibit B, which requires the payment of

$75.37 million plus interest, 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, if any. *See*, 18 U.S.C. §3663(a)(1)(B)(ii). Therefore, the United States agrees that it will not seek a separate restitution order as to OMP 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 in this paragraph regarding the appropriate disposition of this case, if at any time between its execution of this Agreement and sentencing, OMP:

i. Fails to admit a complete factual basis for the plea;

ii. Fails to truthfully admit its conduct in the offense of conviction;

iii. Falsely denies, or frivolously contests, relevant conduct for which OMP is accountable under U.S.S.G. §1B1.3;

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

v. Engages in acts which form a basis for finding that OMP has obstructed or impeded the administration of justice under U.S.S.G. §3C1.1; and/or

vi. Attempts to withdraw its plea.

OMP 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 OMP

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 OMP for conduct which (a) falls within the scope of the Information; (b) was the subject of the investigation by the grand jury in Massachusetts; or (c) was known to the U.S. Attorney, related to Topamax, prior to the date of execution of this agreement. This declination is expressly contingent on:

(1) the guilty plea of OMP being accepted by the Court and not withdrawn;

(2) OMP's performance of all of its obligations as set forth in this Agreement. If

OMP's guilty plea is not accepted by the court or is withdrawn for any reason, or if OMP should fail to perform an obligation under this 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 OMP, in connection with the conduct encompassed by this plea agreement, within the scope of the grand jury investigation, or known to the U.S. Attorney.

6. Payment of Mandatory Special Assessment

OMP agrees to pay the mandatory special assessment to the Clerk of Court on or before the date of sentencing.

7. Cooperation

OMP shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing federal investigation of its current and former officers, agents, and employees relating to Topamax. OMP 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. OMP 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.

Provided, however, notwithstanding any provision of this agreement, that: (1) OMP 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) OMP is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) OMP is not required to waive any claim of privilege or work product protection.

In addition, OMP 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 grand jury investigation, trial or other criminal proceeding in the District of Massachusetts relating to Topamax, and that are not covered by the attorney-client privilege or work product doctrine.

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

OMP's plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). OMP 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 OMP.

OMP 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 OMP immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. OMP 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 United States does not compromise any civil or administrative liability, including but not limited to any False Claims Act or tax liability which OMP may have incurred or may incur as a result of its conduct and its plea of guilty to the attached Information.

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

11. Waiver of Defenses

If OMP's guilty plea is not accepted by the Court for whatever reason, or is later withdrawn for whatever reason, or if OMP breaches this Agreement, OMP hereby waives, and agrees it will not interpose, if charges are filed within six months of the date on which such guilty plea is rejected or withdrawn or a breach is declared by the USAO, 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 OMP may already have for conduct occurring before April 25, 2001.

12. Breach of Agreement

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

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

a. are wholly dependant upon OMP's timely compliance with the provisions of the attached Civil Settlement Agreement, including the requirement in the agreement that OMP pay to the United States and to the various state Medicaid Programs the amount of $75.37 million, plus interest continuing until and including the day before complete payment is made in accord with the terms of the Civil Settlement Agreement; and that

b. failure by OMP to comply fully with the terms of this Agreement or the attached Civil Settlement Agreement will constitute a breach of this Agreement.

In the event OMP at any time hereafter breaches any material provision of this Agreement, OMP 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 OMP as set forth in this Agreement; and (2) OMP 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, OMP 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 OMP may already have for conduct occurring before April 25, 2001.

13. Corporate Authorization

OMP's acknowledgment of this Agreement and execution of this Agreement on behalf of the corporation is attached as Exhibit C. OMP shall provide to the U.S. Attorney and the Court a certified copy of a resolution of Ortho-McNeil Pharmaceutical, LLC's governing authority, 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 OMP to plead guilty to the charge 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 D. OMP agrees that either a duly authorized corporate officer or a duly authorized attorney for OMP, at the discretion of the Court, shall appear on behalf of OMP and enter the guilty plea and will also appear for the imposition of sentence.

14. Who Is Bound By Agreement

This Agreement is binding upon OMP 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 on the matters set forth above in Paragraph 5. The non-prosecution provisions in Paragraph 5 are also binding on the Criminal Division of the United States Department of Justice. A copy of the letter to Acting United States Attorney Michael K. Loucks from Lanny A. Breuer, Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Agreement is attached as Exhibit E. OMP understands that this Agreement does not bind any state or local prosecutive authorities, the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury .

15. Complete Agreement

This Agreement contains the complete agreement between the parties relating to the disposition of this case. No promises, representations, agreements or conditions have been entered into other than those set forth in this 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 as agreed by the Parties on the record in court.

If this letter accurately reflects the Agreement entered into between the United States and your client, please have the authorized representative of Ortho-McNeil Pharmaceutical, LLC sign the Acknowledgment of Agreement below. Please also sign as Witness and return the original of this letter to Assistant U.S. Attorney Jeremy Sternberg of the United States Attorney's Office of the District of Massachusetts.

