

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA :
 :
 v. : **CRIMINAL NO. 13-**
 :
 JANSSEN PHARMACEUTICALS, INC. :

GUILTY PLEA AGREEMENT

Under Federal Rule of Criminal Procedure 11(c)(1)(C), the United States, the defendant, Janssen Pharmaceuticals, Inc. (JPI) and the defendant's counsel enter into the following guilty plea agreement. Any reference to the United States or the government in this agreement, unless as otherwise specifically provided for in this plea agreement, shall mean the Office of the United States Attorney for the Eastern District of Pennsylvania, and the Consumer Protection Branch, Civil Division, of the Department of Justice.

1. JPI agrees to plead guilty to a one count Information charging it with the introduction into interstate commerce of drugs that were misbranded, a misdemeanor, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1), and not to contest forfeiture as set forth in the notice of forfeiture seeking criminal forfeiture of \$66,000,000 in substitute assets, in lieu of the drugs which were illegally misbranded and are no longer available, all arising from the defendant's illegal misbranding of its drug Risperdal between March 3, 2002 and December 31, 2003. The defendant further acknowledges its waiver of rights, as set forth in the attachment to this agreement.

2. The parties agree that this plea agreement is made pursuant to Fed.R.Crim.P. 11(c)(1)(C) and that the following specific sentence is the appropriate disposition

of this case. Taking into consideration the factors set forth in 18 U.S.C. §§ 3553(a) and 3572, the agreed upon sentence is as follows:

- a. JPI agrees to pay the special assessment in the amount of \$125 on the date of sentencing.
- b. JPI agrees to pay \$400,000,000 to resolve this Information, of which \$334,000,000 will be applied as a criminal fine, and \$66,000,000 will be applied as substitute assets to satisfy the forfeiture obligation. The defendant will pay these amounts within 10 business days of the date of sentencing. The defendant and the government agree that these fine and forfeiture payments represent a fair and just resolution of all issues associated with loss, fine and forfeiture calculations.
- c. JPI agrees that, as a result of its acts or omissions, the forfeitable property, that is, the drugs which were misbranded, are no longer available for forfeiture as they cannot be located or have been transferred, sold or deposited with a third party, or otherwise disposed of, within the meaning of federal law. As a result, JPI agrees to the entry and satisfaction of a judgment and preliminary order of forfeiture on the date of the guilty plea, forfeiting to the United States the sum of \$66,000,000 as substitute assets for the pertinent drugs. JPI will make payment to the United States, by means of a wire transfer to the United States Marshals Service or

check payable to same, in the amount of \$66,000,000, this amount representing substitute assets of the offense for which it is pleading guilty, subject to forfeiture in full satisfaction of the judgment and preliminary order of forfeiture.

- d. The government agrees that if JPI is placed under a Corporate Integrity Agreement with the Department of Health and Human Services before the date of sentencing, JPI will not be placed on probation.

3. Under a separate civil settlement among JPI, the United States and various States, executed contemporaneously with this guilty plea agreement, JPI will pay \$1,253,024,000 concerning Risperdal.

4. JPI waives any and all defenses and objections in this matter which might be available under the Double Jeopardy and Excessive Fines clauses of the Eighth Amendment. The parties agree that to avoid complicating and prolonging the sentencing process, the appropriate disposition of this case does not include a restitution order.

5. JPI waives any claim under the Hyde Amendment, 18 U.S.C. § 3006A (Statutory Note), for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter.

6. The defendant understands that the intent of this plea agreement is that the business entity JPI as it exists on July 6, 2011, is the entity which is pleading guilty to the offense charged. (JPI was previously known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) prior to June 22, 2011). Should JPI or its corporate parent elect to reorganize JPI by transferring

assets or lines of business to any affiliate, division, or subsidiary, or otherwise significantly changing this JPI business entity before the conviction is final, any penalty satisfied, or any period of supervision completed, this plea agreement, together with all of the obligations that it establishes and any obligations flowing from any judgment in this case shall bind all assignees, successors-in-interest, or transferees of the defendant. JPI agrees that it shall not, through a change of name, business reorganization, sale or purchase of assets, divestiture of assets, or similar action, seek to avoid the obligations and conditions set forth in this plea agreement.

