GRANTED

ant shall serve copies of this ORDER on any pro se parties, pursuant to CRCP 5, and file a certificate of service with the Court within 10 days.

Kenneth M. Laff

Entered: Sep 03 2012 09:22AM

Kenneth M. Laff
District Court Judge

DISTRICT COURT, DENVER COUNTY, COLORADO 1437 Bannock Street, Room 256 Denver, Colorado 80202	COURT USE ONLY DATE OF ORDER INDICATED ON ATTACHMENT EFILED Document CO Denver County District Court 2nd JD Filing Date: Sep 03 2012 07:53AM MDT Filing ID: 46228072 Review Clerk: Kathleen J Kelley
STATE OF COLORADO, ex rel. JOHN W. SUTHERS, ATTORNEY GENERAL Plaintiffs, v. JANSSEN PHARMACEUTICALS, INC.; AND JOHNSON & JOHNSON Defendants.	
	Case No.: Div:

FINAL JUDGMENT AND CONSENT DECREE

AND NOW, comes the Plaintiff, Attorney General John W. Suthers, having filed an action pursuant to the Colorado Consumer Protection Act, Colo. Rev. Stat. § 6-1-101 through 115 (2012) ("CCPA"), and the parties having consented to entry of this Final Judgment and Consent Decree ("Judgment").

NOW THEREFORE, upon the Judgment of the parties hereto, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED AS FOLLOWS:**

PARTIES

1. Plaintiff, the State of Colorado, by and through Colorado Attorney General John Suthers, is the Plaintiff in this case ("State"). The Division is charged with,

among other things, the responsibility of enforcing the CCPA under Colo. Rev. Stat. § 6-1-103. (2012).

2. Janssen Pharmaceuticals, Inc. ("Janssen") is a subsidiary of Johnson & Johnson. Janssen does business in the State of Colorado. Janssen's executive offices are located at 1125 Trenton Harbourton Road, P.O. Box 200, Titusville, NJ 08560. Johnson & Johnson's executive offices are located at One Johnson & Johnson Plaza, New Brunswick, NJ 08933. At all times relevant hereto, Janssen engaged in trade affecting consumers, within the meaning of the CCPA under Colo. Rev. Stat. § 6-1-103. (2012), in the State of Colorado, including, but not limited to Denver County. Johnson & Johnson consents to the jurisdiction of the Court solely for the purposes of this Consent Judgment.

FINDINGS

1. This Court has jurisdiction over the subject matter of this lawsuit and over all Parties.

2. The terms of this Judgment shall be governed by the laws of the State of Colorado.

3. Entry of this Judgment is in the public interest and reflects a negotiated agreement among the Parties.

4. The Parties have agreed to resolve the issues resulting from the Covered Conduct involving Atypical Antipsychotics by entering into this Judgment. [1]

5. Janssen is willing to enter into this Judgment regarding the Covered Conduct solely in order to resolve the Attorneys General's concerns under the Colorado **Consumer Protection Laws** as to the matters addressed in this Judgment and thereby

[1] This agreement is entered into pursuant to and subject to the State Consumer Protection Laws cited in footnote 2.

avoid unnecessary expense, inconvenience, and uncertainty. Nothing contained herein may be taken as or construed to be an admission or concession of any violation of law or regulation, or of any other matter of fact or law, or of any liability or wrongdoing (including allegations of the Complaint), all of which Janssen expressly denies. Janssen does not admit any violation of law, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Janssen. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. It is the intent of the Parties that this Judgment shall not be binding or admissible in any other matter, including, but not limited to, any investigation or litigation, other than in connection with the enforcement of this Judgment. No part of this Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that **the State** may file an action to enforce the terms of this Judgment.

6. Janssen is entering into this Judgment solely for the purpose of settlement of the instant action. This Judgment does not create a waiver or limit Janssen's legal rights, remedies, or defenses in any other action by the Signatory Attorney General, and does not waive or limit Janssen's right to defend itself from, or make argument in, any other matter, claim, or suit, including, but not limited to, any investigation or litigation relating to the subject matter or terms of this Judgment. Nothing in this Judgment shall waive, release, or otherwise affect any claims, defenses, or positions Janssen may have in connection with any investigations, claims, or other matters **the State** is not releasing

hereunder. Notwithstanding the foregoing, **the State** may file an action to enforce the terms of this Judgment.

