STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of Colorado ("the State"); Janssen Pharmaceuticals, Inc. ("Janssen") and Johnson & Johnson (collectively, "Defendants"), hereinafter collectively referred to as "the Parties."

II. PREAMBLE

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

A. Johnson & Johnson is a New Jersey corporation headquartered in New Brunswick, New Jersey. Janssen is a New Jersey corporation and a subsidiary of Johnson & Johnson. Janssen is 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. At all relevant times, Defendants distributed, marketed, and sold pharmaceutical products in the United States, including the drugs Risperdal® and Invega®.

B. Victoria Starr and Kurtis J. Barry (collectively, "Relators") have filed the following *qui tam* actions against Defendants (collectively, the "Civil Actions"):

i. On April 7, 2004, relator Victoria Starr filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned *United States of America ex rel. Victoria Starr v. Janssen Pharmaceutica Prods. L.P.,* Civil Action No. 04-

1529. Relator filed her operative Fourth Amended Complaint on March 3, 2010.

ii. On January 8, 2010, relator Kurtis J. Barry filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned *United States of America ex rel. Kurtis J. Barry v. Ortho-McNeil-Janssen Pharms., Inc. and Johnson & Johnson, Inc.,* Civil Action No. 10-98. Relator filed his operative Second Amended Complaint on December 20, 2010.

C. Janssen has entered or will enter into a plea agreement with the United States Attorney for the Eastern District of Pennsylvania and, if the plea agreement is approved by the Court, will plead guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to introducing a misbranded drug, Risperdal®, into interstate commerce in violation of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) & 333(a)(1). *United States v. Janssen Pharmaceuticals, Inc.,* Criminal Action No. [to be assigned] (E.D. Pa.) (the "Federal Criminal Action").

D. Defendants have entered into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States of America (as that term is defined in the Federal Settlement Agreement), hereinafter referred to as the "United States."

E. The State contends that Defendants caused claims for payment for Risperdal® and Invega® to be submitted to the State's Medicaid Program (see 42 U.S.C. §§ 1396-1396w-5).

F. The State contends that it has certain civil and administrative causes of action against Defendants for engaging in the following conduct concerning the marketing, promotion, and sale of Risperdal® and Invega® (the "Covered Conduct"):

(1) **Risperdal®:** During the period January 1, 1999 through December 31, 2005, Defendants knowingly: (a) promoted the sale and use of Risperdal® for conditions and for patients for which it was not approved as safe and effective by the Food and Drug Administration, including the treatment and/or control of: (i) behavioral disturbances in elderly dementia patients, (ii) conduct disorders, attention deficit hyperactivity disorders, and other uses in children and adolescents under the age of 18, (iii) conduct disorders in individuals with mental retardation and developmental disabilities, and (iv) various non-psychotic mental disorders; some of which were not medically accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) and were not covered by state Medicaid programs; (b) made false and misleading statements about the safety and efficacy of Risperdal®; and (c) offered and paid illegal remuneration to health care professionals and long term care pharmacy providers to induce them to promote and/or prescribe Risperdal®, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) and state anti-kickback statutes.

(2) **Invega®:** On December 19, 2006, FDA approved Invega® for the treatment of schizophrenia. On July 31, 2009, FDA approved Invega® for the acute treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressants. During the period January 1, 2007 through December 31, 2009, Defendants knowingly: (a) promoted the sale and

use of Invega® for conditions for which it was not approved as safe and effective by the Food and Drug Administration; some of which were not medically accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) and were not covered by state Medicaid programs; and (b) made false and misleading statements about the safety and efficacy of Invega®.

As a result of the foregoing conduct, the State alleges that Defendants knowingly caused false and/or fraudulent claims for Risperdal® and Invega® to be submitted to, or caused purchases by, the State's Medicaid program.

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 State that its allegations are not well-founded. Except for the specific conduct for which Janssen is pleading guilty as described in the plea agreement filed in the Federal Criminal Action, Defendants expressly deny the allegations of the State as set forth herein and in the Civil Actions. Neither this Agreement, nor the performance of any obligation arising under it, including any payment, nor the fact of settlement, is intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting on the merits of the dispute except as set forth in this paragraph. The contentions and allegations that are described herein are not intended to constitute evidence admissible in a court or other tribunal.

H. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these causes of action, 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 in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Defendants agree to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) below), collectively, the sum of $1,273,024,000, plus accrued interest on that amount of 1.375% per annum commencing on June 17, 2012, and continuing until and including the day 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 the Federal Settlement Agreement, and subject to the terms of this Agreement. This debt shall forever be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) Defendants shall pay to the United States the sum of $749,240,137, plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Defendants shall pay to the Medicaid Participating States the sum of $523,783,863, plus accrued interest as set forth above ("Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of sub-paragraph (d) below ("Medicaid Participating State Settlement Amount"), no later than ten (10)

business days after: (i) the expiration of the 60-day opt-in period for Medicaid Participating States described in sub-paragraph (c) below or, (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea in the Federal Criminal Action and imposes the agreed-upon sentence, whichever occurs later. The Medicaid Participating State Settlement Amount shall be paid by electronic funds transfer to the New York State Attorney General's National Global Settlement Account ("NY State Account") pursuant to written instructions from the State Negotiating Team ("State Team"), which written instructions shall be delivered to counsel for Defendants. After making the Medicaid State Settlement Amount payable to the NY State Account, Defendants shall have no continuing obligations with respect to payment of the aggregate amount to the Medicaid Participating States.

(c) Defendants shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Defendants and the State Team have agreed or in a form otherwise agreed to by Defendants and an individual State; provided, however, that Defendants reserve the right not to execute a Medicaid State Settlement Agreement with any State that is engaged in litigation with Defendants in a matter relating to Risperdal® and/or Invega® or with any State that has litigated Medicaid claims relating to Risperdal® and/or Invega® State Medicaid Program liability. The State shall constitute a Medicaid Participating State provided the Agreement is fully executed by the State and delivered to Defendants' attorneys within 60 days of receiving this Agreement, and provided that Defendants do not exercise a reservation of the right, if applicable, not to execute this Agreement pursuant to the terms of this sub-paragraph. If

the State does not fully execute the Agreement and deliver it to Defendants' attorneys within 60 days, Defendants' offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for Defendants and the State Team to extend the 60-day period.

(d) The total portion of the amount paid by Defendants in settlement for the Covered Conduct for the State is $7,751,289.83, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of $3,836,059.52, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 60 days of receiving this Settlement Agreement or if Defendants elect not to execute this Agreement because of litigation as specified in sub-paragraph (c) immediately above, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Defendants absent written agreement between counsel for Defendants and the State Team to extend the time period for executing this Agreement.

(e) Defendants may, at their sole discretion, waive any rights that they have reserved with respect to payment of any of the State Amounts as defined in Paragraphs III.1(c) and III.1(d).

2. Within 14 days of its receipt of the State Amount described above, the State agrees to dismiss with prejudice any state law claims which the State has authority to dismiss, including claims asserted in the Civil Actions and claims for Medicaid restitution, Medicaid damages or Medicaid civil fines or civil penalties under state statutes that are similar to the FDCA, currently pending against the Released Entities as

defined in Paragraph 3 below in State or Federal courts for the Covered Conduct. The State further agrees to file a stipulation of dismissal without prejudice as to all other claims against the Released Entities in the Civil Actions. Contingent upon the receipt of its State Amount, the State, if properly served with one or more of the Civil Actions and liable to pay a Relator's share, agrees to pay, as soon as feasible after such receipt, such amounts as have been or will be negotiated with the Plaintiff-Relator(s) in the Civil Action(s), which shall be set forth in side letters issued to and executed by the Plaintiff-Relator(s) in the Civil Action(s).

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Defendants set forth in this Agreement, and conditioned upon receipt by the State of its share of the Medicaid State Settlement Amount, the State on behalf of itself, and its officers, agents, agencies, political subdivisions and departments to the extent authorized by law, agrees to release Defendants, their predecessors and current and former parents, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers, and employees, individually and collectively (collectively, the "Released Entities"), from any civil or administrative monetary cause of action that the State and its officers, agents, agencies, political subdivisions and departments to the extent authorized by law, have or may have for any claims submitted or caused to be submitted to the State Medicaid Program as a result of the Covered Conduct. The payment of the Medicaid State Settlement Amount fully discharges the Released Entities from any obligations to pay Medicaid restitution, Medicaid damages, and/or any Medicaid civil fine or civil penalty to the State for the Covered Conduct.