7. JPI understands, agrees and has had explained to it by counsel that the Court may impose the following statutory maximum sentence for the one count of conviction: a fine of \$200,000, or twice the gross gain derived from the offense or gross loss resulting from the offense, whichever is greater; a special assessment of \$125; criminal forfeiture; restitution; and a five-year term of probation. The parties agree that the agreed-upon fine amount in this case is below the statutory maximum amount authorized by the provisions of 18 U.S.C. § 3571(d). JPI further understands that the terms and conditions of any Court supervision may be changed and extended by the Court if the defendant violates any of the terms and conditions of that supervision.

8. With respect to the defendant's conduct, the parties stipulate to the following facts and basis for the plea, criminal fine and forfeiture:

- a. JPI marketed Risperdal through Janssen Pharmaceutica Inc., a predecessor company to OMJPI and JPI. Risperdal was a drug within the meaning of 21 U.S.C. § 321(g)(1).

- b. Shipments of a drug in interstate commerce must be accompanied by labeling bearing adequate directions for use for each of the drug's intended uses.
- c. In December 1993, the United States Food and Drug Administration (FDA) approved Risperdal for the management of the manifestations of psychotic disorders. In March 2002, the FDA approved a change in the indication for Risperdal, approving Risperdal for the treatment of schizophrenia instead of the management of the manifestations of psychotic disorders. In December 2003, the FDA additionally approved Risperdal for "the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder" for adults.
- d. Between March 3, 2002 and December 31, 2003, JPI, through Janssen Pharmaceutica's ElderCare sales force, promoted Risperdal to health care providers for treatment of psychotic symptoms and associated behavioral disturbances exhibited by elderly non-schizophrenic dementia patients. JPI's promotion of Risperdal for these additional intended uses caused Risperdal to be misbranded under 21 U.S.C. § 352(f)(1), because Risperdal's labeling did not bear adequate directions for these intended uses.
- e. Between March 3, 2002, and December 31, 2003, Janssen Pharmaceutica Inc. caused shipments of Risperdal to be introduced

into interstate commerce, and these shipments constituted misbranded drugs due to the conduct described above.

9. For purposes of this plea agreement, the United States agrees to accept JPI's stipulation as to the nature of its unlawful off-label promotion as set forth in paragraph 8(d) above. However, JPI understands that the United States contends that the scope of JPI's off-label promotion was broader than that to which it has stipulated here, and that the United States contends that such illegal promotion of Risperdal extended to promotion for treatment of symptoms or behavioral disturbances in elderly non-schizophrenic patients regardless of whether such symptoms or behavioral disturbances were associated with an underlying psychosis. JPI also understands that the United States contends that the unlawful off-label promotion of Risperdal by JPI occurred between May 1, 1998 and November 30, 2005. JPI does not agree that the nature and scope of its conduct or the time period exceeded its stipulation in paragraph 8(d) above.

10. JPI has agreed to be placed under a 5-year Corporate Integrity Agreement with the Inspector General of the U.S. Department of Health and Human Services.

11. With regard to the Information to be filed pursuant to this agreement, JPI waives all defenses under the Constitution or Speedy Trial Act, and any applicable statutes of limitations, as described in this paragraph. JPI agrees that prosecution of the offense conduct described in paragraph one above is timely as of the date that this agreement is signed and as of the date that the guilty plea will be entered in District Court. In the event that this agreement is not consummated, any party withdraws from it, or it is otherwise not fully carried out, including the following circumstances described in subparagraphs (a) through (d) of this paragraph, JPI

waives all defenses based on the Speedy Trial Act and any statute of limitations with respect to the offense conduct set forth in the Information to be filed pursuant to this agreement or released in paragraph 12 below, for a period of 90 days from the latest of any of these events: (a) JPI's guilty plea is not accepted by the Court for any reason; (b) JPI's conviction is later vacated for any reason; (c) JPI violates any of the terms or conditions of this agreement; or (d) JPI's plea is withdrawn. JPI understands and agrees that, should it seek to withdraw its plea, or if this plea agreement is not carried out for any of the reasons identified in this paragraph, it may then be prosecuted for any criminal violation of which the United States has knowledge arising out of this investigation, subject to any applicable statute of limitation or other time-related protection not waived in this paragraph or elsewhere.