Very truly yours,

CARMEN M. ORTIZ
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

By: _____
JEREMY M. STERNBERG
Assistant U.S. Attorney
District of Massachusetts

By: _____
SUSAN G. WINKLER
Assistant U.S. Attorney
District of Massachusetts

ACKNOWLEDGMENT OF AGREEMENT

The Officers and Member (the "Board") have authorized me to execute this Plea Agreement on behalf of OMP. The Board has read this Plea Agreement and the attached criminal Information, in their entirety and has discussed them fully in consultation with OMP's attorney. The Board acknowledges that these documents fully set forth OMP's agreement with the United States. The Board further states that no additional promises or representations have been made to OMP by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement.

Dated: 4/27/2010

President
Ortho-McNeil Pharmaceuticals, LLC

Dated:

Christopher A. Wray
Mark A. Jensen
King & Spalding LLP
Counsel for Ortho-McNeil Pharmaceuticals, LLC

Robert L. Ullmann
Nutter McClennen & Fish LLP
Counsel for Ortho-McNeil Pharmaceuticals, LLC

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Dated:

_____
President
Ortho-McNeil Pharmaceuticals, LLC

Dated: 4/27/2010

_____
Christopher A. Wray
Mark A. Jensen
King & Spalding LLP
Counsel for Ortho-McNeil Pharmaceuticals, LLC

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Robert L. Ullmann
Nutter McClennen & Fish LLP
Counsel for Ortho-McNeil Pharmaceuticals, LLC

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Dated:

_____
President
Ortho-McNeil Pharmaceuticals, LLC

Dated: 4/27/2010

_____
Christopher A. Wray
Mark A. Jensen
King & Spalding LLP
Counsel for Ortho-McNeil Pharmaceuticals, LLC

_____
Robert L. Ullmann
Nutter McClennen & Fish LLP
Counsel for Ortho-McNeil Pharmaceuticals, LLC

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA)	**CRIMINAL NO.**
)	
)	**VIOLATIONS:**
)	**21 U.S.C. §§331(a), 333(a)(1) and 352(f)(1)**
)	**(distribution of a misbranded drug;**
v.)	**inadequate directions for use)**
ORTHO-MCNEIL)	
PHARMACEUTICAL, LLC,)	
Defendant.)	

INFORMATION

The United States Attorney charges that:

PRELIMINARY ALLEGATIONS

At all times material hereto, unless otherwise alleged:

The Defendant

1. **ORTHO-MCNEIL PHARMACEUTICAL, LLC**, formerly known as Ortho-McNeil Pharmaceutical, Inc., ("**ORTHO**") was a Delaware corporation with its principal place of business in Raritan, New Jersey. It was a subsidiary of Johnson & Johnson, a Delaware corporation with its principal place of business in New Brunswick, New Jersey, with publicly traded shares listed on the New York Stock Exchange (ticker symbol: JNJ).

Background

2. **ORTHO** was engaged in, among other things, the development, manufacture, promotion, sale and interstate distribution of prescription drugs intended for human use in the United States. **ORTHO** distributed prescription drugs or directed the distribution of prescription

drugs to all fifty states and the District of Columbia.

The FDA and the FDCA

3. 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 are safe and effective for their intended uses and that the labeling of such drugs bears true and accurate information.

4. The FDCA prohibited causing the delivery for introduction into interstate commerce of new drugs that are not approved for use by the FDA or drugs that are misbranded.

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

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 must also provide, to the satisfaction of FDA, data generated in adequate and well-controlled clinical investigations that demonstrated that the drug would be 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 it had an approved NDA, including approval for the proposed labeling. Moreover, if approved, the sponsor was permitted to promote and market the drug only for the medical conditions of use and dosages specified in the approved labeling. Uses not approved by the FDA, including dosages not approved in the drug's approved labeling, 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 and dosages different from the conditions for use and dosage specified in the approved labeling. The new or amended NDA must 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 will be 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. The FDCA provided that a drug was misbranded if, among other things, "its labeling is false or misleading in any particular." The FDCA also provided that a drug is misbranded if, among other things, the labeling does not contain adequate directions for use. As the phrase was used in the FDCA, adequate directions for use could not be written for medical indications or uses for which the drug had not been proven to be safe and effective through adequate and well-controlled clinical investigations.

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

The Topamax Approval Process

11. In or about 1994, as amended on June 27, 1996, **ORTHO** submitted an NDA for approval of a drug called Topamax (also known by the chemical name topiramate), 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, **ORTHO** sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy. On or about December 24, 1996, the FDA approved Topamax for that specific use

only. This approved use for Topamax will be referred to throughout this Information as the "Approved Use." Because **ORTHO** had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and efficacy of Topamax for any such uses, Topamax was not approved for any use or condition other than the Approved Use. Further, Topamax was not exempt, pursuant to 21 U.S.C. §355(i), from the prohibition of introducing into interstate commerce a new drug for medical indications beyond the conditions prescribed, recommended, or suggested in the approved labeling thereof.

