IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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

UNITED STATES' MEMORANDUM FOR
ENTRY OF PLEA AND SENTENCING

Introduction

The United States of America, by and through its counsel, the United States Attorney for the Eastern District of Pennsylvania and the United States Department of Justice, Civil Division, Consumer Protection Branch (collectively, the government), now submits for the assistance of the Court this memorandum concerning the entry of a criminal guilty plea and the sentencing in the above case. This matter arises from the actions of defendant Janssen Pharmaceuticals, Inc. (JPI), through its predecessor corporation Janssen Pharmaceutica, Inc., introducing the drug Risperdal into interstate commerce without adequate directions for an intended use, in part evidenced by its promotion of Risperdal for uses not approved by the United States Food and Drug Administration (FDA) (off-label promotion), between March 2002 and December 2003[1] and thereby introducing a misbranded drug into interstate commerce, in violation of Title 21, United States Code, Section 331(a) and 333(a)(1), a misdemeanor. For the

[1] The plea agreement contains a waiver of the statute of limitations (¶ 11), and a tolling agreement has been agreed to.

reasons set forth below, the government recommends that the Court accept JPI's guilty plea and impose sentence on JPI in accordance with the parties' agreement.

The government and JPI have agreed that the appropriate resolution of this matter consists of a guilty plea by JPI pursuant to a plea agreement. JPI has signed a plea agreement pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C) under which, with the Court's approval, it will plead guilty to the charge of introducing a misbranded drug into interstate commerce, in violation of 21 U.S.C. § 331(a) and 333(a)(1). Under the plea agreement, the parties have agreed that the appropriate sentence in this case is a fine of $334,000,000 and forfeiture of $66,000,000. The parties also recommend that the Court proceed to impose sentence immediately, without requiring a presentence investigation.

The plea agreement resolves a significant criminal investigation into the practices in the United States of Janssen Pharmaceutica, Inc. (Janssen) with respect to its distribution and intended uses of the antipsychotic drug Risperdal for treatment of elderly patients. During the period which was the subject of this investigation, Janssen was a wholly-owned subsidiary of Johnson & Johnson. In December 2007, in a corporate reorganization, Janssen was combined with another Johnson & Johnson subsidiary to form the new wholly-owned subsidiary named Ortho-McNeil-Janssen Pharmaceuticals, Inc. In June of 2011, this subsidiary's name was changed to Janssen Pharmaceuticals, Inc., the defendant here. The essence of the criminal charge is that Janssen introduced Risperdal into interstate commerce for intended uses which were not approved by the (FDA), which resulted in the drug being misbranded.

This guilty plea is part of a global resolution that includes a civil settlement agreement with the United States and relators (resolving four civil actions brought under the *qui*

tam provisions of the False Claims Act), and a Corporate Integrity Agreement with the Department of Health and Human Services, Office of Inspector General.

I. CRIMINAL CHARGE

The information here charges JPI with one count of introducing misbranded Risperdal into interstate commerce in violation of the federal Food Drug and Cosmetic Act (FDCA) at 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1).

A. Statutory Basis

As the information explains, the FDCA governs the interstate distribution of drugs for human use. The FDCA and its implementing regulations prohibit the sponsor of a new drug (i.e. the drug company) from distributing that drug in interstate commerce until the sponsor has obtained approval from the FDA, after an intensive application and review process. Information ¶¶ 5-6. To obtain that approval, the sponsor must file a New Drug Application (NDA) with the FDA, which identifies all of the uses of the drug intended by the sponsor, and includes proposed labeling for those uses. Id. at ¶ 6. The sponsor must also provide data based on proper clinical trials that demonstrates to the FDA's satisfaction that the drug would be safe and effective for those intended uses. 21 U.S.C. §§ 331(d) and 355(b). Id.