12. Except as provided herein, the United States agrees that, other than the charges to be filed in the Information in this case, it will not bring any other criminal charges against JPI, its present and former parents, affiliates, divisions, and subsidiaries; or their predecessors, successors and assigns for conduct which (a) falls within the scope of the criminal investigation in the Eastern District of Pennsylvania relating to JPI's sale, promotion, or marketing of its drug Risperdal in the United States; or (b) was known to the United States Attorney's Office for the Eastern District of Pennsylvania or the Consumer Protection Branch, Civil Division, of the Department of Justice as of the date of the execution of this plea agreement, and which concerned the sale, promotion, or marketing of Risperdal in the United States. The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the Eastern District of Pennsylvania, the Consumer Protection Branch, Civil Division, of the Department of Justice, and the United States Attorney's Offices for each of the

other 93 judicial districts of the United States. The non-prosecution provisions in this paragraph are also binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of JPI that are or may be conducted in the future by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of JPI's products to foreign customers, which investigations are expressly excluded from the release in this paragraph.

Attached as an exhibit to this agreement is a copy of the letter to United States Attorney Zane David Memeger from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this agreement.

13. JPI understands that this guilty plea agreement does not bind any other government agency, or any component of the Department of Justice, except as specified in this agreement. Further, JPI understands that the United States takes no position as to the proper tax treatment of any of the payments made by JPI pursuant to this plea agreement, any civil settlement agreement, or any Corporate Integrity Agreement reached with the Department of Health and Human Services.

14. In exchange for the undertakings made by the government in entering this plea agreement pursuant to Fed.R.Crim.P. 11(c)(1)(C), JPI voluntarily and expressly waives all rights to appeal or collaterally attack the defendant's conviction, sentence, or any other matter relating to this prosecution, whether such a right to appeal or collateral attack arises under 18 U.S.C. § 3742, 28 U.S.C. § 1291, 28 U.S.C. § 2255, or any other provision of law. This waiver is not intended to bar the assertion of constitutional claims that the relevant case law holds cannot be waived.

15. JPI waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act, 5 U.S.C. § 552a.

16. JPI is satisfied with the legal representation provided by its lawyers; JPI and its lawyers have fully discussed this guilty plea agreement; and JPI is agreeing to plead guilty because JPI admits that it is guilty of the offense described in paragraph 1.

17. JPI will acknowledge acceptance of this guilty plea agreement by the signature of its counsel and of an authorized corporate officer. JPI shall provide to the government for attachment to this plea agreement a notarized resolution by JPI's Board of Directors authorizing the corporation to enter a plea of guilty, and authorizing a corporate officer to execute this agreement.

18. The parties agree to waive the presentence investigation and report pursuant to Rule 32(c)(1) of the Federal Rules of Criminal Procedure, and will jointly request that JPI be sentenced at the time that the guilty plea is entered and accepted by the Court.

19. It is agreed that this guilty plea agreement contains no additional promises, agreements or understandings other than those set forth in this written guilty plea agreement, and that no additional promises, agreements or understandings will be entered into unless in writing and signed by all parties.

SIGNATURES FOR THE UNITED STATES

STUART F. DELERY
Assistant Attorney General
Civil Division
United States Department of Justice



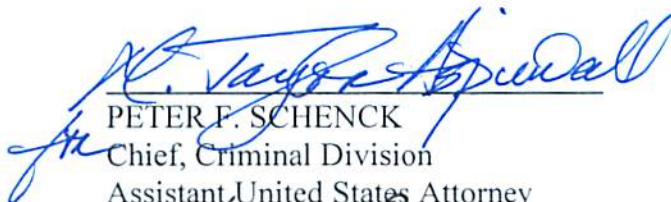
MICHAEL S. BLUME
Director
Consumer Protection Branch
United States Department of Justice



ZANE DAVID MEMEGER
United States Attorney

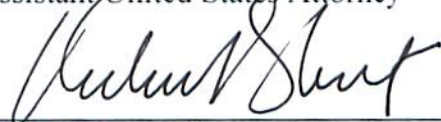


JILL FURMAN
Deputy Director
Consumer Protection Branch
United States Department of Justice



PETER F. SCHENCK
Chief, Criminal Division
Assistant United States Attorney

PERHAM GORJI
Trial Attorney
Consumer Protection Branch
United States Department of Justice



RICHARD A. LLORET
Chief, Health Care Fraud Section
Assistant United States Attorney

KEVIN J. LARSEN
Former Trial Attorney
Consumer Protection Branch
United States Department of Justice
(currently an Assistant United States Attorney)



ALBERT S. GLENN
SCOTT M. CULLEN
Assistant United States Attorneys

DATED: October 29, 2013

SIGNATURE FOR JANSSEN PHARMACEUTICALS, INC.