7. This Judgment (or any portion thereof) shall in no way prohibit, limit, or restrict Janssen from making representations with respect to an Atypical Antipsychotic that are permitted or authorized under Federal law, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), U.S. Food and Drug Administration ("FDA") regulations, or FDA Guidances for Industry. Further, the Judgment shall in no way prohibit, limit, or restrict Janssen from making representations with respect to an Atypical Antipsychotic that are required or authorized by, or consistent with the FDA-approved Labeling or prescribing information for an Atypical Antipsychotic, or by any Investigational New Drug Application, New Drug Application, Supplemental New Drug Application, or Abbreviated New Drug Application filed with the FDA so long as the representation, taken in its entirety, is not false, misleading or deceptive.

8. Nothing in this Judgment shall require Janssen to:

a. Take any action that is prohibited by the FDCA or any regulation promulgated thereunder, or by the FDA; or

b. Fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA.

DEFINITIONS

The following definitions shall be used in construing this Judgment:

1. **"Atypical Antipsychotic"** shall mean all of Janssen's products that are FDA-approved drug formulations containing risperidone and/or paliperidone.

2. **"Clinically Relevant Information"** shall mean information that reasonably prudent clinicians would consider relevant when making prescribing decisions regarding an Atypical Antipsychotic.

3. **"Clinical Response"** shall mean a non-Promotional, scientific communication to address Unsolicited Requests for medical information.

4. **"Covered Conduct"** shall mean Janssen's Promotional and marketing practices, sampling practices, dissemination of information and remuneration to HCPs in the United States in connection with Atypical Antipsychotics through the Effective Date of the Judgment.

5. **"Effective Date"** shall mean the date on which a copy of this Judgment, duly executed by Janssen and by the **Signatory Attorney General**, is approved by, and becomes a Judgment of the Court.

6. **"FDA Guidances for Industry"** shall mean final documents issued by the FDA pursuant to 21 U.S.C. § 371(h) that represent the FDA's current thinking on a topic.

7. **"Health Care Professional"** or **"HCP"** shall mean any physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical products.

8. **"Janssen"** shall mean Janssen Pharmaceuticals, Inc., including all of its subsidiaries, predecessors, successors and assigns doing business in the United States.

9. **"Janssen's Law Department"** shall mean personnel of the Janssen Law Department or its designee providing legal advice to Janssen.

10. **"Janssen Marketing"** shall mean Janssen personnel responsible for marketing Janssen's Atypical Antipsychotics in the U.S.

11. **"Janssen Sales"** shall mean the Janssen sales force responsible for U.S. Atypical Antipsychotic sales, including, but not limited to, Janssen personnel whose employment responsibilities include working with public or private entities in determining whether to include Atypical Antipsychotics on their prescription drug formularies or preferred drug lists.

12. **"Janssen Scientific Affairs Medical Education Department"** or **"JSA MED"** shall mean the organization within Janssen responsible for oversight of medical education grants, including the acceptance, review, approval, and payment of all medical education grant requests.

13. **"Janssen Scientifically Trained Personnel"** shall mean Janssen personnel who are highly trained experts with specialized scientific and medical knowledge, usually with an advanced scientific degree (e.g., an MD, PhD, or PharmD), whose roles involve the provision of specialized, medical or scientific information, scientific analysis and/or scientific information to HCPs and includes Regional Medical Research Specialists, but excludes anyone performing sales, marketing, promotional ride alongs, or other commercial roles.

14. **"Labeling"** shall mean all labels and other written, printed, or graphic matter (a) upon any article or any of its containers or wrappers, or (b) accompanying such article.

15. **"Multistate Executive Committee"** shall mean the Attorneys General and their staffs representing Arizona, Delaware, District of Columbia, Florida, Illinois, Kansas, Maryland, North Carolina, Ohio, Pennsylvania and Vermont.

16. **"Multistate Working Group"** shall mean the Attorneys General and their staff representing Alabama, Arizona, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, Wisconsin and Wyoming.

17. **"Off-Label"** shall mean a use not consistent with the indications section of an Atypical Antipsychotic's Labeling approved by the FDA at the time information regarding such use was communicated.

