

NO. 13-CI-002488

JEFFERSON CIRCUIT COURT
DIVISION 3
HON. MITCH PERRY

COMMONWEALTH OF KENTUCKY
ex rel. JACK CONWAY, ATTORNEY GENERAL

PLAINTIFF

v.

JANSSEN PHARMACEUTICALS, INC.
f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.
f/k/a JANSSEN PHARMACEUTICA, INC.

JANSSEN RESEARCH & DEVELOPMENT, LLC
f/k/a JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH
& DEVELOPMENT, LLC.

and JOHNSON & JOHNSON, INC.

DEFENDANTS

FINAL JUDGMENT AND CONSENT DECREE

AND NOW, comes the Plaintiff, the Commonwealth of Kentucky *ex rel.* Jack Conway, Attorney General, having filed an action pursuant to the Kentucky Consumer Protection Act and the Parties having consented to entry of this Final Judgment and Consent Decree (“Judgment”).

NOW THEREFORE, upon the Judgment of the Parties hereto, pursuant to KRS 367.190 **IT IS HEREBY ORDERED, ADJUDGED AND DECREED AS FOLLOWS:**

PARTIES

1. The Commonwealth of Kentucky *ex rel.* Jack Conway, Attorney General, is the plaintiff in this case. The Office of the Attorney General of Kentucky is charged with, among other things, the responsibility of enforcing the Kentucky Consumer Protection Act, KRS 367.110 et seq.

2. Janssen Pharmaceuticals, Inc. (“Janssen”), Janssen Research & Development, LLC (“JR&D”), and Johnson & Johnson (“J&J”) are the defendants in this case. Janssen is a

subsidiary of J&J. Janssen does business in the Commonwealth of Kentucky. Janssen's executive offices are located at 1125 Trenton Harbourton Road, P.O. Box 200, Titusville, NJ 08560. JR&D is a subsidiary of J&J. JR&D consents to the jurisdiction of the Court solely for the purposes of this Judgment and enforcement thereof. JR&D's executive offices are located at 920 Route 202, Raritan, New Jersey 08869. J&J consents to the jurisdiction of the Court solely for the purposes of this Judgment and enforcement thereof. J&J'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 Kentucky Consumer Protection Act, in the Commonwealth of Kentucky, including, but not limited to Jefferson County.

FINDINGS

1. This Court has jurisdiction over the subject matter of this Action and over all Parties.
2. The terms of this Judgment shall be governed by the laws of the Commonwealth of Kentucky.
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.
5. Janssen is willing to enter into this Judgment regarding the Covered Conduct solely in order to resolve the Commonwealth of Kentucky's concerns under the Kentucky Consumer Protection Act, KRS 367.110 *et seq.*, as to the matters addressed in this Judgment and thereby 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 Defendants expressly deny. Defendants do not admit any violation of law, and do not admit any wrongdoing that was or could have been alleged by the Commonwealth of Kentucky 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 Defendants. 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 Commonwealth of Kentucky may file an action to enforce the terms of this Judgment.

6. Defendants are entering into this Judgment solely for the purpose of settlement of the instant Action. This Judgment does not create a waiver or limit Defendants' legal rights, remedies, or defenses in any other action by the Commonwealth of Kentucky, and does not waive or limit Defendants' right to defend themselves 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 Defendants may have in connection with any investigations, claims, or other matters the Commonwealth of Kentucky is not releasing hereunder. Notwithstanding the foregoing, the Commonwealth of Kentucky 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 for an Atypical Antipsychotic, New Drug Application for an Atypical Antipsychotic, Supplemental New Drug Application for an Atypical Antipsychotic, or Abbreviated New Drug Application for an Atypical Antipsychotic 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. “**Action**” shall mean the civil action filed by the Commonwealth of Kentucky against Janssen Pharmaceuticals, Inc.; Janssen Research & Development, LLC; and Johnson & Johnson (erroneously named Johnson & Johnson, Inc.) in the Circuit Court of Jefferson County, Kentucky, Division 3, captioned *Commonwealth of Kentucky ex rel. Jack Conway,*

Attorney General v. Janssen Pharmaceuticals, Inc. f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. f/k/a Janssen Pharmaceutica, Inc.; Janssen Research & Development, LLC f/k/a Johnson & Johnson Pharmaceutical Research & Development, LLC; and Johnson & Johnson, Inc., No. 13-CI-002488.