DATE: 10/31/13


JOSEPH G. BRAUNREUTHER
Deputy General Counsel

SIGNATURES OF JPI=s ATTORNEYS

DATE: _____

CHRISTOPHER A. WRAY
MARK A. JENSEN
BRANDT LEIBE
King & Spalding

DATE: _____

RICHARD L. SCHEFF
Montgomery, McCracken, Walker &
Rhoads, LLP

DATE: _____

THEODORE WELLS, JR.
Paul, Weiss, Rifkind, Wharton, & Garrison
LLP

SIGNATURE FOR JANSSEN PHARMACEUTICALS, INC.

DATE: _____

JOSEPH G. BRAUNREUTHER
Deputy General Counsel


SIGNATURES OF JPI's ATTORNEYS

DATE: 10/31/13



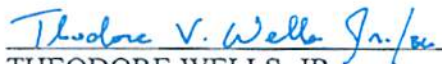
CHRISTOPHER A. WRAY
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DATE: 10/31/13



RICHARD L. SCHEFF
Montgomery, McCracken, Walker &
Rhoads, LLP

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THEODORE WELLS, JR.
Paul, Weiss, Rifkind, Wharton, & Garrison
LLP

Attachment

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA :
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 v. : **CRIMINAL NO. 13-**
 :
 JANSSEN PHARMACEUTICALS, INC. :

ACKNOWLEDGMENT OF RIGHTS

Janssen Pharmaceuticals, Inc. (JPI), through its properly authorized officer(s), hereby acknowledges that it has certain rights that it will be giving up by pleading guilty.

1. JPI understands that it does not have to plead guilty.
2. JPI may plead not guilty and insist upon a trial.
3. At that trial, JPI understands:
 - a. that JPI would have the right to be tried by a jury that would be selected from the Eastern District of Pennsylvania and that along with its attorney, JPI would have the right to participate in the selection of that jury;
 - b. that the jury could only convict JPI if all twelve jurors agreed that they were convinced of JPI's guilt beyond a reasonable doubt;
 - c. that the government would have the burden of proving JPI's guilt beyond a reasonable doubt and that JPI would not have to prove anything;
 - d. that JPI would be presumed innocent unless and until such time as the jury was convinced beyond a reasonable doubt that the government had proven that JPI were guilty;
 - e. that JPI would have the right to be represented by a lawyer at this trial and at any appeal following the trial, and that if

JPI could not afford to hire a lawyer, the court would appoint one for JPI free of charge;

- f. that through JPI's lawyer JPI would have the right to confront and cross-examine the witnesses against JPI;
- g. that JPI could call witnesses to testify in its defense if JPI wanted to, and JPI could subpoena witnesses for this purpose if JPI wanted to; and
- h. that JPI would not have to call witnesses to testify or otherwise present any defense if JPI did not want to, and that if JPI did not present any evidence, the jury could not hold that against JPI.

4. JPI understands that if it pleads guilty, there will be no trial and JPI would be giving up all of the rights listed above, as well as any other rights associated with the trial process arising under statute, common-law, or judicial precedent.

5. JPI understands that if JPI decides to enter a plea of guilty, the judge will ask JPI's representatives questions under oath, and that if any of those representatives lie on behalf of JPI in answering those questions, those persons could be prosecuted for the crime of perjury, that is, for lying under oath.

6. JPI understands that if it pleads guilty, it has waived its right to appeal, except as set forth in appellate waiver provisions of the plea agreement.

