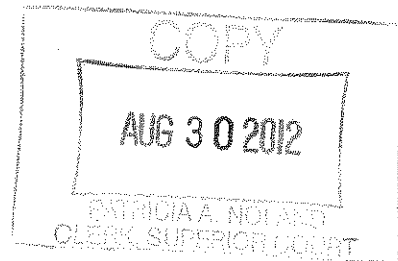


1 Thomas C. Horne
2 Attorney General
3 Firm Bar No. 14000
4 Noreen R. Matts
5 Assistant Attorney General
6 State Bar No. #010363
7 noreen.matts@azag.gov
8 Office of the Attorney General
9 Consumer Protection & Advocacy Section
10 400 W. Congress, South Bldg., Suite 315
11 Tucson, Arizona 85701-1367
12 Telephone: (520) 628-6504
13 Facsimile: (520) 628-6503
14 Pima County Computer No. 36732
15 Attorneys for Plaintiff



11 **IN THE SUPERIOR COURT OF THE STATE OF ARIZONA**

12 **IN AND FOR THE COUNTY OF PIMA**

13 STATE OF ARIZONA, *ex rel.* THOMAS C.
14 HORNE, Attorney General,

No. **C20125362**

15 Plaintiff

16 vs.

COMPLAINT FOR INJUNCTIVE AND
OTHER RELIEF

17 Janssen Pharmaceuticals,., a
18 Pennsylvania corporation, and Johnson &
19 Johnson, a New Jersey corporation,

Charles Harrington

20 Defendants.
21

22 The State of Arizona brings this action pursuant to the Arizona Consumer Fraud
23 Act, A.R.S. § 44-1521, *et seq.*, to obtain restitution, declaratory and injunctive relief,
24 civil penalties, attorneys' fees and costs, investigative expenses and other relief to
25 prevent the unlawful acts and practices alleged in this Complaint.

26 **JURISDICTION AND VENUE**

27 1. This Court has jurisdiction over the subject matter and Janssen
28 Pharmaceuticals, Inc. and Johnson & Johnson to enter appropriate orders, both prior

1 to and following a determination of liability pursuant to A.R.S. § 44-1528.

2 2. Venue is proper in Pima County, Arizona.

3 **PARTIES**

4 3. Plaintiff is the State of Arizona, *ex rel.* Thomas C. Horne, the Attorney
5 General of Arizona ("the State") who is authorized to bring this action under the
6 Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*, ("the Act").

7 4. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania
8 corporation with its principal place of business at 1125 Trenton Harbourn Road,
9 Titusville, New Jersey, and is a wholly-owned subsidiary of Johnson & Johnson.

10 5. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania
11 corporation with its principal place of business at 1125 Trenton Harbourn Road,
12 Titusville, New Jersey, and is a wholly-owned subsidiary of Johnson & Johnson.

13 6. Defendant Johnson & Johnson is a New Jersey corporation with its
14 principal place of business at One Johnson & Johnson Plaza, New Brunswick, New
15 Jersey. Defendant Janssen and Defendant Johnson & Johnson, through its wholly-
16 owned subsidiary Janssen, transacts business in Arizona and nationwide by
17 manufacturing, marketing, promoting, selling and distributing atypical antipsychotic
18 prescription drugs containing risperidone or paliperidone, the most popular product is
19 known by the trade name Risperdal (which includes Risperdal Consta and Risperdal
20 M-Tab).

21 **BACKGROUND**

22 9. Risperdal is one of several second-generation antipsychotic prescription
23 drugs (also referred to as "atypical antipsychotics") developed to reduce some of the
24 side effects caused by traditional antipsychotic drugs.

25 10. In January 1994, Janssen launched Risperdal, the trade name for its
26 atypical antipsychotic drug containing the chemical risperidone. At the time, the only
27 Food and Drug Administration ("FDA")-approved indication for Risperdal use was for
28 "the management of manifestations of psychotic disorders" in adults.

1 11. In September 2000, the FDA narrowed the approved indication and use
2 for Risperdal from "indicated for the management of the manifestations of psychotic
3 disorders" to "indicated for the treatment of schizophrenia."

4 12. In 2003, the FDA approved Risperdal M-Tab (an orally dissolving form of
5 Risperdal) and Risperdal Consta (a long-acting injectible form of Risperdal) for the
6 treatment of schizophrenia in adults.

7 13. The FDA subsequently approved Risperdal for the following indications:
8 as monotherapy for the short-term treatment of acute manic or mixed episodes
9 associated with Bipolar I Disorder in adults; as adjunctive therapy, with lithium or
10 valproate, for the short-term treatment of acute manic or mixed episodes associated
11 with Bipolar I Disorder in adults; the treatment of irritability associated with autistic
12 disorder in children and adolescents; the treatment of schizophrenia in adolescents
13 ages 13-17; and for the short-term treatment of manic or mixed episodes of Bipolar I
14 Disorder in children and adolescents ages 10-17.

15 14. The FDA has never approved the use of Risperdal by adults, children, or
16 the elderly for the treatment of depression, anxiety, attention deficit disorder ("ADD"),
17 attention deficit and hyperactivity disorder ("ADHD"), conduct disorder, sleep
18 disorders, anger management, dementia, Alzheimer's disease, post traumatic stress
19 disorder, or for mood enhancement or mood stabilization.

20 **JANSSEN'S MARKETING OF RISPERDAL**

21 15. Federal and state laws allow physicians to prescribe FDA-approved
22 drugs for conditions or diseases for which specific FDA approval has not been
23 obtained when, through the exercise of independent professional judgment, the
24 physician determines the drug in question is an appropriate treatment for an individual
25 patient. This practice is referred to as prescribing for an "off-label" use.

26 16. However, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.
27 § 301 *et seq.*, pharmaceutical manufacturers may not promote or market their
28

1 products for any use not specifically approved by the FDA. This prohibited practice is
2 known as "off-label marketing."

