

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 of the Department of Health and Human Services (“OIG-HHS”) (collectively the “United States”); Bernard Lisitza (“Relator”); and Johnson & Johnson, Johnson & Johnson Health Care Systems, Inc. (“JJHCS”) and Janssen Pharmaceuticals, Inc. (“Janssen”) (collectively, “Defendants”). Collectively, all of the above will be referred to as “the Parties.”

II. RECITALS

A. Johnson & Johnson is a New Jersey corporation headquartered in New Brunswick, New Jersey. JJHCS and Janssen are subsidiaries of Johnson & Johnson. JJHCS is a New Jersey corporation headquartered in Piscataway, New Jersey. Janssen is a Pennsylvania corporation headquartered in Titusville, New Jersey and is the successor in interest to Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Products, L.P., and Ortho-McNeil Pharmaceutical Products, Inc.

B. On October 28, 2003, Relator filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned *United States ex rel. Lisitza v. Pfizer, Inc., Bristol Myers Squibb Co., and Ortho-McNeil Pharmaceutical, Inc.*, No. 03-5958, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), which was subsequently transferred to the District of Massachusetts and captioned as Case No. 07-10288 (the “*Lisitza* action”). On April 20, 2005, David Kammerer filed a *qui tam* action in the United States District Court for the Southern District of Illinois, captioned *United States ex rel. Kammerer v. Abbott Labs., et al.*, Case No. 05-286, which was transferred to the District of Massachusetts and captioned as Case No. 05-11518 (the “*Kammerer* action”). The United States moved for leave to intervene in the *Lisitza* and *Kammerer* actions on December 15, 2009, and filed its Complaint-in-Intervention on January 15, 2010 (“Complaint-in-Intervention”). On February 25, 2011, the Court dismissed David Kammerer as a relator in the *Kammerer* action.

C. Defendants have entered or will be entering into separate settlement agreements, described in Paragraph III.1(b) below (the “Medicaid State Settlement Agreements”) with the States of California, Indiana, Kentucky, Massachusetts, and Virginia (the “Five Intervening States”) in settlement of the Covered Conduct, defined below.

D. The United States contends that Defendants caused claims for payment for the drugs Risperdal®, Duragesic®, Aciphex®, Propulsid®, Levaquin®, Ultram®, and Procrit® to be submitted to the Medicaid program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”).

E. The United States contends that it has certain civil claims against Defendants arising from their conduct in causing the submission of claims to Medicaid, as specified in the United States’ Complaint-in-Intervention. That conduct is referred to herein as the “Covered Conduct.”

F. The United States also contends that it has certain administrative claims against Defendants as specified in Paragraph III.4, below, for engaging in the Covered Conduct.

G. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by Defendants, nor a concession by the United States that its claims are not well founded. Defendants expressly deny the allegations of the United States and Relator as set forth herein and in the *Lisitz* and *Kammerer* actions and deny that they engaged in any wrongful conduct in connection with the Covered Conduct.

H. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement and to Relator’s reasonable expenses, attorneys’ fees, and costs.

I. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

III. TERMS AND CONDITIONS

1. Defendants shall pay to the United States and the Five Intervening States, collectively, one hundred forty-nine million dollars (\$149,000,000), plus interest at the rate of

1.375 percent per annum from June 17, 2012, and continuing until and including the day of payment (collectively, the “Settlement Amount”). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Five Intervening States on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States and the Five Intervening States, under the following terms and conditions:

(a) Defendants shall pay to the United States the sum of \$132,145,963, plus accrued interest as set forth above (“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 fifteen (15) business days after the Effective Date of this Agreement.

(b) Defendants shall deposit the sum of \$16,854,037, plus accrued interest as set forth above (“Medicaid State Settlement Amount”) into one or more interest-bearing money market or bank accounts that are held in the name of J&J, but segregated from other J&J accounts (the “State Settlement Accounts”), and make payment from the State Settlement Accounts to the Five Intervening States pursuant to the terms of the Medicaid State Settlement Agreements that Defendants have entered or will enter into with the Five Intervening States.

2. Subject to the exceptions in Paragraph III.5 (concerning excluded claims) below, and conditioned upon Defendants’ full payment of the Settlement Amount, the United States releases Defendants, together with their current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; and their current and former owners, officers, directors, employees and affiliates; and the predecessors, successors, transferees, and assigns of any of them, from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision creating a cause of action for civil damages or civil penalties which the Civil Division of the Department of Justice has actual or present authority to assert and compromise pursuant to 28 C.F.R. Pt. 0, Subpart I, 0.45(d); or the common law theories of payment by mistake, unjust enrichment, disgorgement, and fraud.