The FDCA prohibited a sponsor from introducing a new drug into interstate commerce until the FDA determined that the sponsor had presented sufficient evidence of the drug's safety and efficacy for its intended uses and approved the NDA (including the proposed labeling). 21 U.S.C. § 355(a), Information at ¶ 7. Only after the FDA approved the NDA is the sponsor permitted to promote and market the drug, and then only for the particular use or uses specified in the approved labeling. Information at ¶ 7. Such approved uses are said to be within

the drug's approved indication. Id. Uses not approved by the FDA, and not included in the drug's approved labeling, were known as "unapproved" or "off-label" uses. Id. A determination by the FDA that a drug is safe and effective for one use does not mean that the drug is safe and effective for a different use. Id.

Under the FDCA and its implementing regulations, a drug sponsor who wanted to market an approved drug for any use beyond what is in its approved indication was required to submit a supplemental New Drug Application (sNDA) to the FDA supported by evidence in the form of randomized and well-controlled clinical studies, sufficient to demonstrate that the drug was safe and effective for each additional proposed use. Id. at ¶ 8. The sponsor may not lawfully label or promote the drug for any new intended use without the prior approval of the FDA. Id. Once the FDA had approved an NDA, any changes in the drug's FDA-approved labeling had to be submitted to the FDA for review and approval. Id. at ¶ 9.

Under the FDCA, a drug was "misbranded" if its labeling did not bear "adequate directions for use." 21 U.S.C. § 352(f)(1); Information at ¶ 10. "Adequate directions for use" meant directions under which a layperson could use a drug safely and effectively for the purposes for which it was intended. 21 C.F.R. § 201.5; Information at ¶ 10. A prescription drug, by definition, could not bear adequate directions for use by a layperson, but an FDA-approved prescription drug, bearing the FDA-approved labeling, could be exempt from the adequate directions for use requirement if it met a number of requirements, including that it was sold only for an FDA-approved use. Information at ¶ 10. A prescription drug that was introduced for an intended use that was unapproved, or off-label, would not qualify for this exemption and therefore was misbranded. 21 C.F.R. § 201.100; Information at ¶ 10. The FDCA prohibited

introducing, delivering for introduction, or causing the introduction or delivery for introduction into interstate commerce, of any drug that was misbranded. 21 U.S.C. § 331(a). Information at ¶ 10.

B. The Criminal Charge

The specific criminal charge which the information alleges and to which JPI has agreed to plead guilty is that JPI (through its predecessor, Janssen) introduced misbranded Risperdal into interstate commerce between March 3, 2002 and December 31, 2003. Information at ¶ 67. The drug Risperdal was misbranded because JPI distributed it for intended uses which were not within its approved indication ("off-label" use), and it was therefore shipped without adequate instructions for that intended use. Id. at ¶ 10.

The information alleges that in December, 1993, the FDA approved Risperdal for "the management of the manifestations of psychotic disorders." Id. at ¶ 14. On March 3, 2002, the FDA approved a narrowing of Risperdal's indication to the "treatment of schizophrenia," replacing the original indication.[2] Id. at ¶ 24. JPI admits and is pleading guilty to introduction of a misbranded drug between March 3, 2002 and December 31, 2003, and this is the time period alleged in the charging paragraph of the information. Id. at ¶ 67. However, the information also alleges in its factual allegations that Janssen intended Risperdal for off-label uses, as demonstrated by Janssen's promotional efforts, over a longer period of time than that to which JPI is pleading guilty, both before and after this March 3, 2002, labeling change. The information alleges the nature of the unapproved intended use slightly differently for the time periods before and after the

[2] In December, 2003, the FDA approved the additional indication of "short-term treatment of acute manic or mixed Bi-Polar I episodes as adjunctive therapy in adults." Id. at ¶ 27.

labeling change in March of 2002 because of this change in indication. Off-label promotion can be evidence of a new and unapproved intended use.

The information alleges that between May of 1998 and March 3, 2002, Janssen sold Risperdal for the intended use of the treatment of behaviors and psychological symptoms associated with dementia, including behavioral disturbances associated with dementia, which were not psychotic symptoms and with no regard for whether or not such symptoms or behaviors were a consequence of psychosis or psychotic symptoms. Id. at ¶ 50. These intended uses were outside Risperdal's FDA-approved labeling during that time period because these uses were not limited to psychotic symptoms or symptoms arising from psychotic disorders. Id.