12. From at least January of 2001 through in or about November of 2003, unapproved uses for Topamax included bipolar disorder, mood disorder, drug and alcohol dependence, and essential tremor, among other uses. These and other unapproved uses for Topamax will be collectively referred to herein as "Unapproved Uses."

13. **ORTHO** did not file a new NDA seeking FDA approval for any Unapproved Uses during the time period addressed in this Information.

14. However, **ORTHO** promoted Topamax to psychiatrists and other physicians for certain Unapproved Uses through a program known as the Doctor For A Day Program.

The Doctor For A Day Program

15. The Doctor For A Day Program was coordinated and approved by **ORTHO** management, and paid for by **ORTHO**. As part of the Doctor for A Day Program, a physician joined an **ORTHO** sales representative on a series of sales calls to physicians and made lunch and/or dinner presentations to a group of physicians on the attributes of Topamax. One of **ORTHO's** managers described the program as follows to one of his colleagues: "We currently run doc for a day program with our Topamax brand. Essentially, a clinician takes a full day out

of their practice, hence the cost of honorarium. The rep schedules a luncheon with their biggest practice and then coordinates field calls in the morning and afternoon with the MD accompanying them on their field day."

16. The **ORTHO** Doctor For A Day Program was promotional, and in some instances imparted off-label promotional messages to physicians. Some of the **ORTHO** sales representatives told doctors, in the presence of one particular Doctor For A Day, that "he can talk to you about things I can't talk to you about."

17. Payments for the **ORTHO** Doctor For A Day program were often made out of a Topamax Target Marketing Account. The fee for a Doctor For A Day ranged between $1,500 and $3,000 plus expenses.

18. An e-mail to **ORTHO's** National Sales Manager described the physicians participating in the Doctor For A Day program as functioning like "sales reps" who would be "paraded from office to office. . ."

19. **ORTHO**'s sales representatives who used the Doctor For A Day Program sometimes prepared Return on Investment ("ROI") forms. Generally, the ROI was positive (on average in excess of 4x), including in the areas of Unapproved Uses.

20. Most of **ORTHO's** sales calls made during the Doctor For A Day Program were unsolicited.

21. One **ORTHO** sales representative touted in writing to **ORTHO** management, in or about September 2001, that "[t]he physicians seem to be responding well [to the visit by the Doctor For A Day]. Many have dabbled in off label areas . . ."

22. Another **ORTHO** sales representative touted in writing to **ORTHO** management, on

or about November 2001, after a visit by a Doctor For A Day (Dr. O): "I tried to have him see doctors that were medium to hi volume that had very low to no topamax usage. All of the doctors committed to trying it [Topamax] for at least one of the areas that he spoke about." Some of these areas included certain Unapproved Uses.

23. **ORTHO** used a number of different doctors as Doctors For A Day. One of the most heavily used was Dr. O, a general neurologist with an interest in using Topamax for a variety of off-label uses, including essential tremor. **ORTHO** used Dr. O as a Doctor For a Day approximately 200 times in many states throughout the country and paid him in excess of $500,000 for his efforts.

24. On March 11, 2003, Dr. O, as part of the Doctor For A Day Program, made sales visits with an **ORTHO** sales representative to two psychiatrists, among other physicians, and promoted Topamax for certain Unapproved Uses.

25. In the course of **ORTHO's** use of Dr. O as part of the Doctor For A Day Program, **ORTHO** used him to promote Topamax to psychiatrists and at psychiatric institutions for certain Unapproved Uses.

26. During **ORTHO's** use of Dr. O as a Doctor For A Day, Dr. O made dosing suggestions for Topamax to physicians, including 100-400 mg for tremor, an off-label use. Some **ORTHO** sales representatives made dosing cards with these off-label dosing suggestions so that they could refer to these cards on sales calls when Dr. O was not with them.

27. **ORTHO** also used other Doctors For A Day, including a headache specialist, Dr. L, who visited many psychiatrists on sales calls with Topamax representatives.

28. **ORTHO** also used two physicians who were trained as both neurologists and

psychiatrists, both of whom were practicing psychiatrists, Dr. A and Dr. J, as Doctors For A Day. **ORTHO** used these Doctors For A Day to promote Topamax, including to psychiatrists, for certain Unapproved Uses.

29. Dr. A accompanied **ORTHO** sales representatives on a number of sales calls to psychiatrists and touted its use for mood stabilization and certain other Unapproved Uses. Dr. A provided Topamax dosing suggestions to physicians during the Doctor For A Day Program for a number of psychiatric related conditions.

30. In 2002, an **ORTHO** sales representative visited a psychiatrist in Worcester, Massachusetts with Dr. O, a Doctor For A Day, who told the psychiatrist in Worcester that Topamax was effective for treating bipolar disorder.

31. **ORTHO** noted in March 2002 in evaluating Dr. J that his best use is in "nonepilepsy use of Topamax," an interesting comment when epilepsy was the only area in which Topamax was FDA approved. After a particular Doctor For A Day Program involving Dr. J, **ORTHO** also noted that after Dr. J had spoken to a psychiatrist, "[b]ased on his [Dr. J's] presentation, she will start to use Topamax."