18. **"Parties"** shall mean Janssen and the **Signatory Attorney General**.

19. **"Promotional," "Promoting,"** or **"Promote"** shall mean representations made to HCPs, patients, consumers, payors and other customers, and other practices intended to increase sales in the United States or that attempt to influence prescribing practices of HCPs in the United States, including direct-to-consumer.

20. **"Promotional Materials"** shall mean any item used to Promote an Atypical Antipsychotic.

21. **"Promotional Media"** shall mean Promotional Materials in any media format for use in speaker programs.

22. **"Promotional Speaker"** shall mean an HCP speaker engaged to Promote an Atypical Antipsychotic in the United States.

23. **"Related Entity"** means any entity by or in which any physician or HCP receiving any payment is employed, has tenure, or has an ownership interest.

24. **"Reprints Containing Off-Label Information"** shall mean articles or reprints from a Scientific or Medical Journal, as defined in 21 C.F.R. 99.3(j), or Reference Publication, as defined in 21 C.F.R. 99.3(i), describing an Off-Label use of an Atypical Antipsychotic.

25. **"Signatory Attorney General"** shall mean the Attorney General of Colorado, or his authorized designee, who has agreed to this Judgment.

26. **"State Consumer Protection Laws"** shall mean the consumer protection laws under which the Attorneys General have conducted the investigation, which are cited in footnote 2.[2]

27. **"Unsolicited Request"** shall mean a request for information regarding an Atypical Antipsychotic communicated to an agent of Janssen that has not been prompted by Janssen.

COMPLIANCE PROVISIONS

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[2] ALABAMA – *Alabama Deceptive Trade Practices Act*, Ala. Code § 8-19-1 et seq.; ARIZONA – *Arizona Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; COLORADO – *Colorado Consumer Protection Act*, Colo. Rev. Stat. § 6-1-101 *et seq.*; CONNECTICUT - *Connecticut Unfair Trade Practices Act*, Conn. Gen. Stat. §§ 42-110a *et seq.*; DELAWARE – *Delaware Consumer Fraud Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, *District of Columbia Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 *et seq.*; FLORIDA – *Florida Deceptive and Unfair Trade Practices Act, Part II*, Chapter 501, Florida Statutes, 501.201 *et. seq.*; HAWAII – *Uniform Deceptive Trade Practice Act*, Haw. Rev. Stat. Chpt. 481A and Haw. 501.201 *et seq.*; IDAHO - Idaho Code Ann. §§ 48-601 through 48-619;ILLINOIS – *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/2 *et seq.*; INDIANA - Ind. Code §§ 24-5-0.5-1 through 41-5-0.5-12; IOWA - *Iowa Consumer Fraud Act*, Iowa Code Section 714.16; KANSAS - *Kansas Consumer Protection Act*, K.S.A. 50-623 *et seq.*; MAINE – *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 *et seq.*; MARYLAND - *Maryland Consumer Protection Act*, Md. Code Ann., Com. Law §§ 13-101 *et seq.*; MICHIGAN – *Michigan Consumer Protection Act*, MCL § 445.901 *et seq.*; MINNESOTA - *Minnesota Deceptive Trade Practices Act*, Minn. Stat. §§ 325D.43-48; *Minnesota False Advertising Act*, Minn. Stat. § 325F.67; *Minnesota Consumer Fraud Act*, Minn. Stat. §§ 325F.68-70; *Minnesota Deceptive Trade Practices Against Senior Citizens or Disabled Persons Act*, Minn. Stat. § 325F.71.; MISSOURI – *Missouri Merchandising Practices Act*, Mo. Rev. Stat. §§ 407 *et seq.*; NEBRASKA – *Uniform Deceptive Trade Practices Act*, NRS §§ 87-301 *et seq.*; NEVADA – *Deceptive Trade Practices Act*, Nevada Revised Statutes 598.0903 *et seq.*; NEW HAMPSHIRE - *New Hampshire Consumer Protection Act*, RSA 358-A; NEW JERSEY – *New Jersey Consumer Fraud Act*, NJSA 56:8-1 *et seq.*; NEW YORK – General Business Law Art. 22-A, §§ 349-50, and Executive Law § 63(12); NORTH CAROLINA – *North Carolina Unfair and Deceptive Trade Practices Act*, N.C.G.S. 75-1.1, *et seq.*; NORTH DAKOTA – *Unlawful Sales or Advertising Practices*, N.D. Cent. Code § 51-15-02 *et seq.*; OHIO – *Ohio Consumer Sales Practices Act*, R.C. 1345.01, *et seq.*; OKLAHOMA – *Oklahoma Consumer Protection Act* 15 O.S. §§ 751 *et seq.*; OREGON – *Oregon Unlawful Trade Practices Act*, Or. Rev. Stat. § 646.605 et seq.; PENNSYLVANIA – *Pennsylvania Unfair Trade Practices and Consumer Protection Law*, 73 P.S. 201-1 *et seq.*; RHODE ISLAND - *Rhode Island Deceptive Trade Practices Act*, Rhode Island General Laws § 6-13.1-1 *et seq.*; SOUTH DAKOTA – *South Dakota Deceptive Trade Practices and Consumer Protection*, SDCL ch. 37-24; TENNESSEE – *Tennessee Consumer Protection Act*, Tenn. Code Ann. 47-18-101 *et seq.*; TEXAS – *Texas Deceptive Trade Practices-Consumer Protection Act*, Tex. Bus. And Com. Code 17.47, *et seq.*; VERMONT – *Consumer Fraud Act*, 9 V.S.A. §§ 2451 *et seq.*; WASHINGTON – *Unfair Business Practices/Consumer Protection Act*, RCW §§ 19.86 *et seq.*; WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations); WYOMING - Wyo. Stat. Ann. §§ 40-12-101 through 40-12-114.