3 17. Janssen promoted Risperdal through the use of various marketing
4 practices that were designed to result in the increase of off-label use of Risperdal.
5 These practices included: setting sales goals and creating incentives that motivated
6 sales representatives to promote Risperdal for unapproved uses; sponsoring and
7 arranging speaker programs that promoted unapproved uses; conducting sham
8 "consulting" programs in which physicians were paid to learn about Risperdal's
9 unapproved uses; and rewarding physicians who prescribed and promoted Risperdal
10 for unapproved uses with lucrative consulting agreements.

11 18. Despite having narrow FDA approval for Risperdal, Janssen promoted
12 and marketed Risperdal off-label for the treatment of a variety of conditions and to a
13 variety of patient populations for the treatment of conditions not included within the
14 FDA-approved indications, including depression, anxiety, ADD, ADHD, conduct
15 disorder, sleep disorders, anger management, dementia, Alzheimer's, and post
16 traumatic stress disorder.

17 19. Through these marketing efforts, Janssen sought to enhance Risperdal's
18 off-label market penetration across a wide range of diagnoses and patient populations,
19 including child and geriatric patients who were unlikely to have indications for which
20 the use of Risperdal had been approved by the FDA.

21 20. To expand Risperdal's use in the geriatric population, for example, Janssen
22 created and deployed an "ElderCare" sales force in mid-1998, the purpose of which
23 was to focus specifically on Risperdal's use to treat dementia in the elderly. Eventually,
24 the FDA required Janssen to add a black box warning (the FDA's most severe
25 warning), for Risperdal and other atypical antipsychotic products that, "Treatment of
26 behavioral disorders in elderly patients with dementia with atypical antipsychotic
27 medications is associated with increased mortality."
28

1 21. While building its market for Risperdal, whether for on-label or off-label
2 uses, Janssen also masked, withheld, or failed to disclose negative information
3 contained in scientific studies concerning the safety and efficacy of Risperdal.

4 22. On November 10, 2003, for example, Janssen sent a form letter to
5 thousands of health care providers to downplay any connection between the use of
6 Risperdal and the development of diabetes. The letter stated, in part, "a body of
7 evidence from published peer-reviewed epidemiology research suggests that
8 RISPERDAL is not associated with a risk of increased diabetes when compared to
9 untreated patients or patients treated with conventional antipsychotics. Evidence also
10 suggests that RISPERDAL is associated with a lower risk of diabetes than some other
11 studied atypical antipsychotics." The letter prompted the FDA on April 19, 2004 to
12 issue a "Warning Letter" to Janssen, stating that the letter "misleadingly omits
13 information about Risperdal, minimizes potentially fatal risks associated with the drug,
14 and claims superior safety to other drugs in its class without adequate substantiation,"
15 in violation of the Federal Food, Drug, and Cosmetic Act.

16 **VIOLATIONS OF THE CONSUMER FRAUD ACT**

17 23. Plaintiff realleges and incorporates by reference herein each and every
18 allegation contained in the preceding paragraphs 1 through 22.

19 24. The Consumer Fraud Act at A.R.S. § 44-1522 (A) states the following:

20 (A) The act, use, or employment by any person of any deception,
21 deceptive act or practice, fraud, false pretense, false promise,
22 misrepresentation, or concealment, suppression or omission of
23 any material fact with intent that others rely upon such
24 concealment, suppression or omission, in connection with the sale
 or advertisement of any merchandise whether or not any person
 has in fact been misled, deceived, or damaged thereby, is
 declared to be an unlawful practice.

25 25. Defendants, in the course of marketing, promoting, selling, and
26 distributing the prescription drug Risperdal have engaged in deceptive or misleading
27 practices which are unlawful under the Arizona Consumer Fraud Act, A.R.S. § 44-
28 1521, *et seq.* by promoting Risperdal for uses that have not been shown to be safe or

1 effective and by failing to adequately disclose the risks associated with the use of
2 Risperdal.

3 26. Defendants, in the course of marketing, promoting, selling, and
4 distributing the prescription drug Risperdal have engaged in deceptive or misleading
5 practices which are unlawful under the Arizona Consumer Fraud Act, A.R.S. § 44-
6 1521, *et seq.* by representing that Risperdal has sponsorship, approval,
7 characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

8 **RELIEF REQUESTED**

9 WHEREFORE, the State respectfully requests that this Court:

10 A. Issue a permanent injunction prohibiting Defendants, its agents,
11 employees, and all other persons and entities, corporate or otherwise, in active
12 concert or participation with Defendants, from engaging in any conduct that violates
13 A.R.S. § 44-1521 *et seq.*

14 B. Order Defendants to restore to consumers any monies which Defendants
15 acquired by their deceptive practices, or in the alternative, if restoring consumer losses
16 is not possible, order Defendants, to pay monies which are restitutionary in nature and
17 designed to address the alleged deceptive practices in which Defendants engaged as
18 set out in this complaint.

19 C. Order Defendants to pay to the State of Arizona a civil penalty of up to
20 \$10,000.00 for each willful violation of the Arizona Consumer Fraud Act pursuant to
21 A.R.S. § 44-1531.

22 D. Order Defendants to reimburse the Attorney General for the costs of
23 investigation and reasonable attorneys' fees pursuant to A.R.S. § 44-1534.

24
25
26
27 ///

28 ///

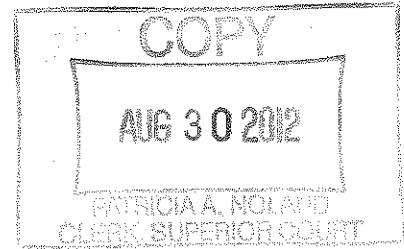
1 E. Grant such other and further relief as the Court deems equitable and
2 proper.