32. On March 18, 2001, **ORTHO** conducted a Doctor For A Day Program in Massachusetts using Dr. O, one of several Doctor For A Day Programs conducted by **ORTHO** in Massachusetts.

33. On numerous occasions in 2001, 2002 and 2003, **ORTHO** distributed a shipment of Topamax from outside of Massachusetts to Massachusetts.

COUNT ONE

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

34. The allegations in paragraphs 1 through 33 are realleged and incorporated by reference herein.

35. Beginning as early as January 2001, and continuing thereafter until in or about November 2003, in the District of Massachusetts and elsewhere, the defendant,

ORTHO-MCNEIL PHARMACEUTICAL, LLC

did, through its Doctor For A Day Program, introduce and cause the introduction into interstate commerce, directly and indirectly, into Massachusetts and elsewhere, quantities of Topamax, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321(g), which was approved for use for the treatment of epilepsy, for other unapproved uses, which was misbranded within the meaning of 21 U.S.C.§352(f)(1), in that Topamax's labeling lacked adequate direction for such uses.

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

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

By: _____
JEREMY M. STERNBERG
SUSAN G. WINKLER
ASSISTANT U.S. ATTORNEYS

JILL FURMAN
DEPUTY DIRECTOR
OFFICE OF CONSUMER LITIGATION

EXHIBIT B

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 and on behalf of the Office of Inspector General ("HHS-OIG") of the Department of Health and Human Services ("HHS"), TRICARE Management Activity ("TMA"), and the United States Office of Personnel Management ("OPM"), (collectively the "United States"); the Relators as identified in Paragraphs B and C of the Preamble to this Agreement ("Relators"); and Ortho-McNeil-Janssen Pharmaceuticals, Inc. 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. Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMJPI") is a Pennsylvania corporation headquartered in Titusville, New Jersey. OMJPI has developed, manufactured, distributed, marketed and sold pharmaceutical products in the United States, including a drug sold under the trade name of Topamax®.

B. On or about August 5, 2003, Angela Maher and Anastasia Savka-Klovski (collectively, the "Maher Relators") filed a qui tam action in the United States District Court for the District of Massachusetts captioned United States ex rel. Maher, et al. v. Ortho-McNeil Pharmaceutical, Civil Action No. 03-11445-WGY (D. Mass.). On or about May 30, 2006, the Maher Relators filed a Fourth Amended Complaint in the District of Massachusetts under the same caption and case number, and this Fourth Amended Complaint sets forth the current allegations in the qui tam action;

C. On or about December 2, 2003, Dr. Gary R. Spivack filed a qui tam action in the United States District Court for the Eastern District of New York captioned United States ex rel. Spivack v. Johnson & Johnson, and Ortho-McNeil Pharmaceutical Inc., Civil Action No. CV-03-6075 (JBW) (E.D.N.Y.), and, on or about August 12, 2004, the action was transferred pursuant to 28 U.S.C. § 1404(a) to the District of Massachusetts, where it was assigned docket number 04-CV-11886-MLW. On or about December 7, 2007, Dr. Spivack filed a Second Amended Complaint in the same court under the same caption and case number, and this Second Amended Complaint sets forth the current allegations in the qui tam action;

The qui tam actions identified above in Paragraphs (B) and (C) shall be referred to collectively as the "Civil Actions."

D. Ortho-McNeil Pharmaceutical, LLC has agreed to enter into a plea agreement with the United States Attorney for the District of Massachusetts and the Office of Consumer Litigation of the Department of Justice and has agreed to plead guilty, pursuant to Fed. R. Crim. P. 11, to specific conduct described in the plea agreement to be filed in United States v. Ortho-McNeil Pharmaceutical, LLC, Criminal Action No. [to be assigned] (District of Massachusetts) (the "Federal Criminal Action").

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

F. The United States alleges that OMJPI caused to be submitted claims for payment for Topamax® to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v. The United States further alleges that OMJPI caused claims for payment for Topamax® 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 Topamax® by the Department of Veterans' Affairs ("DVA").

G. The United States contends that it and the Medicaid Participating States have certain civil claims against OMJPI, as specified in Paragraph 2 below, for engaging in the following conduct concerning the marketing, promotion and sale of Topamax® (hereinafter the "Covered Conduct"):

> During the period January 1, 2001 through December 31, 2003, OMJPI illegally marketed Topamax® by, *inter alia*, promoting the sale and use of Topamax® for a variety of psychiatric conditions (including, but not limited to, bipolar disorder and drug and alcohol dependency) other than those for which its use was approved by the Food and Drug Administration ("FDA") (i.e., "off-label" uses), in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331, et seq. Certain of these uses were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which State Medicaid programs provided coverage. As a result, OMJPI knowingly caused false or fraudulent claims for Topamax® to be submitted to, or caused purchases by, Medicaid, the TRICARE Program, FEHBP, and the DVA.