I. Promotional Activities

A. Janssen shall not make, or cause to be made, any written or oral claim that is false, misleading or deceptive regarding an Atypical Antipsychotic.

The following subsections of Section I. shall be effective for five years from the Effective Date of this Judgment.

B. Janssen shall not Promote an Atypical Antipsychotic for Off-Label uses.

C. In Promotional Materials for Atypical Antipsychotics, Janssen shall clearly and conspicuously disclose the risks associated with the Atypical Antipsychotic as set forth in the product's boxed warning and shall present information about effectiveness and risk in a balanced manner.

D. Janssen shall not compensate an HCP for merely attending a Promotional activity.

E. Janssen shall not present patient profiles/types based on selected symptoms of the FDA-approved indication(s) when Promoting an Atypical Antipsychotic, unless:

1. The Atypical Antipsychotic's specific FDA-approved indication(s) is stated clearly and conspicuously in the same spread (i.e., on the same page or on a facing page) in any Promotional Materials that refer to selected symptoms;

2. With respect to Promotional Media:

a. Janssen states, clearly and conspicuously, the FDA-approved indication(s) on the same slide or page in which selected symptoms are first presented; and

b. With respect to each subsequent reference to selected symptoms, Janssen states on the same slide or page that the Atypical Antipsychotic is not approved for the selected symptom referenced in the slide or page and includes on the same slide or page a shorthand reference to the FDA-approved indications (e.g., "[Atypical Antipsychotic] is not approved for X selected symptom referenced in this slide. See complete list of FDA-approved indications at p. Y").

3. Promotional Materials have a reference indicating that the full constellation of symptoms and the relevant diagnostic criteria should be consulted and are available in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV or current version), where applicable.

F. Janssen shall require that all Promotional Speakers' Promotional Materials and Promotional Media for Atypical Antipsychotics, comply with Janssen's obligations in the above Sections I.A.- E.

G. Janssen's systems and controls shall:

1. Be designed to ensure that financial incentives do not motivate Janssen Sales and/or Marketing to engage in improper promotion, sales, and marketing of Atypical Antipsychotics; and

2. Require the review, and modification, if necessary, of call plans of Janssen Sales and Janssen Marketing personnel who Promote an Atypical Antipsychotic to ensure that Janssen Sales and/or Janssen Marketing Promote Atypical Antipsychotics only for FDA-approved uses.

II. Dissemination and Exchange of Medical Information

A. General Terms

1. The content of Janssen's communications concerning Off-Label uses of an Atypical Antipsychotic shall not be false, misleading or deceptive.

The following subsections of Section II. shall be effective for five years from the Effective Date of this Judgment.