2. **“Atypical Antipsychotic”** shall mean all of Janssen’s products that are FDA-approved drug formulations containing risperidone and/or paliperidone.

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

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

5. **“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.

6. **“Effective Date”** shall mean the date on which a copy of this Judgment, duly executed by Defendants and by the Attorney General, is approved by, and becomes a Judgment of the Court.

7. **“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.

8. **“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.

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

10. **“Janssen’s Law Department”** shall mean personnel of the Janssen Law Department or its designee providing legal advice to Janssen.

11. **“Janssen Marketing”** shall mean Janssen personnel responsible for marketing Janssen’s Atypical Antipsychotics in the U.S.

12. **“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.

13. **“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.

14. **“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.

15. **“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.

16. **“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.

17. **“Parties”** shall mean Janssen Pharmaceuticals, Inc.; Janssen Research & Development, LLC; and Johnson & Johnson and the Commonwealth of Kentucky *ex rel.* Jack Conway, Attorney General.

18. **“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.

19. **“Promotional Materials”** shall mean any item used to Promote an Atypical Antipsychotic.

20. **“Promotional Media”** shall mean Promotional Materials in any media format for use in speaker programs.

21. **“Promotional Speaker”** shall mean an HCP speaker engaged to Promote an Atypical Antipsychotic in the United States.

22. **“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.

23. **“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.

24. **“Attorney General”** shall mean the Attorney General of the Commonwealth of Kentucky, or his authorized designee, who has agreed to this Judgment.

25. “**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

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 until August 30, 2017:

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 until August 30, 2017:

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 until August 30, 2017:

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 Commonwealth of Kentucky 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 August 30, 2017, Janssen shall be required to file reports with the Office of Inspector General of the Department of Health and Human Services (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 until August 30, 2017:

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 \$15,500,000 to the Commonwealth of Kentucky by wire transfer pursuant to the instructions provided to counsel. Said payment shall be used by the Commonwealth as and for attorneys' 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 costs of the inquiry leading hereto, and may be used to fund or assist in funding programs directed at mental illness treatment, including but not limited to education and outreach or for other uses permitted by state law, at the sole discretion of the Attorney General. The Office of the Attorney General may retain \$3,100,000 as its reasonable costs of litigation, pursuant to KRS 48.005 and as determined by the Court. The Parties acknowledge that the payment described herein is not a fine, penalty, or payment in lieu thereof.

VIII. Release

A. By its execution of this Judgment, the Commonwealth of Kentucky releases Defendants and all 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 Kentucky Attorney General has asserted or could have asserted against the Released Parties under the Kentucky Consumer Protection Act or any amendment thereto; common law claims concerning unfair, deceptive, or fraudulent trade practices; and Medicaid claims, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud, or other abuse (whether common law, statutory, or otherwise), and/or kickback violations related to the Commonwealth of Kentucky’s Medicaid program, other than those asserted or that could be asserted under Sections VIII.B.2 and VIII.B.3 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 Commonwealth of Kentucky;

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

a. State or federal antitrust violations; and

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

3. Actions on behalf of state program payors of the Commonwealth arising from the purchase of any Atypical Antipsychotic or any other Janssen drug, except for the release of civil penalties under the Kentucky Consumer Protection Act, KRS 367.110 *et seq.* and/or the Kentucky Medicaid Fraud Statute, KRS 205.8451 *et seq.*; and

4. Any claims individual consumers have or may have under the Kentucky Consumer Protection Act or other applicable law against any person and/or entity, including Released Parties.

IX. Dispute Resolution

A. For the purposes of resolving disputes with respect to compliance with this Judgment, should the Attorney 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 the 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 the Attorney General may take any action if the 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 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 Attorney General makes or requests copies of any documents during the course of that inspection, the Attorney General will provide a list of those documents to Janssen.