H. The United States also contends that it has certain administrative claims against OMJPI, as specified in Paragraphs 4 through 6 below, for engaging in the Covered Conduct;

I. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts nor liability by OMJPI nor a concession by the Government that its claims are not well founded;

J. With the exception of such admissions that are made in connection with any guilty plea by Ortho-McNeil Pharmaceutical, LLC in connection with the Federal Criminal Action, OMJPI expressly denies the allegations of the United States and the Relators as set forth herein and in the Civil Actions and denies that it has engaged in any wrongful conduct in connection with the Covered Conduct;

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. OMJPI agrees to pay to the United States and the Medicaid Participating States collectively, the sum of seventy-five million three hundred and seventy-three thousand dollars ($75,370,000.00), plus interest at the rate of 3.25 percent per annum from August 1, 2009, and continuing until and including the day before payment is made under this Agreement (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) OMJPI shall pay to the United States the sum of $50,688,483.52, plus interest accrued on this amount at the rate of 3.25 percent per annum from August 1, 2009, continuing until and including the day before payment is made ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than seven (7) business days after (i) this Agreement is fully executed by the Parties and delivered to OMJPI's attorneys; or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as described in Preamble Paragraph D in connection with the Federal Criminal Action and imposes the agreed-upon sentence, whichever occurs later.

(b) OMJPI shall pay to the Medicaid Participating States the sum of $24,681,516.48, plus interest accrued on this amount at the rate of 3.25 percent per annum from August 1, 2009, continuing until and including the day before payment is made ("Medicaid State Settlement Amount"). The Medicaid State Settlement Amount shall be paid by electronic funds transfer to an interest bearing account pursuant to the written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the Medicaid State Settlement Agreements that OMJPI will enter into with the Medicaid Participating States no later than seven (7) business days after (i) this Agreement is fully executed by the Parties and delivered to OMJPI's attorneys; or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as described in Preamble Paragraph D in connection with the Federal Criminal Action and imposes the agreed-upon sentence, whichever occurs later.

(c) Contingent upon the United States receiving the Federal Settlement Amount from OMJPI, the United States agrees to pay, as soon as feasible after receipt,

to the Maher Relators $9,123,927.00, plus the pro rata share of the actual accrued interest paid to the United States by OMJPI on the amount set forth in Paragraph 1(a) above. No other relator payments shall be made by the United States with respect to the matters covered by this Agreement. All Relators represent that they have entered into separate agreements concerning the allocation of the Relators' Share among themselves.

2. Subject to the exceptions in Paragraph 7 (concerning excluded claims), below, in consideration of the obligations of OMJPI set forth in this Agreement, conditioned upon OMJPI's payment in full of the Settlement Amount, the United States (on behalf of itself, its officers, agencies, and departments) agrees to release OMJPI, its predecessors, and its current and former divisions, parents, subsidiaries, successors and assigns and their current and former directors, officers, and employees from any civil or administrative monetary claim that the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; 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 0, Subpart I, 0.45(d) and common law claims for fraud, payment by mistake, disgorgement and unjust enrichment.

3. Subject to the exceptions in Paragraph 7 (concerning excluded claims), below, in consideration of the obligations of OMJPI in this Agreement, conditioned upon OMJPI's full payment of the Settlement Amount, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, agree to release OMJPI, its

predecessors, and its current and former divisions, parents, subsidiaries, successors and assigns and their current and former directors, officers, and employees from any civil monetary claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733, for the Covered Conduct; provided, however, that Relators do not release OMJPI for any claims under 31 U.S.C. §§ 3730(d).

4. In consideration of the obligations of OMJPI set forth in this Agreement and the Corporate Integrity Agreement ("CIA") entered into between HHS-OIG and OMJPI, conditioned upon OMJPI's full payment of the Settlement Amount, HHS-OIG agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the Medicare, Medicaid and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against OMJPI under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims), below, and as reserved in this Paragraph. HHS-OIG expressly reserves all rights to comply with any statutory obligations to exclude OMJPI 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. Nothing in this Paragraph precludes HHS-OIG from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

5. In consideration of the obligations of OMJPI set forth in this Agreement and, conditioned upon OMJPI's payment in full 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 OMJPI, its predecessors, and its current and former divisions, parents, affiliates, subsidiaries, successors and assigns, and their current and former directors, officers, and employees under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 7 below (concerning excluded claims), and as reserved in this Paragraph. TMA expressly reserves authority to exclude OMJPI 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, for conduct and practices, for which claims have been reserved in Paragraph 7, below.

6. In consideration of the obligations of OMJPI set forth in this Agreement and conditioned upon OMJPI's full payment of the Settlement Amount, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action against OMJPI, its predecessors, and its current and former divisions, parents, affiliates, subsidiaries, successors and assigns, and their current and former directors, officers, and employees under 5 U.S.C. § 8902a or 5 C.F.R. Part 970 for the Covered Conduct, except as reserved in Paragraph 7 below (concerning excluded claims), except if required by 5 U.S.C. § 8902a(b). Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including OMJPI and the Relators) are the following claims of the United States:

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

(b) Any criminal liability;

(c) Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs, suspension, 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 defective or deficient products and services, including quality of goods and services;

(g) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or

(h) Any liability for failure to deliver items or services due.