B. Clinical Responses

1. Janssen, through Janssen Scientifically Trained Personnel, shall have ultimate responsibility for developing and approving all Clinical Responses regarding an Atypical Antipsychotic, including any that may describe Off-Label information. Additional approvals may be provided by Janssen's Law Department. Janssen shall not distribute any such materials unless:

a. Clinically Relevant Information is included in these materials to provide scientific balance;

b. Data in these materials are presented in an unbiased, non-Promotional manner; and

c. These materials are clearly and conspicuously distinguishable from sales aids and other Promotional Materials.

d. Nothing in this subsection II.B shall prohibit Janssen Scientifically Trained Personnel from disseminating materials that are permitted to be distributed under Federal law.

2. Janssen Sales and Janssen Marketing personnel shall not develop the medical content of Clinical Responses regarding an Atypical Antipsychotic.

3. Clinical Responses regarding an Atypical Antipsychotic may be disseminated only by Janssen Scientifically Trained Personnel to HCPs, and Janssen's

Sales and Marketing shall not disseminate these materials to HCPs except in circumstances implicating public health and safety issues. In such circumstances, Janssen's Sales and Marketing may disseminate a Clinical Response directly to HCPs when expressly authorized by the Health Care Compliance Officer, the Vice President of Medical/Scientific Affairs responsible for the Atypical Antipsychotic(s) included in the Clinical Response(s), and Senior Counsel from the Janssen Law Department.

4. Janssen shall not knowingly disseminate any Clinical Response, including one that describes any Off-Label use of an Atypical Antipsychotic, that makes any false, misleading or deceptive representation regarding an Atypical Antipsychotic or any false, misleading or deceptive statement concerning a competing product.

C. Responses to Unsolicited Requests for Off-Label Information

1. In responding to an Unsolicited Request for Off-Label information regarding an Atypical Antipsychotic, including any request for a specific article related to Off-Label uses, Janssen shall:

a. advise the requestor that the request concerns an Off-Label use;

b. and inform the requestor of the drug's FDA-approved indication(s) and dosage, and other relevant Labeling information.

2. If Janssen elects to respond to an Unsolicited Request for Off-Label information regarding an Atypical Antipsychotic, Janssen Scientifically Trained Personnel, shall provide specific, accurate, objective, and scientifically balanced responses. Any such response shall not Promote an Atypical Antipsychotic for any Off-Label use(s).

3. Any written response to an Unsolicited Request for Off-Label information regarding an Atypical Antipsychotic shall include:

a. An existing Clinical Response Letter prepared in accordance with Section II.B;

b. A Clinical Response Letter prepared in response to the request in accordance with Section II.B; or

c. A report containing the results of a reasonable literature search using terms from the request.

4. Only Janssen Scientifically Trained Personnel may respond in writing to an Unsolicited Request for Off-Label information regarding an Atypical Antipsychotic.

5. Janssen Sales and Janssen Marketing personnel may respond orally to an Unsolicited Request for Off-Label information regarding an Atypical Antipsychotic only by offering to request on behalf of the requester that a Clinical Response Letter prepared in accordance with Section II.B or other information set forth in Section II.C above be sent in follow-up or by offering to put the requester in touch with the scientific exchange call center. Janssen Non-Scientifically Trained Personnel shall not characterize, describe, identify, name, or offer any opinions about or summarize any such Off-Label information.

D. Reprints

1. Janssen shall not disseminate information describing any Off-Label or unapproved use of an Atypical Antipsychotic, unless such information and materials comply with applicable FDA regulations and FDA Guidances for Industry.

2. Janssen Scientifically Trained Personnel shall be responsible for the identification, selection, approval and dissemination of Reprints Containing Off-Label Information regarding Atypical Antipsychotics. Neither Janssen Sales nor Janssen Marketing personnel shall disseminate these materials, unless Janssen has a pending filing with FDA for approval of the new indication described in the Reprint.

3. Requests to proactively disseminate a Reprint Containing Off-Label Information regarding Atypical Antipsychotics shall be submitted to the Promotional Review Committee, which includes representatives from Clinical, Medical Affairs, Janssen's U.S. Compliance Department, Janssen's Law Department, and Promotional Regulatory Affairs, to examine the facts and justification for the request to distribute a Reprint Containing Off-Label Information on a case-by-case basis.