3 DATED this 30th day of August, 2012.

4
5 THOMAS C. HORNE
6 ATTORNEY GENERAL

7 By: Noreen R. Matts
8 NOREEN R. MATTS
9 Assistant Attorney General
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

1 Thomas C. Horne
2 Attorney General
3 Firm Bar No. 14000
4 Noreen R. Matts
5 Assistant Attorney General
6 State Bar No. #010363
7 noreen.matts@azag.gov
8 Office of the Attorney General
9 Consumer Protection & Advocacy Section
10 400 W. Congress, South Bldg., Suite 315
11 Tucson, Arizona 85701-1367
12 Telephone: (520) 628-6504
13 Facsimile: (520) 628-6503
14 Pima County Computer No. 36732
15 Attorneys for Plaintiff



11 IN THE SUPERIOR COURT OF THE STATE OF ARIZONA
12 IN AND FOR THE COUNTY OF PIMA

14 STATE OF ARIZONA, *ex rel.* THOMAS C.
15 HORNE, Attorney General,

16 Plaintiff

17 vs.

18 Janssen Pharmaceuticals, Inc., a
19 Pennsylvania corporation, and Johnson &
20 Johnson, a New Jersey corporation,

21 Defendants.

No. C20125362

JOINT MOTION TO ENTER CONSENT
JUDGMENT

Charles Harrington

23 The parties, by and through undersigned counsel, respectfully move this Court
24 to enter an Order Re: Consent Judgment, a copy of which Order is filed
25 contemporaneously with this Motion.

26 1. The State of Arizona filed a Complaint alleging violations of A.R.S. § 44-
27 1521 *et seq.*, the Consumer Fraud Act, against defendants Janssen Pharmaceuticals,
28 Inc. and Johnson & Johnson.

1 2. The State of Arizona, by its counsel, and Janssen Pharmaceuticals, Inc.
2 and Johnson & Johnson, by their counsel, have agreed to the entry of this Order by
3 the Court without trial or adjudication of any issue of fact or law.

4 3. The terms of the Consent Judgment ("Judgment") shall be governed by
5 the laws of the State of Arizona.

6 **JURISDICTION AND VENUE**

7 1. The Superior Court has jurisdiction to enter appropriate orders pursuant
8 to A.R.S. § 44-1528.

9 2. Venue is proper in Pima County, Arizona.

10 **PARTIES**

11 1. Plaintiff is the State of Arizona, *ex rel.* Thomas C. Horne, the Attorney
12 General of Arizona ("the State") who is authorized to bring this action under the
13 Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*, ("the Act").

14 2. Janssen Pharmaceuticals, Inc. ("Janssen") is a subsidiary of Johnson &
15 Johnson. Janssen does business in the State of Arizona. Janssen's executive offices
16 are located at 1125 Trenton Harbourn Road, P.O. Box 200, Titusville, NJ 08560. At
17 all times relevant hereto, Janssen engaged in trade affecting consumers, within the
18 meaning of the Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*, in the State of
19 Arizona. At all times relevant hereto Janssen engaged in the offer, promotion, and
20 sale of goods in the State of Arizona. Johnson & Johnson consents to the jurisdiction
21 of this Court solely for the purposes of this Consent Judgment.

22 **FINDINGS**

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

25 2. The terms of this Judgment shall be governed by the laws of the State of
26 Arizona.

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

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

3 5. Janssen is willing to enter into this Judgment regarding the Covered
4 Conduct solely in order to resolve the Attorneys General's concerns under the State
5 Consumer Protection Laws as to the matters addressed in this Judgment and thereby
6 avoid unnecessary expense, inconvenience, and uncertainty. Nothing contained
7 herein may be taken as or construed to be an admission or concession of any violation
8 of law or regulation, or of any other matter of fact or law, or of any liability or
9 wrongdoing (including allegations of the Complaint), all of which Janssen expressly
10 denies. Janssen does not admit any violation of law, and does not admit any
11 wrongdoing that was or could have been alleged by any Attorney General before the
12 date of the Judgment. No part of this Judgment, including its statements and
13 commitments, shall constitute evidence of any liability, fault, or wrongdoing by
14 Janssen. This Judgment is made without trial or adjudication of any issue of fact or
15 law or finding of liability of any kind. It is the intent of the Parties that this Judgment
16 shall not be binding or admissible in any other matter, including, but not limited to, any
17 investigation or litigation, other than in connection with the enforcement of this
18 Judgment. No part of this Judgment shall create a private cause of action or confer
19 any right to any third party for violation of any federal or state statute except that a
20 State may file an action to enforce the terms of this Judgment.

21 6. Janssen is entering into this Judgment solely for the purpose of
22 settlement of the instant action. This Judgment does not create a waiver or limit
23 Janssen's legal rights, remedies, or defenses in any other action by the Signatory
24 Attorney General, and does not waive or limit Janssen's right to defend itself from, or
25 make argument in, any other matter, claim, or suit, including, but not limited to, any
26

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

1 investigation or litigation relating to the subject matter or terms of this Judgment.
2 Nothing in this Judgment shall waive, release, or otherwise affect any claims,
3 defenses, or positions Janssen may have in connection with any investigations,
4 claims, or other matters the State is not releasing hereunder. Notwithstanding the
5 foregoing, a State may file an action to enforce the terms of this Judgment.

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

17 8. Nothing in this Judgment shall require Janssen to:

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

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

22 DEFINITIONS

23 The following definitions shall be used in construing this Judgment:

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

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

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

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

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

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

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

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

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

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

23 11. **"Janssen Sales"** shall mean the Janssen sales force responsible for
24 U.S. Atypical Antipsychotic sales, including, but not limited to, Janssen personnel
25 whose employment responsibilities include working with public or private entities in
26 determining whether to include Atypical Antipsychotics on their prescription drug
27 formularies or preferred drug lists.
28

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

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

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

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

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

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

28 18. **“Parties”** shall mean Janssen and the Signatory Attorney General.

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

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

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

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

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

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

18 25. **“Signatory Attorney General”** shall mean the Attorney General of
19 Arizona, or her authorized designee, who has agreed to this Judgment.

20 26. **“State Consumer Protection Laws”** shall mean the consumer
21 protection laws under which the Attorneys General have conducted the investigation,
22 which are cited in footnote 2.²

23
24 ² ALABAMA – Alabama Deceptive Trade Practices Act, Ala. Code § 8-19-1 et seq.; ARIZONA – Arizona
25 Consumer Fraud Act, A.R.S. § 44-1521 et seq.; COLORADO – Colorado Consumer Protection Act,
26 Colo. Rev. Stat. § 6-1-101 et seq.; CONNECTICUT - Connecticut Unfair Trade Practices Act, Conn.
27 Gen. Stat. §§ 42-110a et seq.; DELAWARE – Delaware Consumer Fraud Act, Del. CODE ANN. tit. 6,
28 §§ 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

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

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.