4. Notwithstanding any term of this Agreement, the State specifically does not release any person or entity from any of the following liabilities:

(a) Any criminal, civil, or administrative liability arising under state revenue codes;

(b) Any criminal liability not specifically released by this Agreement;

(c) Any civil or administrative liability that any person or entity, including any Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation or rule not expressly covered by the release in Paragraph 3 above (regarding liability to the State Medicaid Program), including but not limited to, any and all of the following claims: (i) State or federal antitrust violations; (ii) Claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) Any liability to the State for any conduct other than the Covered Conduct;

(e) Any liability which may be asserted on behalf of any other payors or insurers, including those that are paid by the State's Medicaid program on a capitated basis;

(f) Any liability based upon obligations created by this Agreement;

(g) Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid program;

(h) Any liability for express or implied warranty claims or other claims for defective or deficient products or services provided by Defendants;

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

(j) Any liability based on a failure to deliver goods or services due.

5. This Agreement is expressly conditioned upon resolution of the Federal Criminal Action. In consideration of the acceptance of Janssen's plea of guilty in the Federal Criminal Action, the State's Medicaid Fraud Control Unit agrees that it shall not take any of the following actions with respect to the Released Entities for the Covered Conduct: further criminal investigation or prosecution, or referral to any agency for criminal investigation or prosecution, including for any violations of state statutes similar to the FDCA.

6. In consideration of the obligations of Defendants set forth in this Agreement, conditioned on execution of a Corporate Integrity Agreement ("CIA") with the Office of the Inspector General of the United States Department of Health and Human Services ("OIG-HHS") in connection with this matter, and conditioned on receipt by the State of its share of the Medicaid State Settlement Amount, the State agrees to release and refrain from instituting, recommending, directing, or maintaining any administrative action seeking exclusion from the State's Medicaid program against Defendants for the conviction in the Federal Criminal Action or for the Covered Conduct, except as reserved in Paragraph 4 above. The State's Medicaid Fraud Control Unit further agrees to refrain from recommending, causing, or attempting any administrative action or sanction, including debarment, by any other government agency of the State for the Covered Conduct. Nothing in this Agreement precludes the State from taking action against Defendants in the event that Defendants are excluded by the federal government, or for

conduct and practices other than the Covered Conduct or the conviction in the Federal Criminal Action.

7. Defendants waive and shall not assert any defenses they may have to criminal prosecution or administrative action for the Covered Conduct, which defenses may be based in whole or in part on a contention, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or the Excessive Fines Clause of the Eighth Amendment of the Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

8. In consideration of the obligations of the State set forth in this Agreement, Defendants waive and discharge the State, its agencies, political subdivisions, employees, servants, and agents from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which Defendants have asserted, could have asserted, or may assert in the future against the State, its agencies, political subdivisions, employees, servants, and agents, arising from the State's investigation and prosecution of the Covered Conduct.

9. The amount that Defendants must pay to the State pursuant to Paragraph III.1 above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the State's Medicaid program, or any other state payor, for the Covered Conduct; and if applicable, Defendants agree not to resubmit to the State's Medicaid program or any other state payor, any previously denied claims, which denials were based on the Covered Conduct, and agree not to appeal or cause the appeal of any such denials of claims.

10. Defendants shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.

11. Defendants expressly warrant that they have reviewed their financial condition and that they are currently solvent, and that payment of the Settlement Amount described in Paragraph 1 shall not render Defendants insolvent.

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

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

14. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any liability against any other person or entity.

15. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of state and federal revenue codes.

16. In addition to all other payments and responsibilities under this Agreement, Defendants agree to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees and expenses. Defendants will pay this amount by separate check made payable to the National Association of Medicaid Fraud

Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

17. This Agreement is governed by the laws of the State, except disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions of the CIA, and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

18. The undersigned Defendants' signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

19. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

20. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

21. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

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

STATE OF COLORADO

JOHN SUTHERS, ATTORNEY GENERAL
STATE OF COLORADO

By: _____ Dated: July 30, 2013
Timothy X. Sokas
First Assistant Attorney General
Director, Medicaid Fraud Control Unit

FOR THE STATE OF COLORADO MEDICAID PROGRAM:

COLORADO DEPARTMENT OF HEALTH
CARE POLICY & FINANCING

By: _____ Dated: 8/5/13
Susan E. Birch, MBA, BSN, RN
Executive Director

[Defendants]

By: _____ Dated: _____

[Signatory for J&J]
[Title]

By: _____ Dated: _____

[Signatory for Janssen Pharmaceuticals, Inc.]
[Title]

By: _____ Dated: _____

Counsel for Defendant

(May need multiple blocks)