8. Each Relator, and his/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 for 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, Relators for themselves individually, and for their heirs, successors, agents, and assigns, fully and finally release, waive, and forever discharge 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 their respective Civil Actions; and from any other claims for a share of the Federal Settlement Amount; and in full settlement of any claims Relators 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 Relators arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement. Relators do not release the Medicaid Participating States from any claims that Relators have for a share of any settlement or judgment obtained by the Medicaid Participating States concerning the Covered Conduct.

9. Conditioned upon receipt of the payments described in Paragraph 1(c), above, Relators, for themselves, and for their respective heirs, successors, attorneys, agents, and assigns, hereby fully and finally release and forever discharge OMJPI, its predecessors, and its parents, subsidiaries, divisions, related entities, officers, directors, trustees, agents, servants, employees, representatives, attorneys, consultants, successors, heirs, executors, administrators and assigns, individually and collectively, current or former (collectively, "the OMJPI entities"), from any and all claims for relief, actions, rights, causes of action, suits, debts, obligations, liabilities, demands, losses, damages (including treble damages and any civil penalties), punitive damages, costs and expenses of any kind, character or nature whatsoever, known or unknown, fixed or contingent, in law or in equity, in contract or tort, or under any state or federal statute or regulation or otherwise that Relators have standing to bring, which Relators may now have or claim to have against the OMJPI entities, arising in any way out of or connected in any way with the facts, claims, and circumstances alleged in, arising under, or arising from the filing of, the Civil Actions, or from any other past activities and actions of the OMJPI entities, with the

following exceptions: (a) Relators do not release the OMJPI entities for any claims that Relators have for expenses, reasonable attorneys' fees, and costs pursuant to 31 U.S.C. § 3730(d); and (b) Relator Spivack does not agree to release pending claims, if any, against the OMJPI entities brought by Relator Spivack in other jurisdictions under state laws other than state false claims acts.

10. OMJPI 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.

11. OMJPI 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 OMJPI has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct or arising from the United States' investigation and prosecution of the Civil Actions and the Criminal Action.

12. In consideration of the obligations of the Relators set forth in this Agreement, OMJPI, 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 Relators and their

respective heirs, successors, assigns, agents, and attorneys from any claims or allegations OMJPI has asserted or could have asserted arising from the Covered Conduct or related to the initiation, investigation, and/or prosecution of the Civil Actions by Relators or their attorneys, except as they relate to a claim by Relators for reasonable attorneys' fees, expenses and costs pursuant to 31 U.S.C. § 3730(d).

13. 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 OMJPI 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.

14. OMJPI 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 OMJPI, 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) OMJPI'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 OMJPI 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 OMJPI may make to Relators;

(6) the negotiation of, and the obligations undertaken pursuant to, the CIA to:

(i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and

(ii) prepare and submit reports to HHS-OIG.

However, nothing in this Paragraph 14.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 OMJPI. All costs described or set forth in this Paragraph 14.a are hereafter "Unallowable Costs."

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

(c) Treatment of Unallowable Costs Previously Submitted for Payment:

OMJPI 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 OMJPI 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. OMJPI agrees that the United States, at a minimum, shall be entitled to recoup from OMJPI 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 OMJPI or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on OMJPI 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 OMJPI's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

15. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in

Paragraph 16 below (waiver for beneficiaries paragraph).

16. OMJPI 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 as Covered Conduct.

17. OMJPI 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 OMJPI, 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 OMJPI 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. On the Effective Date of this Agreement or within seven (7) business days of the OMJPI payments rendered in Paragraph III.1, above:

(a) The United States shall file a Notice of Intervention in Part and Declination in Part in each of the Civil Actions as follows:

(1) the United States shall intervene as to the applicable Covered Conduct; and

(2) the United States shall decline or consent to the voluntary dismissal as to all other allegations set forth in the Civil Actions.

(b) Following payment of the Settlement Amount, the Parties shall file a stipulation of dismissal in each of the Civil Actions as follows:

(1) each stipulation of dismissal shall be with prejudice as to the United States' and Relators' claims as to the Covered Conduct in each Civil Action pursuant to and consistent with the terms and conditions of this Agreement;

(2) each stipulation of dismissal shall be without prejudice as to the United States and with prejudice as to Relators as to all other entities and individuals and as to all other claims;

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

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 Relators' attorneys' fees reserved in Paragraph 3, shall be the United States District Court for the District of Massachusetts, except that any disputes arising under the CIA shall be resolved exclusively through the dispute resolution provisions set forth in the CIA.

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

23. 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 OMJPI represent and warrant that they are authorized by OMJPI to execute this Agreement. The individuals signing this Agreement on behalf of each Relator represent and warrant that they are authorized by that Relator to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement.

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

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

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

28. All parties consent to the United States' 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 OMJPI. If either the United States or OMJPI 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, OMJPI waives any affirmative defenses based in whole or in part on the running of the statute of limitations during the period from the Effective Date of this Agreement through 30 days after the effective date of the rescission.