C. The Commonwealth of Kentucky 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 the Attorney

General may take any action if the 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 none 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 the Commonwealth:

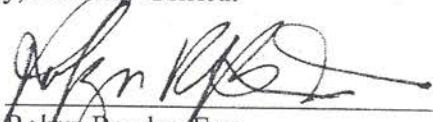
Todd Leatherman
Executive Director, Consumer Protection
Office of the Attorney General
1024 Capitol Center Drive
Frankfort, Kentucky 40601

For Janssen Pharmaceuticals, Inc.;
Janssen Research & Development, LLC;
and Johnson & Johnson:

Lisbeth Warren, Esq.
Assistant General Counsel
Johnson & Johnson
Office of General Counsel
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

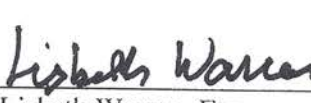
Dated: 12/22/2015

Commonwealth of Kentucky *ex rel.* Jack
Conway, Attorney General

By: 
Robyn Bender, Esq.
Acting Chief Deputy Attorney General
Office of the Attorney General
700 Capital Avenue, Suite 118
Frankfort, Kentucky 40601

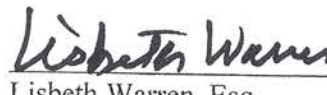
Dated: 12/22/2015

Janssen Pharmaceuticals, Inc.

By:  *by Chapater with permission*
Lisbeth Warren, Esq.
Assistant General Counsel
Johnson & Johnson
Office of General Counsel
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Dated: _____

Janssen Research & Development, LLC

By:  *by Chapater with permission*
Lisbeth Warren, Esq.
Assistant General Counsel
Johnson & Johnson
Office of General Counsel
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Johnson & Johnson

Dated: December 22, 2015

By: Lisbeth Warren by Ch. Petri
Lisbeth Warren, Esq. with permission
Assistant General Counsel
Johnson & Johnson
Office of General Counsel
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Agreed to and Submitted by:

Robyn Bender
Acting Chief Deputy Attorney General
Laura S. Crittenden
Assistant Attorney General
OFFICE OF THE ATTORNEY GENERAL
700 Capital Avenue, Suite 118
Frankfort, KY 40601

LeeAnne Applegate
Assistant Attorney General
Elizabeth Ungar Natter
Assistant Attorney General
OFFICE OF THE ATTORNEY GENERAL
1024 Capital Center Drive, Suite 200
Frankfort, KY 40601


Tad Thomas
THE THOMAS FIRM, PLLC
9418 Norton Commons Blvd.
Suite 200
Louisville, KY 40059

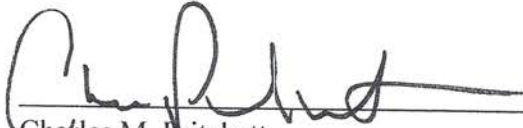
Robert W. Cowan (*Pro Hac Vice*)
Justin C. Jenson (*Pro Hac Vice*)
Elizabeth Dwyer (*Pro Hac Vice*)
Adam Peavy (*Pro Hac Vice*)
BAILEY PEAVY BAILEY PLLC
440 Louisiana Street, Suite 2100
Houston, TX 77002

Attorneys for Plaintiff

SO ORDERED:

Dated: _____

ENTERED IN COURT DAVID L. NICHOLSON, CLERK	
DEC 22 2015	
BY	
DEPUTY CLERK	


Charles M. Fritchett
Sheryl G. Snyder
Theresa A. Canaday
FROST BROWN TODD LLC
400 West Market Street, Suite 3200
Louisville, KY 40020-3363

Susan J. Pope
FROST BROWN TODD LLC
250 West Main Street, Suite 2800
Lexington, KY 40507
Tel: (859) 244-3204
Fax: (859) 231-0011

Joanne C. Lewers (*Pro Hac Vice*)
Chanda A. Miller (*Pro Hac Vice*)
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996

*Attorneys for Defendants Janssen
Pharmaceuticals, Inc.; Janssen Research
& Development, LLC; and Johnson & Johnson*



JUDGE, JEFFERSON CIRCUIT COURT

12-22-2015