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.

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

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

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

9 2. With respect to Promotional Media:

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

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

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

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

26 G. Janssen's systems and controls shall:
27
28

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

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

8 **II. Dissemination and Exchange of Medical Information**

9 A. General Terms

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

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

14 B. Clinical Responses

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

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

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

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

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

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

4 3. Clinical Responses regarding an Atypical Antipsychotic may be
5 disseminated only by Janssen Scientifically Trained Personnel to HCPs, and
6 Janssen's Sales and Marketing shall not disseminate these materials to HCPs except
7 in circumstances implicating public health and safety issues. In such circumstances,
8 Janssen's Sales and Marketing may disseminate a Clinical Response directly to HCPs
9 when expressly authorized by the Health Care Compliance Officer, the Vice President
10 of Medical/Scientific Affairs responsible for the Atypical Antipsychotic(s) included in the
11 Clinical Response(s), and Senior Counsel from the Janssen Law Department.

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

16 C. Responses to Unsolicited Requests for Off-Label Information

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

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

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

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

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

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

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

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

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

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

20 D. Reprints

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

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

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

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

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

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

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

16 5. Nothing in this Judgment shall preclude Janssen from
17 disseminating reprints which have only an incidental reference to Off-Label
18 information. If reprints have an incidental reference to Off-Label information, such
19 reprints shall contain the disclosures required by Section II.D.4.a. and II.D.4.b in a
20 prominent location, as defined above, and such incidental reference to Off-Label
21 information shall not be referred to or used in a Promotional manner as prohibited by
22 Section II.D.4.c.

23
24 **III. Grants**

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

27 A. Janssen shall disclose information about medical education grants,
28 including continuing medical education ("CME") grants, regarding an Atypical

1 Antipsychotic consistent with the current disclosures of the Janssen Scientific Affairs
2 Medical Education Department at www.janssenime.com (hereinafter, "JSA MED
3 website") and as required by applicable law.

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

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

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

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

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

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

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

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

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

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

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

13 **IV. Payments to Consultants and Speakers**

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

24 **V. Product Samples**

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

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

1 B. If an HCP whose clinical practice is inconsistent with an Atypical
2 Antipsychotic's FDA-approved Labeling requests samples of an Atypical Antipsychotic,
3 Janssen personnel shall refer the HCP to Janssen Medical where the practitioner can
4 speak directly with a Janssen Medical representative who will provide answers to the
5 HCP's questions about the Atypical Antipsychotic and may provide him/her with
6 samples only if appropriate (i.e., if the HCP requests the samples for an on-label use).

7 **VI. Clinical Research Results**

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

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

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

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

25 3. Use statistical analyses and techniques on a retrospective basis
26 to discover and cite findings not soundly supported by the study, or to suggest
27 scientific validity and rigor for data from the study the design or protocol of which is not
28 amenable to formal statistical evaluations;

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

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

9 **VII. Terms Relating to Payment**

10 A. No later than 30 days after the Effective Date of this Judgment, Janssen
11 shall pay \$181,047,437 to be divided and paid by Janssen directly to each Signatory
12 Attorney General of the Multistate Working Group in an amount to be designated by
13 and in the sole discretion of the Multistate Executive Committee. The Parties
14 acknowledge that the payment described herein is not a fine, penalty, or payment in
15 lieu thereof.

16 B. Arizona's portion of the payment will be used for the consumer protection
17 purposes described below in order to redress the alleged unlawful acts and practices
18 described in the Complaint and because it is impractical to identify and compensate
19 specific individuals impacted by such practices in Arizona.

20 C. Arizona's portion of the payment is \$6,094,396.00. The Attorney General
21 shall deposit \$2,000,000.00 into the Consumer Fraud Revolving Fund and use such
22 payment for the following purposes:

- 23 1. \$750,000.000 to cover investigative costs, expenses, and
24 attorneys' fees, both those incurred through the Effective Date and those
25 incurred in monitoring and implementing this Consent Judgment and the
26 Distribution Plan as set forth in Section C below or as otherwise
27 permitted by A.R.S. Section § 44-1531.01(C).
28

1 2. \$1,250,000.00 to be used for the costs of investigation and
2 prosecution of consumer protection pharmaceutical, health fraud or
3 health-related cases; and/or consumer protection cases involving the
4 alleged misrepresentation of scientific studies and/or evidence, or the
5 alleged minimization of the risks of health care products.

6 D. The remaining amount of the payment ("Custodial Funds") is restitutionary
7 in nature, consistent with A.R.S. Section § 44-1528(A) (2). The Arizona Attorney
8 General is the custodian and trustee of the Custodial Funds, which are held in trust to
9 be used solely for the benefit of the third party organizations and individuals in Arizona
10 selected to perform the research, studies, grants, and/or programs specifically
11 identified below. The Custodial Funds shall be deposited into a separate, interest-
12 bearing trust account and shall be used for the exclusive purpose of funding any of the
13 following items, in whole or in part. Nothing in the following sections represents or
14 implies that Janssen engaged in any wrongdoing with regard to the promotion of
15 atypical antipsychotics, and Janssen does not admit any wrongdoing with regard to the
16 promotion of atypical antipsychotics:

17 1. Research, studies, grants, and/or programs (including reasonable
18 administrative expenses) to provide alternatives to the use of atypical
19 antipsychotics for managing the effects of Alzheimer's disease and/or
20 dementia for elderly patients in long term care facilities; and/or

21 2. Research, studies, grants, and/or programs (including reasonable
22 administrative expenses) to provide alternatives to the use of atypical
23 antipsychotics for managing childhood and adolescent developmental
24 and learning disorders; and/or

25 3. Research, studies, grants, and/or programs (including reasonable
26 administrative expenses) and/or education and outreach programs
27 directed at treatments for mental illness and/or mental disorders,
28 including but not limited to anxiety, behavioral and/or mood disorders.