3. Subject to the exceptions in Paragraph III.5 below (concerning excluded claims) and Paragraph III.14 below (concerning Relator's Share and reasonable fees, expenses, and costs), and conditioned upon Defendants' full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Defendants, together with their predecessors, current and former parent corporations; transferees, divisions, affiliates, subsidiaries, successors, and assigns, and their current or former owners, officers, directors, and employees, representatives, agents, servants, consultants, and attorneys, individually or collectively, from any and all civil monetary claim Relator has or may have on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733 and for 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 in tort, or under any federal or state statute or regulations, or otherwise that Relator has standing to bring which Relator may now have or claim to have against Defendants or related 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 *Lisitza* and *Kammerer* actions, or from any other past activities and actions of the Defendants or related entities with the following exception: Relator and Relator's counsel do not release the Defendants or related entities for any claims they may have for reasonable attorneys' fees, expenses and costs pursuant to 31 U.S.C. § 3730(d) and pursuant to any similar state statute.

4. In consideration of the obligations of Defendants in this Agreement and the Corporate Integrity Agreement (CIA) entered into between OIG-HHS and Johnson & Johnson, and conditioned upon Defendants' full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Defendants 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 III.5 (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 Defendants from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph III.5, below.

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

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon such obligations as are created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for failure to deliver goods or services due; or
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

6. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). In connection with this Agreement and the *Lisitza* and *Kammerer* actions, Relator and his heirs, successors, attorneys, agents, and assigns agree that neither this Agreement, nor any dismissal of the *Lisitza* and *Kammerer* actions,

shall waive or otherwise affect the ability of the United States to contend that provisions in the False Claims Act, including 31 U.S.C. §§ 3730(d)(3) and 3730(e), bar Relator from sharing in the proceeds of this Agreement. Moreover, the United States and Relator and his heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the share percentage, if any, that Relator should receive of any proceeds of the settlement of his claim(s).

7. Defendants waive and shall not assert any defenses Defendants may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

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

9. In consideration of the obligations of the Relator set forth in this Agreement, Defendants, on behalf of themselves, their predecessors, and their current and former parent corporations, transferees, divisions, affiliates, subsidiaries, successors, and assigns, and their current or former officers, directors, and employees, fully and finally release, waive, and forever discharge Relator and his heirs, successors, attorneys, agents, and assigns from any claims or allegations that Defendants have asserted or could have asserted arising from the Covered Conduct or related to the initiation, investigation, and/or prosecution of the *Lisitza* and *Kammerer*

actions by the Relator or his attorneys, except as they relate to a claim by Relator for reasonable attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d) and pursuant to any similar state statute.

10. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any other state or Federal carrier or payer, related to the Covered Conduct; and Defendants agree not to resubmit to any Medicare carrier or intermediary or any other state or Federal carrier or payer, any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

11. Defendants agree to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Defendants, their present or former officers, directors, employees, shareholders, and agents in connection with the following are "Unallowable Costs" for government contracting purposes and under the Medicare Program, Medicaid Programs, TRICARE Program, and FEHBP:

- (i) the matters covered by this Agreement;
- (ii) the United States' audit(s) and civil and criminal investigation(s) of the matters covered by this Agreement;
- (iii) Defendants' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (iv) the negotiation and performance of this Agreement and the Medicaid State Settlement Agreements;

- (v) the payments Defendants make to the United States or any State pursuant to this Agreement or the Medicaid State Settlement Agreements, and any payments that Defendants may make to Relator, including costs and attorneys' fees; and
- (vi) the negotiation of, and obligations undertaken pursuant to the CIA to:
 - (a) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (b) prepare and submit reports to OIG-HHS. However, nothing in this Paragraph III.11(a)(vi) 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 Defendants.

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

c. Treatment of Unallowable Costs Previously Submitted for Payment: Defendants further agree that within 90 days of the Effective Date of this Agreement they shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Defendants or any of their 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. Defendants agree that the United States, at a minimum, shall be

entitled to recoup from Defendants 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 Defendants or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Defendants or any of their 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 Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

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 III.2, above, and Paragraph III.13 (waiver for beneficiaries paragraph), below.