4. Reprints Containing Off-Label Information regarding an Atypical Antipsychotic:

a. shall be accompanied by the FDA-approved Labeling for the product, or a clearly and conspicuously described hyperlink that will provide the reader with such information;

b. shall contain a disclosure that is prominently displayed, which would include the first page or as a cover page where practicable, indicating that the article may discuss Off-Label information; and

c. shall not be referred to or used in a Promotional manner.

5. Nothing in this Judgment shall preclude Janssen from disseminating reprints which have only an incidental reference to Off-Label information. If reprints have an incidental reference to Off-Label information, such reprints shall

contain the disclosures required by Section II.D.4.a. and II.D.4.b in a prominent location, as defined above, and such incidental reference to Off-Label information shall not be referred to or used in a Promotional manner as prohibited by Section II.D.4.c.

III. Grants

The following subsections of Section III. shall be effective for five years from the Effective Date of this Judgment.

A. Janssen shall disclose information about medical education grants, including continuing medical education ("CME") grants, regarding an Atypical Antipsychotic consistent with the current disclosures of the Janssen Scientific Affairs Medical Education Department at www.janssenime.com (hereinafter, "JSA MED website") and as required by applicable law.

B. Once posted, Janssen shall maintain this information on the JSA MED website for at least two years, or longer if applicable law so requires, and shall maintain the information in a readily accessible format for review by the States upon written request for a period of five years.

C. JSA MED shall manage all requests for funding related to medical education grants relating to an Atypical Antipsychotic. Approval decisions shall be made by JSA MED and Janssen Medical, and shall be kept separate from the Janssen Sales and Janssen Marketing organizations.

D. Janssen shall not use medical education grants or any other type of grant to Promote an Atypical Antipsychotic. This provision includes, but is not limited to, the following prohibitions:

1. Janssen Sales and Janssen Marketing personnel shall not initiate, coordinate or implement grant applications on behalf of any customer or HCP;

2. Janssen Sales and Janssen Marketing personnel shall not be involved in selecting grantees or medical education speakers; and

3. Janssen shall not measure or attempt to track in any way the impact of grants or speaking fees on participating HCPs' subsequent prescribing habits, practices or patterns.

E. Janssen shall not condition funding of a medical education program grant request relating to an Atypical Antipsychotic upon the requestor's selection or rejection of particular speakers.

F. Janssen shall not suggest, control, or attempt to influence the specific topic, title, content, speakers or audience for CMEs relating to an Atypical Antipsychotic, consistent with Accreditation Council for Continuing Medical Education ("ACCME") guidelines.

G. Janssen Sales and Janssen Marketing personnel shall not approve grant requests regarding an Atypical Antipsychotic, nor attempt to influence the awarding of grants to any customers or HCPs for their prescribing habits, practices or patterns.

H. Janssen shall contractually require each medical education provider to clearly and conspicuously disclose to attendees of a medical education program regarding Atypical Antipsychotics Janssen's financial support of the medical education program and any financial relationship with faculty and speakers at such medical education program.

I. After initial delivery of a CME program regarding an Atypical Antipsychotic, Janssen shall not knowingly fund the same program, nor shall it provide additional funding for re-distribution of the same program, if the program's speakers are Promoting an Atypical Antipsychotic for Off-Label use in that program.

IV. Payments to Consultants and Speakers

Until April 29, 2015, Janssen shall post in a prominent position on its website an easily accessible and readily searchable listing of all HCPs and Related Entities who or which received any payments directly or indirectly from Janssen, in accordance with the terms of Section III.L. of the April, 2010 Corporate Integrity Agreement, between the Office of Inspector General of the Department of Health and Human Services (HHS) and Ortho-McNeil-Janssen Pharmaceuticals, Inc. as if the terms of III.L. are applicable to all such HCPs and Related Entities. After April 29, 2015 and until 5 years from the Effective Date of this Judgment, Janssen shall be required to file reports with HHS consistent with the requirements of Section 6002 of the federal Patient Protection and Affordable Care Act of 2010, and in final regulations by HHS.

V. Product Samples

The following subsections of Section V. shall be effective for five years from the Effective Date of this Judgment.

A. Janssen shall provide samples of an Atypical Antipsychotic only to those HCPs whose clinical practice is consistent with the product's FDA-approved Labeling.