1 **VIII. Release**

2 A. By its execution of this Judgment, the State of Arizona releases Janssen
3 and all of its past and present, parents, subsidiaries, affiliates, predecessors,
4 successors, and assigns and each and all of their current and former officers,
5 directors, shareholders, employees, agents, contractors, and attorneys (collectively,
6 the "Released Parties") from the following: all civil claims, parens patriae claims,
7 causes of action, damages, restitution, fines, costs, attorneys fees, and penalties that
8 the Arizona Attorney General has asserted or could have asserted against the
9 Released Parties under the Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*
10 or any amendment thereto, or common law claims concerning unfair, deceptive, or
11 fraudulent trade practices, other than those asserted or that could be asserted under
12 Sections VIII.B.2 , VIII.B.3, and VIII.B.5 below, resulting from the Covered Conduct up
13 to and including the Effective Date (collectively, the "Released Claims").

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

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

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

23 a. State or federal antitrust violations;

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

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

1 d. State false claims violations.

2 3. Actions on behalf of state program payors of the State of Arizona
3 arising from the purchase of any Atypical Antipsychotic or any other Janssen drug,
4 except for the release of civil penalties under the Arizona Consumer Fraud Act, A.R.S.
5 § 44-1521, *et seq.*

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

9 5. Any claims against Omnicare, Inc.

10 **IX. Dispute Resolution**

11 A. For the purposes of resolving disputes with respect to compliance with
12 this Judgment, should any of the Signatory Attorneys General have a reasonable basis
13 to believe that Janssen has engaged in a practice that violates a provision of this
14 Judgment subsequent to the Effective Date of this Judgment, then such Attorney
15 General shall notify Janssen in writing of the specific objection, identify with
16 particularity the provision of this Judgment that the practice appears to violate, and
17 give Janssen thirty (30) days to respond to the notification; provided, however, that a
18 Signatory Attorney General may take any action if the Signatory Attorney General
19 concludes that, because of the specific practice, a threat to the health or safety of the
20 public requires immediate action. Upon receipt of written notice, Janssen shall provide
21 a good-faith written response to the Attorney General notification, containing either a
22 statement explaining why Janssen believes it is in compliance with the Judgment, or a
23 detailed explanation of how the alleged violation occurred and a statement explaining
24 how Janssen intends to remedy the alleged breach. Nothing in this section shall be
25 interpreted to limit the state's Civil Investigative Demand ("CID") or investigative
26 subpoena authority and Janssen reserves all of its rights with respect to a CID or
27 investigative subpoena issued pursuant to such authority.

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

9 C. The State may assert any claim that Janssen has violated this Judgment
10 in a separate civil action to enforce compliance with this Judgment, or may seek any
11 other relief afforded by law, but only after providing Janssen an opportunity to respond
12 to the notification described in Paragraph IX.A. above; provided, however, that a
13 Signatory Attorney General may take any action if the Signatory Attorney General
14 concludes that, because of the specific practice, a threat to the health or safety of the
15 public requires immediate action.

16 **X. General Provisions**

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

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

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

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

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

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

7 For Janssen Pharmaceuticals, Inc. and Johnson & Johnson:

8 Patricia Lukens
9 Vice President of Law
10 Janssen Pharmaceuticals, Inc.
11 1000 Route 202 South
12 Raritan, New Jersey 08869

13 Joanne Lewers
14 Drinker Biddle & Reath LLP
15 One Logan Square
16 Suite 2000
17 Philadelphia, PA 19103-6996

18 With a cc to:

19 Michael H. Ullmann
20 General Counsel
21 Johnson & Johnson
22 One Johnson & Johnson Plaza
23 New Brunswick, New Jersey 08933

24 For the State of Arizona:

25 Noreen R. Matts
26 Assistant Attorney General
27 Consumer Protection & Advocacy Section
28 400 W. Congress, South Bldg., Suite 315
Tucson, Arizona 85701-1367

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.

1 For Plaintiff,

2

3 THE STATE OF ARIZONA

4

5 By: Noreen R. Matts
6 NOREEN R. MATTS
7 Assistant Attorney General
8 Consumer Protection & Advocacy Section
400 West Congress, S-Bldg., Suite 315
Tucson, Arizona 85701

9

10 Date: August 30, 2012

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

1 Janssen Pharmaceuticals, Inc.

2
3 By: Patricia Clarke Lukens
4 Patricia Clarke Lukens
Secretary

5 Date: 8/29/12
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Johnson & Johnson

By: Lacey P. Elberg
Lacey P. Elberg
Assistant Secretary

Date: 8-29-12

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Janssen Pharmaceuticals, Inc. and Johnson & Johnson

By: Mary S. Ory

Date: 8/30/2012

Local Counsel for Janssen Pharmaceuticals, Inc.
and Johnson & Johnson

1 Thomas C. Horne
2 Attorney General
3 Firm Bar No. 14000
4 Noreen R. Matts
5 Assistant Attorney General
6 State Bar No. #010363
7 noreen.matts@azag.gov
8 Office of the Attorney General
9 Consumer Protection & Advocacy Section
10 400 W. Congress, South Bldg., Suite 315
11 Tucson, Arizona 85701-1367
12 Telephone: (520) 628-6504
13 Facsimile: (520) 628-6503
14 Pima County Computer No. 36732
15 Attorneys for Plaintiff

10 **IN THE SUPERIOR COURT OF THE STATE OF ARIZONA**
11 **IN AND FOR THE COUNTY OF PIMA**

12 STATE OF ARIZONA, *ex rel.* THOMAS C.
13 HORNE, Attorney General,

14
15 Plaintiff

16 vs.

17 Janssen Pharmaceuticals, Inc., a
18 Pennsylvania corporation, and Johnson &
19 Johnson, a New Jersey corporation,

20 Defendants.

No. **C20125362**

ORDER RE: CONSENT JUDGMENT

Charles Harrington

21 Based on the above-listed parties' Joint Motion to Enter Consent Judgment and
22 good cause appearing,

23 **THE COURT HEREBY FINDS AND ORDERS:**

24 The parties, by and through undersigned counsel, have filed a Joint Motion to
25 Enter Consent Judgment, a copy of which is filed contemporaneously with this Order.