13. Defendants agree that they waive 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. Upon receipt of the payment described in Paragraph III.1, above, the Parties shall promptly sign and file a Joint Stipulation of Dismissal in the *Lisitza* and *Kammerer* actions pursuant to Rule 41(a)(1), dismissing with prejudice all claims asserted in the Complaint-in-Intervention subject to the terms and conditions of this Agreement, and dismissing remaining claims, if any, asserted in the *Lisitza* and *Kammerer* actions with prejudice as to Relator and without prejudice as to the United States. However, the following claims shall not be dismissed until they are settled, adjudicated, or otherwise resolved, and the Court is so informed: (i) Relator's claims for a Relator's Share of the Settlement Amount pursuant to 31 U.S.C. § 3730(d)(1) and pursuant to any similar state statute; and (ii) Relator's claims for

reasonable attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d)(1) and pursuant to any similar state statute.

15. Except as expressly provided to the contrary elsewhere 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.

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

17. 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 through the dispute resolution provisions set forth in the CIA. 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 this 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 Defendants' successors, transferees, heirs, and assigns.

22. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

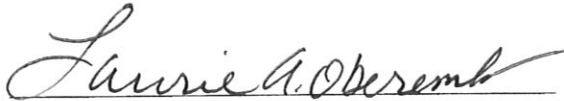
23. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

24. This Agreement is effective on the date of signature of the last signatory to the Agreement (“Effective Date”). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

STUART F. DELERY
Assistant Attorney General

By:

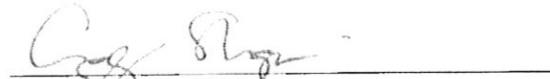


Dated: 11/1/13

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By:



Dated: November 1, 2013

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Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

By:

ROBERT K. DeCONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
United States Department of Health and Human Services

Dated: _____

THE UNITED STATES OF AMERICA

STUART F. DELERY
Assistant Attorney General

By:

Dated: _____

MICHAEL D. GRANSTON
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PATRICK KLEIN
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Commercial Litigation Branch
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United States Department of Justice

CARMEN M. ORTIZ
United States Attorney for the District of Massachusetts

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Dated: _____

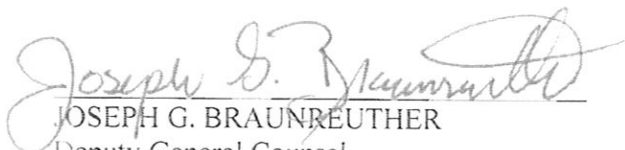
GREGG SHAPIRO
GEORGE B. HENDERSON, II
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

By:

Dated: 10/31/13

Robert K. DeConti
ROBERT K. DeCONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
United States Department of Health and Human Services

DEFENDANTS

By:  Dated: 10/21/13
JOSEPH G. BRAUNREUTHER
Deputy General Counsel
Johnson & Johnson

By: _____ Dated: _____
WILLIAM SARRAILLE
Sidley Austin LLP
Counsel for Defendants Johnson & Johnson Health Care Systems, Inc., and
Janssen Pharmaceuticals, Inc.

By: _____ Dated: _____
MARK D. SELTZER
Nixon Peabody LLP
Counsel for Defendants Johnson & Johnson Health Care Systems, Inc., and
Janssen Pharmaceuticals, Inc.


DEFENDANTS

By:

JOSEPH G. BRAUNREUTHER
Deputy General Counsel
Johnson & Johnson

Dated: _____

By:



WILLIAM SARRAILLE
Sidley Austin LLP

Dated: 10/31/13

Counsel for Defendants Johnson & Johnson Health Care Systems, Inc., and
Janssen Pharmaceuticals, Inc.

By:

MARK D. SELTZER
Nixon Peabody LLP

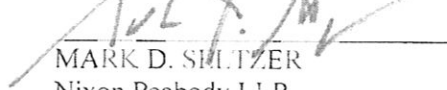
Dated: _____

Counsel for Defendants Johnson & Johnson Health Care Systems, Inc., and
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DEFENDANTS

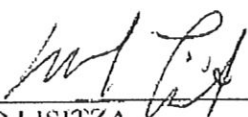
By: _____ Dated: _____
JOSEPH G. BRAUNREUTHER
Deputy General Counsel
Johnson & Johnson

By: _____ Dated: _____
WILLIAM SARRAILLE
Sidley Austin LLP
Counsel for Defendants Johnson & Johnson Health Care Systems, Inc., and
Janssen Pharmaceuticals, Inc.

By:  _____ Dated: 10/21/13
MARK D. SMITZER
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Counsel for Defendants Johnson & Johnson Health Care Systems, Inc., and
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RELATOR


By:



BERNARD LISITZA
Relator

Dated: October 15, 2013

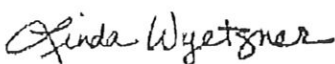
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MICHAEL BEHN
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Dated: October 15, 2013

By:



LINDA WYETZNER
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Dated: October 15, 2013