B. If an HCP whose clinical practice is inconsistent with an Atypical Antipsychotic's FDA-approved Labeling requests samples of an Atypical Antipsychotic, Janssen personnel shall refer the HCP to Janssen Medical where the practitioner can

speak directly with a Janssen Medical representative who will provide answers to the HCP's questions about the Atypical Antipsychotic and may provide him/her with samples only if appropriate (*i.e.*, if the HCP requests the samples for an on-label use).

VI. Clinical Research Results

A. Janssen shall report clinical research regarding Atypical Antipsychotics in an accurate, objective and balanced manner, and as required by applicable law. For all Janssen-sponsored clinical trials and to the extent permitted by the National Library of Medicine, Janssen shall register clinical trials and submit clinical trial results to the federal clinical trial registry and results data bank on the publicly accessible NIH website (www.clinicaltrials.gov) as required by the FDA Amendments Act of 2007, Public Law No. 110-85, 121 Stat 823, and any accompanying regulations that may be promulgated pursuant to that Act.

B. When presenting information about a clinical study regarding an Atypical Antipsychotic in any Promotional Materials, Janssen shall not do any of the following in a manner that causes the Promotional Materials to be false, misleading, or deceptive:

1. Present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;

2. Use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the cited average results;

3. Use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific

validity and rigor for data from the study the design or protocol of which is not amenable to formal statistical evaluations;

4. Present the information in a way that implies that the study represents larger or more general experience with the drug than it actually does; or

5. Use statistics on numbers of patients, or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case. If any results derived from pooling data are presented, Janssen shall disclose the method of pooling.

VII. Terms Relating to Payment

No later than 30 days after the Effective Date of this Judgment, Janssen shall pay $181,047,437 to be divided and paid by Janssen directly to each **Signatory Attorney General** of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. Said payment shall be used by the States as and for attorney's fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, including future consumer protection enforcement, consumer education, litigation, or local consumer aid fund or revolving fund, used to defray the cost of inquiry leading hereto, and my be used to fund or assist in funding programs directed at mental illness treatment, including but no limited to education and outreach. Colorado's allotted share shall be held in trust by the Colorado Attorney General to be used first for reimbursement of the State's actual

costs and attorney fees and, second, to be held along with any interest thereon, in trust by the Attorney General for future consumer education, consumer fraud, or antitrust enforcement actions,

VIII. Release

A. By its execution of this Judgment, the State of Colorado releases Janssen and all of its past and present, parents, subsidiaries, affiliates, predecessors, successors, and assigns and each and all of their current and former officers, directors, shareholders, employees, agents, contractors, and attorneys (collectively, the "Released Parties") from the following: all civil claims, *parens patriae* claims, causes of action, damages, restitution, fines, costs, attorneys fees, and penalties that the Colorado Attorney General has asserted or could have asserted against the Released Parties under the CCPA under Colo. Rev. Stat. § 6-1-103. (2012) or any amendment thereto, or common law claims concerning unfair, deceptive, or fraudulent trade practices, other than those asserted or that could be asserted under Sections VIII.B.2 , VIII.B.3, and VIII.B.5 below, resulting from the Covered Conduct up to and including the Effective Date (collectively, the "Released Claims").

B. Notwithstanding any term of this Judgment, specifically reserved and excluded from the Released Claims as to any entity or person, including Released Parties, are any and all of the following:

1. Any criminal liability that any person or entity, including Released Parties, has or may have to the State of Colorado;

2. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Colorado not expressly covered by the release in Section VIII.A above, including, but not limited to, any and all of the following claims:

a. State or federal antitrust violations;

b. Claims involving "best price," "average wholesale price," or "wholesale acquisition cost," or any practices related to the reporting of prices;

c. Medicaid claims, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program; and

d. State false claims violations.

3. Actions on behalf of state program payors of the State of Colorado arising from the purchase of any Atypical Antipsychotic or any other Janssen drug, except for the release of civil penalties under the Colo. Rev. Stat. § 6-1-103. (2012).

4. Any claims individual consumers have or may have under the State of Colorado above-cited consumer protection law against any person and/or entity, including Released Parties.