26 1. The State of Arizona filed a Complaint alleging violations of A.R.S. § 44-
27 1521 *et seq.*, the Consumer Fraud Act, against defendants Janssen Pharmaceuticals,
28 Inc. and Johnson & Johnson.

1 2. The State of Arizona, by its counsel, and Janssen Pharmaceuticals, Inc.
2 and Johnson & Johnson, by their counsel, have agreed to the entry of this Order by
3 the Court without trial or adjudication of any issue of fact or law.

4 3. The terms of the Consent Judgment ("Judgment") shall be governed by
5 the laws of the State of Arizona.

6 **JURISDICTION AND VENUE**

7 1. The Superior Court has jurisdiction to enter appropriate orders pursuant
8 to A.R.S. § 44-1528.

9 2. Venue is proper in Pima County, Arizona.

10 **PARTIES**

11 1. Plaintiff is the State of Arizona, *ex rel.* Thomas C. Horne, the Attorney
12 General of Arizona ("the State") who is authorized to bring this action under the
13 Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*, ("the Act").

14 2. Janssen Pharmaceuticals, Inc. ("Janssen") is a subsidiary of Johnson &
15 Johnson. Janssen does business in the State of Arizona. Janssen's executive offices
16 are located at 1125 Trenton Harbourton Road, P.O. Box 200, Titusville, NJ 08560. At
17 all times relevant hereto, Janssen engaged in trade affecting consumers, within the
18 meaning of the Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*, in the State of
19 Arizona. At all times relevant hereto Janssen engaged in the offer, promotion, and
20 sale of goods in the State of Arizona. Johnson & Johnson consents to the jurisdiction
21 of this Court solely for the purposes of this Consent Judgment.

22 **FINDINGS**

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

25 2. The terms of this Judgment shall be governed by the laws of the State of
26 Arizona.

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

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

5 5. Janssen is willing to enter into this Judgment regarding the Covered
6 Conduct solely in order to resolve the Attorneys General's concerns under the State
7 Consumer Protection Laws as to the matters addressed in this Judgment and thereby
8 avoid unnecessary expense, inconvenience, and uncertainty. Nothing contained
9 herein may be taken as or construed to be an admission or concession of any violation
10 of law or regulation, or of any other matter of fact or law, or of any liability or
11 wrongdoing (including allegations of the Complaint), all of which Janssen expressly
12 denies. Janssen does not admit any violation of law, and does not admit any
13 wrongdoing that was or could have been alleged by any Attorney General before the
14 date of the Judgment. No part of this Judgment, including its statements and
15 commitments, shall constitute evidence of any liability, fault, or wrongdoing by
16 Janssen. This Judgment is made without trial or adjudication of any issue of fact or
17 law or finding of liability of any kind. It is the intent of the Parties that this Judgment
18 shall not be binding or admissible in any other matter, including, but not limited to, any
19 investigation or litigation, other than in connection with the enforcement of this
20 Judgment. No part of this Judgment shall create a private cause of action or confer
21 any right to any third party for violation of any federal or state statute except that a
22 State may file an action to enforce the terms of this Judgment.

23 6. Janssen is entering into this Judgment solely for the purpose of
24 settlement of the instant action. This Judgment does not create a waiver or limit
25

26 _____
27 ¹ This agreement is entered into pursuant to and subject to the State Consumer Protection Laws cited in footnote 2.
28

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.

- a. Take any action that is prohibited by the FDCA or any regulation thereunder, or by the FDA; or
- b. Fail to take any action that is required by the FDCA or any regulation thereunder, or by the FDA.

The following definitions shall be used in construing this Judgment:

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

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

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

8 4. **“Covered Conduct”** shall mean Janssen’s Promotional and marketing
9 practices, sampling practices, dissemination of information and remuneration to HCPs
10 in the United States in connection with Atypical Antipsychotics through the Effective
11 Date of the Judgment.

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

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

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

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

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

26 10. **“Janssen Marketing”** shall mean Janssen personnel responsible for
27 marketing Janssen’s Atypical Antipsychotics in the U.S.
28

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

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

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

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

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

23 16. **“Multistate Working Group”** shall mean the Attorneys General and
24 their staff representing Alabama, Arizona, Colorado, Connecticut, Delaware, District of
25 Columbia, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Maine, Maryland,
26 Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New
27 York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode
28

1 Island, South Dakota, Tennessee, Texas, Vermont, Washington, Wisconsin and
2 Wyoming.

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

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

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

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

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

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

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

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

24 25. **"Signatory Attorney General"** shall mean the Attorney General of
25 [your state/commonwealth], or her authorized designee, who has agreed to this
26 Judgment.
27
28

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.

I. Promotional Activities

2835459

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

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

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

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

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

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

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

18 2. With respect to Promotional Media:

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

22 b. With respect to each subsequent reference to selected
23 symptoms, Janssen states on the same slide or page that the Atypical Antipsychotic is
24 not approved for the selected symptom referenced in the slide or page and includes on
25 the same slide or page a shorthand reference to the FDA-approved indications (e.g.,
26 "[Atypical Antipsychotic] is not approved for X selected symptom referenced in this
27 slide. See complete list of FDA-approved indications at p. Y").
28

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

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

8 G. Janssen's systems and controls shall:

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

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

16 **II. Dissemination and Exchange of Medical Information**

17 A. General Terms

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

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

22 B. Clinical Responses

23 1. Janssen, through Janssen Scientifically Trained Personnel, shall
24 have ultimate responsibility for developing and approving all Clinical Responses
25 regarding an Atypical Antipsychotic, including any that may describe Off-Label
26 information. Additional approvals may be provided by Janssen's Law Department.
27 Janssen shall not distribute any such materials unless:
28

- 1 a. Clinically Relevant Information is included in these
2 materials to provide scientific balance;
3 b. Data in these materials are presented in an unbiased, non-
4 Promotional manner; and
5 c. These materials are clearly and conspicuously
6 distinguishable from sales aids and other Promotional Materials.
7 d. Nothing in this subsection II.B shall prohibit Janssen
8 Scientifically Trained Personnel from disseminating materials that
9 are permitted to be distributed under Federal law.