UNITED STATES OF AMERICA

TONY WEST
Assistant Attorney General

By: _____ Dated: 4/23/10
JOYCE R. BRANDA
Director
COLIN M. HUNTLEY
Trial Attorney
Commercial Litigation Branch, Civil Division
United States Department of Justice

CARMEN M. ORTIZ
United States Attorney, District of Massachusetts

By: _____ Dated: 4/27/2010
ZACHARY A. CUNHA
Assistant U.S. Attorney
United States Attorney's Office
District of Massachusetts

By: _____ Dated: 4/28/10

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

By: Rhonda L. Bershok (Acting Deputy Gen. Counsel) Dated: April 23, 2010
For: LAUREL C. GILLESPE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

By: _____ Dated: 4-22-10

SHIRLEY R. PATTERSON
Acting Deputy Associate Director
for Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

By: _____ Dated: 4/22/2010

J. DAVID COPE
Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.

By: _____ Dated: 4/27/2010
MICHELLE R. RYAN
Officer
Ortho-McNeil-Janssen Pharmaceuticals, Inc.

By: _____ Dated: _____
CHRISTOPHER A. WRAY
King & Spalding LLP
Counsel for Ortho-McNeil-Janssen Pharmaceuticals, Inc.

By: _____ Dated: _____
MARK A. JENSEN
King & Spalding LLP
Counsel for Ortho-McNeil-Janssen Pharmaceuticals, Inc.

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.

By: _____ Dated: _____

MICHELLE R. RYAN
Officer
Ortho-McNeil-Janssen Pharmaceuticals, Inc.

By: _____ Dated: 4/27/2010

CHRISTOPHER A. WRAY
King & Spalding LLP
Counsel for Ortho-McNeil-Janssen Pharmaceuticals, Inc.

By: _____ Dated: 4/27/2010

MARK A. JENSEN
King & Spalding LLP
Counsel for Ortho-McNeil-Janssen Pharmaceuticals, Inc.

RELATORS

By: Angela Maher Dated: 4/23/2010
ANGELA MAHER
Relator

By: _____ Dated: _____
ANASTASIA SAVKA-KLOVSKI
Relator

By: _____ Dated: 4/23/2010
DAVID L. HARON
MONICA P. NAVARRO
Frank, Haron, Weiner and Navarro
Counsel for Relators Maher and Savka-Klovski

By: _____ Dated: _____
DR. GARY R. SPIVACK
Relator

By: _____ Dated: _____
ERIKA A. KELTON
LARRY P. ZOGLIN
Phillips & Cohen LLP
Counsel for Relator Spivack

RELATORS

By: _____ Dated: _____
ANGELA MAHER
Relator

By: Anastasia Savka-Klovski Dated: April 22, 2010
ANASTASIA SAVKA-KLOVSKI
Relator

By: _____ Dated: _____
DAVID L. HARON
MONICA P. NAVARRO
Frank, Haron, Weiner and Navarro
Counsel for Relators Maher and Savka-Klovski

By: _____ Dated: _____
DR. GARY R. SPIVACK
Relator

By: _____ Dated: _____
ERIKA A. KELTON
LARRY P. ZOGLIN
Phillips & Cohen LLP
Counsel for Relator Spivack

RELATORS

By: _____ Dated: _____
ANGELA MAHER
Relator

By: _____ Dated: _____
ANASTASIA SAVKA-KLOVSKI
Relator

By: _____ Dated: _____
DAVID L. HARON
MONICA P. NAVARRO
Frank, Haron, Weiner and Navarro
Counsel for Relators Maher and Savka-Klovski

By: _____ Dated: 4/23/10
DR. GARY R. SPIVACK
Relator

By: Erin A. Kelton Dated: 4/26/10
ERIKA A. KELTON
LARRY P. ZOGLIN
Phillips & Cohen LLP
Counsel for Relator Spivack

EXHIBIT C

ACKNOWLEDGMENT OF AGREEMENT

The Officers and Member (the "Board") have authorized me to execute this Plea Agreement on behalf of OMP. The Board has read this Plea Agreement and the attached criminal Information, in their entirety and has discussed them fully in consultation with OMP's attorney. The Board acknowledges that these documents fully set forth OMP's agreement with the United States. The Board further states that no additional promises or representations have been made to OMP by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement.

Dated: 4/27/2010

President
Ortho-McNeil Pharmaceuticals, LLC

Dated:

Christopher A. Wray
Mark A. Jensen
King & Spalding LLP
Counsel for Ortho-McNeil Pharmaceuticals, LLC

Robert L. Ullmann
Nutter McClennen & Fish LLP
Counsel for Ortho-McNeil Pharmaceuticals, LLC

ACKNOWLEDGMENT OF AGREEMENT

The Officers and Member (the "Board") have authorized me to execute this Plea Agreement on behalf of OMP. The Board has read this Plea Agreement and the attached criminal Information, in their entirety and has discussed them fully in consultation with OMP's attorney. The Board acknowledges that these documents fully set forth OMP's agreement with the United States. The Board further states that no additional promises or representations have been made to OMP by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement.