5. Any claims against Omnicare, Inc.

IX. Dispute Resolution

A. For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the **Signatory Attorneys General** have a reasonable basis to believe that Janssen has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date of this Judgment, then such Attorney General shall

notify Janssen in writing of the specific objection, identify with particularity the provision of this Judgment that the practice appears to violate, and give Janssen thirty (30) days to respond to the notification; provided, however, that a **Signatory Attorney General** may take any action if the **Signatory Attorney General** concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action. Upon receipt of written notice, Janssen shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why Janssen believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how Janssen intends to remedy the alleged breach. Nothing in this section shall be interpreted to limit the state's Civil Investigative Demand ("CID") or investigative subpoena authority and Janssen reserves all of its rights with respect to a CID or investigative subpoena issued pursuant to such authority.

B. Upon giving Janssen thirty (30) days to respond to the notification described above, the **Signatory Attorney General** shall also be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody, or control of Janssen that relate to Janssen's compliance with each provision of this Judgment, pursuant to that State's CID or investigative subpoena authority. If the **Signatory Attorney General** makes or requests copies of any documents during the course of that inspection, the **Signatory Attorney General** will provide a list of those documents to Janssen.

C. The State may assert any claim that Janssen has violated this Judgment in a separate civil action to enforce compliance with this Judgment, or may seek any other

relief afforded by law, but only after providing Janssen an opportunity to respond to the notification described in Paragraph IX.A. above; provided, however, that a **Signatory Attorney General** may take any action if the **Signatory Attorney General** concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

X. General Provisions

A. Janssen shall not cause third parties acting on its behalf to engage in practices from which Janssen is prohibited by this Judgment.

B. This Judgment represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, neither prior versions of this Judgment nor prior versions of any of its terms that were not entered by the Court in this Judgment may be introduced for any purpose whatsoever.

C. This Court retains jurisdiction of this Judgment and the Parties hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

D. This Judgment may be executed in counterparts, and a facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an original signature.

E. The parties agree that neither of them shall be deemed the drafter of this Judgment and that, in construing this Judgment, no provision hereof shall be construed in favor of one party on the ground that such provision was drafted by the other.

F. All Notices under this Order shall be provided to the following address via Overnight Mail:

For Janssen Pharmaceuticals, Inc. and Johnson & Johnson:

Patricia Lukens
Vice President of Law
Janssen Pharmaceuticals, Inc.
1000 Route 202 South
Raritan, New Jersey 08869

Joanne Lewers
Drinker Biddle & Reath LLP
One Logan Square
Suite 2000
Philadelphia, PA 19103

CC: Michael H. Ullmann
General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

For Attorney General: Colorado Attorney General, 1525 Sherman Street, 7th Floor, Denver, CO 80203

G. To the extent that any provision of this Judgment obligates Janssen to change any policy(ies) or procedure(s) and to the extent not already accomplished, Janssen shall implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 120 days after the Effective Date of this Judgment.

EFILED Document
CO Denver County District Court 2nd JD
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For Plaintiff,

JOHN W. SUTHERS
Attorney General

JAY B. SIMONSON
First Assistant Attorney General, 24077
1525 Sherman Street, 7th Floor
Denver, CO 80203
(303) 866-5079
(303) 866-4916 Fax

Date: 8/30/12

Janssen Pharmaceuticals, Inc.

By: Patricia Lukens

Patricia Lukens
Secretary

Date: 8/29/12

Johnson & Johnson

By: _____

Lacey P. Elberg
Assistant Secretary

Date: _____

Janssen Pharmaceuticals, Inc.

By: _____
Patricia Lukens
Secretary

Date: _____

Johnson & Johnson

By: _____
Lacey P. Elberg
Assistant Secretary

Date: 7-25-12

Done and ordered in _____

Dated this day of _____

By _____

DISTRICT COURT JUDGE

Copies furnished to:

This document constitutes a ruling of the court and should be treated as such.

Court:	CO Denver County District Court 2nd JD
Judge:	Kenneth M Laff
File & Serve Transaction ID:	46191823
Current Date:	Sep 03, 2012
Case Number:	2012CV5425
Case Name:	ST OF COLO et al vs. JANSSEN PHARMACEUTICALS INC et al
Court Authorizer:	Laff, Kenneth M

/s/ Judge Laff, Kenneth M