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

13 3. Clinical Responses regarding an Atypical Antipsychotic may be
14 disseminated only by Janssen Scientifically Trained Personnel to HCPs, and
15 Janssen's Sales and Marketing shall not disseminate these materials to HCPs except
16 in circumstances implicating public health and safety issues. In such circumstances,
17 Janssen's Sales and Marketing may disseminate a Clinical Response directly to HCPs
18 when expressly authorized by the Health Care Compliance Officer, the Vice President
19 of Medical/Scientific Affairs responsible for the Atypical Antipsychotic(s) included in the
20 Clinical Response(s), and Senior Counsel from the Janssen Law Department.

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

25 C. Responses to Unsolicited Requests for Off-Label Information
26
27
28

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

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

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

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

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

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

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

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

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

24 5. Janssen Sales and Janssen Marketing personnel may respond
25 orally to an Unsolicited Request for Off-Label information regarding an Atypical
26 Antipsychotic only by offering to request on behalf of the requester that a Clinical
27 Response Letter prepared in accordance with Section II.B or other information set
28

1 forth in Section II.C above be sent in follow-up or by offering to put the requester in
2 touch with the scientific exchange call center. Janssen Non-Scientifically Trained
3 Personnel shall not characterize, describe, identify, name, or offer any opinions about
4 or summarize any such Off-Label information.

5 D. Reprints

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

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

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

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

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

25 b. shall contain a disclosure that is prominently displayed,
26 which would include the first page or as a cover page where
27
28

1 practicable, indicating that the article may discuss Off-Label
2 information; and

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

4 5. Nothing in this Judgment shall preclude Janssen from
5 disseminating reprints which have only an incidental reference to Off-Label
6 information. If reprints have an incidental reference to Off-Label information, such
7 reprints shall contain the disclosures required by Section II.D.4.a. and II.D.4.b in a
8 prominent location, as defined above, and such incidental reference to Off-Label
9 information shall not be referred to or used in a Promotional manner as prohibited by
10 Section II.D.4.c.

11 **III. Grants**

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

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

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

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

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

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

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

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

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

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

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

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

26 I. After initial delivery of a CME program regarding an Atypical
27 Antipsychotic, Janssen shall not knowingly fund the same program, nor shall it provide
28

1 additional funding for re-distribution of the same program, if the program's speakers
2 are Promoting an Atypical Antipsychotic for Off-Label use in that program.

3 **IV. Payments to Consultants and Speakers**

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

14 **V. Product Samples**

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

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

19 B. If an HCP whose clinical practice is inconsistent with an Atypical
20 Antipsychotic's FDA-approved Labeling requests samples of an Atypical Antipsychotic,
21 Janssen personnel shall refer the HCP to Janssen Medical where the practitioner can
22 speak directly with a Janssen Medical representative who will provide answers to the
23 HCP's questions about the Atypical Antipsychotic and may provide him/her with
24 samples only if appropriate (i.e., if the HCP requests the samples for an on-label use).

25 **VI. Clinical Research Results**

26 A. Janssen shall report clinical research regarding Atypical Antipsychotics
27 in an accurate, objective and balanced manner, and as required by applicable law.
28

1 For all Janssen-sponsored clinical trials and to the extent permitted by the National
2 Library of Medicine, Janssen shall register clinical trials and submit clinical trial results
3 to the federal clinical trial registry and results data bank on the publicly accessible NIH
4 website (www.clinicaltrials.gov) as required by the FDA Amendments Act of 2007,
5 Public Law No. 110-85, 121 Stat 823, and any accompanying regulations that may be
6 promulgated pursuant to that Act.

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

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

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

16 3. Use statistical analyses and techniques on a retrospective basis
17 to discover and cite findings not soundly supported by the study, or to suggest
18 scientific validity and rigor for data from the study the design or protocol of which is not
19 amenable to formal statistical evaluations;

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

22 5. Use statistics on numbers of patients, or counts of favorable
23 results or side effects, derived from pooling data from various insignificant or dissimilar
24 studies in a way that suggests either that such statistics are valid if they are not or that
25 they are derived from large or significant studies supporting favorable conclusions
26 when such is not the case. If any results derived from pooling data are presented,
27 Janssen shall disclose the method of pooling.
28

1 **VII. Terms Relating to Payment**

2 A. No later than 30 days after the Effective Date of this Judgment, Janssen
3 shall pay \$181,047,437 to be divided and paid by Janssen directly to each Signatory
4 Attorney General of the Multistate Working Group in an amount to be designated by
5 and in the sole discretion of the Multistate Executive Committee. The Parties
6 acknowledge that the payment described herein is not a fine, penalty, or payment in
7 lieu thereof.

8 B. Arizona's portion of the payment will be used for the consumer protection
9 purposes described below in order to redress the alleged unlawful acts and practices
10 described in the Complaint and because it is impractical to identify and compensate
11 specific individuals impacted by such practices in Arizona.

12 C. Arizona's portion of the payment is \$6,094,396.00. The Attorney General
13 shall deposit \$2,000,000.00 into the Consumer Fraud Revolving Fund and use such
14 payment for the following purposes:

15 1. \$750,000.000 to cover investigative costs, expenses, and
16 attorneys' fees, both those incurred through the Effective Date and those
17 incurred in monitoring and implementing this Consent Judgment and the
18 Distribution Plan as set forth in Section C below or as otherwise permitted by
19 A.R.S. Section § 44-1531.01(C).

20 2. \$1,250,000.00 to be used for the costs of investigation and
21 prosecution of consumer protection pharmaceutical, health fraud or health-
22 related cases; and/or consumer protection cases involving the alleged
23 misrepresentation of scientific studies and/or evidence, or the alleged
24 minimization of the risks of health care products.