Dated:

_____
President
Ortho-McNeil Pharmaceuticals, LLC

Dated: 4/27/2010

_____
Christopher A. Wray
Mark A. Jensen
King & Spalding LLP
Counsel for Ortho-McNeil Pharmaceuticals, LLC

_____
Robert L. Ullmann
Nutter McClennen & Fish LLP
Counsel for Ortho-McNeil Pharmaceuticals, LLC

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President
Ortho-McNeil Pharmaceuticals, LLC

Dated: 4/27/2010

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Christopher A. Wray
Mark A. Jensen
King & Spalding LLP
Counsel for Ortho-McNeil Pharmaceuticals, LLC

_____
Robert L. Ullmann
Nutter McClennen & Fish LLP
Counsel for Ortho-McNeil Pharmaceuticals, LLC

EXHIBIT D

EXHIBIT D

ORTHO-MCNEIL PHARMACEUTICAL, LLC

SECRETARY'S CERTIFICATE

I, Patricia C. Lukens, do hereby certify that I am Secretary of Ortho-McNeil Pharmaceutical, LLC, (the "Company"), and do hereby further certify that:

Attached hereto as Annex A is a true, correct, and complete copy of the resolutions of the Officers and Member of the Company adopted as of the 27th of April 2010. Such resolutions have not been modified, amended or rescinded and remain in full force and effect as of the date hereof.

IN WITNESS WHEREOF, I have executed this Certificate on behalf of the Company on this 27 day of April 2010.

ORTHO-MCNEIL PHARMACEUTICAL, LLC

By: Patricia C Lukens

Name: Patricia C. Lukens
Title: Secretary

ANNEX A

ORTHO-MCNEIL PHARMACEUTICAL, LLC
UNANIMOUS WRITTEN CONSENT OF THE
OFFICERS AND MEMBER

The undersigned, acting for the Member (the "Member") of Ortho-McNeil Pharmaceutical, LLC (the "Company"), hereby waive all notice of the time, place or purpose of a meeting and consent to, approve and adopt the following resolutions without a meeting:

WHEREAS, the Officers and Member (the "Board") of the Company have authority to enter into the plea agreement (the "Plea Agreement") in connection with United States of America v. Ortho-McNeil Pharmaceutical, LLC (the "Case");

WHEREAS, the Board has reviewed in its entirety the criminal Information (the "Information") charging the Company in the Case and the Plea Agreement;

WHEREAS, the Board has consulted with legal counsel, including a full discussion of the Plea Agreement and Information;

WHEREAS, the Board has been advised of the contents of the Information, as well as of the Plea Agreement and its Exhibits (collectively, the "Documents"), and has discussed the Documents fully with the Company's legal counsel;

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

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

FURTHER RESOLVED, that Michelle R. Ryan, an officer of the Company, or any other officer of the Company, is hereby authorized and directed to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement;

FURTHER RESOLVED, that a duly authorized corporate officer or a duly authorized attorney for the Company is hereby authorized and directed to appear (1) on behalf of the Company and enter such guilty plea and (2) for the imposition of the sentence; and

FURTHER RESOLVED, that Michelle R. Ryan, an officer of the Company, or any other officer of the Company, and Christopher A. Wray, a duly authorized attorney for the Company, are hereby authorized and directed to acknowledge, on behalf of the Company, that the Documents fully set forth the agreements made between the Company and the United States and that no additional promises or representations have been made to the Company by any officials of the United States in connection with the Plea Agreement, other than those set forth in the Documents.

IN WITNESS WHEREOF, the undersigned have executed this consent as of the 27 of April, 2010.

Michelle R. Ryan, Officer

Patricia C. Lukens, Officer, on behalf of the Member

Marci A. Blazer, Officer

Douglas K. Chia, Officer

Laurence S. Rickles, Officer

John F. Sharkey, Officer

IN WITNESS WHEREOF, the undersigned have executed this consent as of the 27 of April, 2010.

Michelle R. Ryan, Officer

Patricia C. Lukens, Officer, on behalf of the Member

Marci A. Blazer, Officer

Douglas K. Chia, Officer

Laurence S. Rickles, Officer

John F. Sharkey, Officer

EXHIBIT E

U.S. Department of Justice

Criminal Division

Office of the Assistant Attorney General *Washington, D.C. 20530*

NOV - 3 2009

The Honorable Michael K. Loucks
Acting United States Attorney
District of Massachusetts
Boston, Massachusetts 02210

Attention: Jeremy M. Sternberg
Assistant United States Attorney

Re: Global Non-prosecution Agreement for Ortho-McNeil Pharmaceutical, LLC

Dear Mr. Loucks:

This is in response to your request for authorization to enter into a global case disposition agreement with the business entity known as Ortho-McNeil Pharmaceutical, LLC.

I hereby approve the terms of the Plea Agreement, including Paragraphs 5 and 14, in which the United States Attorney's Offices and 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,

Lanny A. Breuer
Assistant Attorney General

BRUCE C. SWARTZ
DEPUTY ASSISTANT ATTORNEY GENERAL
CRIMINAL DIVISION