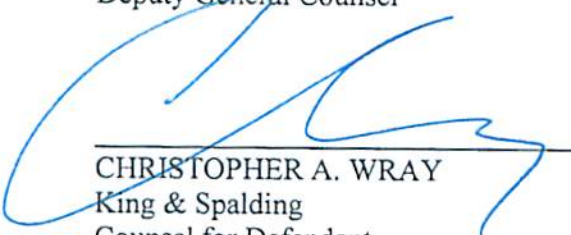
7. Understanding that JPI has all these rights and that by pleading guilty JPI is giving them up, JPI still wishes to plead guilty.


JOSEPH G. BRAUNREUTHER
Deputy General Counsel

CHRISTOPHER A. WRAY
King & Spalding
Counsel for Defendant

7. Understanding that JPI has all these rights and that by pleading guilty JPI is giving them up, JPI still wishes to plead guilty.

JOSEPH G. BRAUNREUTHER
Deputy General Counsel



CHRISTOPHER A. WRAY
King & Spalding
Counsel for Defendant

EXHIBITS



U.S. Department of Justice

Criminal Division

Office of the Assistant Attorney General

Washington, D.C. 20530

NOV 16 2011

The Honorable Zane David Memeger
United States Attorney for the
Eastern District of Pennsylvania
615 Chestnut Street, Suite 1250
Philadelphia, Pennsylvania 19106

Attention: Albert S. Glenn
Assistant United States Attorney

Re: Global Non-Prosecution Agreement for Janssen Pharmaceuticals, Incorporated

Dear Mr. Memeger:

This is in response to your request for authorization to enter into a global Non-Prosecution Agreement with the business entity known as Janssen Pharmaceuticals, Incorporated.

I hereby approve the terms of the Non-Prosecution Agreement, including Paragraphs 12 and 13, in which the United States Attorney's Offices and the Department of Justice agree, with the exceptions noted in those paragraphs, not to initiate criminal prosecutions as set out therein.

You are authorized to make this approval a matter of record in this proceeding.

Sincerely,

Lanny A. Breuer
Assistant Attorney General


KENNETH A. BLANCO
DEPUTY ASSISTANT ATTORNEY GENERAL
CRIMINAL DIVISION

JANSSEN PHARMACEUTICALS, INC.

SECRETARY'S CERTIFICATE

I, Patricia C. Lukens, do hereby certify that I am Secretary of Janssen Pharmaceuticals, Inc., (the "Company"), and do hereby further certify that:

Attached hereto is a true, correct, and complete extract of a resolution of the Board of Directors of the Company adopted as of the 17th of October, 2013. This resolution has not been modified, amended or rescinded and remains in full force and effect as of the date hereof.

IN WITNESS WHEREOF, I have executed this Certificate on behalf of the Company on this 17 of October 2013.

JANSSEN PHARMACEUTICALS, INC.

By: Patricia C. Lukens
Name: Patricia C. Lukens
Title: Secretary

ROBYN HAND
ID # 2413642
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires 10/18/2016
Robyn Hand
Sworn to and subscribed
before me this
17 day of 10, 2013

**EXTRACT OF JANSSEN PHARMACEUTICALS, INC. BOARD OF DIRECTORS
RESOLUTION**

RESOLVED, that the Company is hereby authorized and directed to enter into the Plea Agreement;

FURTHER RESOLVED, that the Company is hereby authorized and directed to plead guilty to the charge specified in the Plea Agreement;

FURTHER RESOLVED, that legal counsel for Johnson & Johnson and/or Janssen Pharmaceuticals, Inc. (in-house and/or external counsel) and/or any other corporate officer or senior executive of the Company is hereby authorized and directed to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement;

FURTHER RESOLVED, that legal counsel for Johnson & Johnson and/or Janssen Pharmaceuticals, Inc. (in-house and/or external counsel) and/or any other corporate officer or senior executive of the Company is hereby authorized and directed to appear (1) on behalf of the Company and enter such guilty plea and (2) for the imposition of sentence; and

FURTHER RESOLVED, that legal counsel for Johnson & Johnson and/or Janssen Pharmaceuticals, Inc. (in-house and/or external counsel) and/or any other corporate officer or senior executive of the Company is hereby authorized and directed to acknowledge on behalf of the Company, that the Documents fully set forth the agreement made between the Company and the United States and that no additional promises or representations have been made to the Company by any officials of the United States in connection with the Plea Agreement, other than those set forth in the Documents.