25 D. The remaining amount of the payment ("Custodial Funds") is restitutionary
26 in nature, consistent with A.R.S. Section § 44-1528(A)(2). The Arizona Attorney
27 General is the custodian and trustee of the Custodial Funds, which are held in trust to
28

1 be used solely for the benefit of the third party organizations and individuals in Arizona
2 selected to perform the research, studies, grants, and/or programs specifically
3 identified below. The Custodial Funds shall be deposited into a separate, interest-
4 bearing trust account and shall be used for the exclusive purpose of funding any of the
5 following items, in whole or in part. Nothing in the following sections represents or
6 implies that Janssen engaged in any wrongdoing with regard to the promotion of
7 atypical antipsychotics, and Janssen does not admit any wrongdoing with regard to the
8 promotion of atypical antipsychotics.:

9 1. Research, studies, grants, and/or programs (including reasonable
10 administrative expenses) to provide alternatives to the use of atypical
11 antipsychotics for managing the effects of Alzheimer's disease and/or dementia,
12 for elderly patients in long term care facilities; and/or

13 2. Research, studies, grants, and/or programs (including reasonable
14 administrative expenses) to provide alternatives to the use of atypical
15 antipsychotics for managing childhood and adolescent developmental and
16 learning disorders; and/or.

17 3. Research, studies, grants, programs (including reasonable
18 administrative expenses), and/or education and outreach programs directed at
19 treatments for mental illness and/or for mental disorders, including but not
20 limited to anxiety, behavioral and/or mood disorders.

21 **VIII. Release**

22 A. By its execution of this Judgment, the State of Arizona releases Janssen
23 and all of its past and present, parents, subsidiaries, affiliates, predecessors,
24 successors, and assigns and each and all of their current and former officers,
25 directors, shareholders, employees, agents, contractors, and attorneys (collectively,
26 the "Released Parties") from the following: all civil claims, parens patriae claims,
27 causes of action, damages, restitution, fines, costs, attorneys fees, and penalties that
28

1 the Arizona Attorney General has asserted or could have asserted against the
2 Released Parties under the Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*
3 or any amendment thereto, or common law claims concerning unfair, deceptive, or
4 fraudulent trade practices, other than those asserted or that could be asserted under
5 Sections VIII.B.2 , VIII.B.3, and VIII.B.5 below, resulting from the Covered Conduct up
6 to and including the Effective Date (collectively, the "Released Claims").

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

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

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

16 a. State or federal antitrust violations;

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

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

24 d. State false claims violations.

25 3. Actions on behalf of state program payors of the State of Arizona
26 arising from the purchase of any Atypical Antipsychotic or any other Janssen drug,
27
28

1 except for the release of civil penalties under the Arizona Consumer Fraud Act, A.R.S.
2 § 44-1521, *et seq.*

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

6 5. Any claims against Omnicare, Inc.

7 **IX. Dispute Resolution**

8 A. For the purposes of resolving disputes with respect to compliance with
9 this Judgment, should any of the Signatory Attorneys General have a reasonable basis
10 to believe that Janssen has engaged in a practice that violates a provision of this
11 Judgment subsequent to the Effective Date of this Judgment, then such Attorney
12 General shall notify Janssen in writing of the specific objection, identify with
13 particularity the provision of this Judgment that the practice appears to violate, and
14 give Janssen thirty (30) days to respond to the notification; provided, however, that a
15 Signatory Attorney General may take any action if the Signatory Attorney General
16 concludes that, because of the specific practice, a threat to the health or safety of the
17 public requires immediate action. Upon receipt of written notice, Janssen shall provide
18 a good-faith written response to the Attorney General notification, containing either a
19 statement explaining why Janssen believes it is in compliance with the Judgment, or a
20 detailed explanation of how the alleged violation occurred and a statement explaining
21 how Janssen intends to remedy the alleged breach. Nothing in this section shall be
22 interpreted to limit the state's Civil Investigative Demand ("CID") or investigative
23 subpoena authority and Janssen reserves all of its rights with respect to a CID or
24 investigative subpoena issued pursuant to such authority.

25 B. Upon giving Janssen thirty (30) days to respond to the notification
26 described above, the Signatory Attorney General shall also be permitted reasonable
27 access to inspect and copy relevant, non-privileged, non-work product records and
28

1 documents in the possession, custody, or control of Janssen that relate to Janssen's
2 compliance with each provision of this Judgment, pursuant to that State's CID or
3 investigative subpoena authority. If the Signatory Attorney General makes or requests
4 copies of any documents during the course of that inspection, the Signatory Attorney
5 General will provide a list of those documents to Janssen.

6 C. The State may assert any claim that Janssen has violated this Judgment
7 in a separate civil action to enforce compliance with this Judgment, or may seek any
8 other relief afforded by law, but only after providing Janssen an opportunity to respond
9 to the notification described in Paragraph IX.A. above; provided, however, that a
10 Signatory Attorney General may take any action if the Signatory Attorney General
11 concludes that, because of the specific practice, a threat to the health or safety of the
12 public requires immediate action.

13 **X. General Provisions**

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

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

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

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

26
27
28 ///

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

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

7 For Janssen Pharmaceuticals, Inc. and Johnson & Johnson:

8 Patricia Lukens
9 Vice President of Law
10 Janssen Pharmaceuticals, Inc.
11 1000 Route 202 South
12 Raritan, New Jersey 08869

13 Joanne Lewers
14 Drinker Biddle & Reath LLP
15 One Logan Square
16 Suite 2000
17 Philadelphia, PA 19103-6996

18 With a cc to:

19 Michael H. Ullmann
20 General Counsel
21 Johnson & Johnson
22 One Johnson & Johnson Plaza
23 New Brunswick, New Jersey 08933

24 For the State of Arizona:

25 Noreen R. Matts
26 Assistant Attorney General
27 Consumer Protection & Advocacy Section
28 400 W. Congress, South Bldg., Suite 315
Tucson, Arizona 85701-1367

DATED this _____ day of _____, 2012.

JUDGE OF THE SUPERIOR COURT