Between March 3, 2002 and November 30, 2005, Janssen sold Risperdal for the treatment of behaviors and psychological symptoms associated with dementia. Id. at ¶ 51. These intended uses were outside Risperdal's FDA-approved labeling during that time period because these uses were not limited to promotion for treatment of schizophrenia (or of bipolar disorder after December 2003).

In each time period, because these intended uses for Risperdal were not within its approved indication, the intended uses were uses for which the label did not provide adequate directions. Id. at ¶ 10. For this reason, JPI's introduction into commerce of Risperdal for these additional intended uses caused Risperdal to be misbranded under 21 U.S.C. § 352(f)(1).

The specific time period of off-label promotion to which JPI has agreed to plead guilty is March 3, 2002 through December 31, 2003. Plea Agreement ¶¶ 1 and 8(d). JPI has agreed that, during that time period, it promoted Risperdal to health care providers for treatment of psychotic symptoms and associated behavioral disturbances exhibited by elderly

non-schizophrenic dementia patients. Id. at ¶ 8(d). This promotion evidenced intended uses outside Risperdal's indication during that period. 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. Id.

II. PLEA AGREEMENT

Defendant JPI has agreed to the terms of a plea agreement with the government. A copy of this plea agreement is attached as Attachment A to this memorandum. This plea agreement is entered into under Federal Rule of Criminal Procedure 11(c)(1)(C), and includes an agreed-upon sentence. The essential terms of the plea agreement are summarized as follows:

1. JPI agrees to plead guilty to a one-count information charging it with introducing a misbranded drug, Risperdal, into interstate commerce, and not to contest forfeiture as set forth in the notice of forfeiture.

2. The agreement is made under Rule 11(c)(1)(C) and the parties agree that the appropriate sentence is: a fine of $334,000,000, a forfeiture judgment of $66,000,000 as substitute assets, and a special assessment of $125. JPI agrees to pay these penalties within 10 business days of the date of sentencing. The parties agree that the misbranded drugs are no longer available, and JPI agrees to the entry of a forfeiture judgment in the amount of $66,000,000 as substitute assets for the pertinent drugs. 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. JPI has also reached a settlement in a civil case involving 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 for attorney's fees and other litigation expenses.

6. The intent of the plea agreement is that JPI as it existed on July 6, 2011, is the entity which is pleading guilty. If the defendant corporation is reorganized, the plea agreement and its obligations shall bind its successors-in-interest. JPI agrees that it shall not, through a reorganization or other action, seek to avoid the obligations and conditions set forth in the plea agreement.

7. JPI understands the maximum penalties for the charged offense.

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 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 caused shipments of Risperdal to be introduced into interstate commerce, and these shipments constituted misbranded drugs due to the conduct described above.

9. 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 Corporate Integrity Agreement with the HHS Inspector General.

11. 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 the current prosecution is timely. 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. If JPI seeks to withdraw its plea, or if this plea agreement is not carried out for any of the reasons identified in this paragraph, JPI 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. The United States will not bring any other criminal charges against JPI or related companies 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 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. These non-prosecution provisions are binding on the United States Attorney for the Eastern District of Pennsylvania, the Consumer Protection Branch, and the United States Attorney's Offices for the other 93 judicial districts of the United States. These non-prosecution provisions 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 to the plea agreement is a copy of the letter to the United States Attorney from the Department of Justice's Criminal Division 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. The government takes no position on the tax treatment of any matters related to this case.

14. JPI waives all rights to appeal or collaterally attack the conviction, sentence, or any other matter relating to this prosecution.

15. JPI waives all rights, whether asserted directly or by a representative, to request or receive 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 or the Privacy Act.

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.

III. COMPONENTS OF THE GLOBAL RESOLUTION

The plea agreement is part of a global resolution reached between the United States and JPI (and, civilly, including other parties) concerning Risperdal. In a separate civil settlement among the United States, Medicaid-participating states, JPI, and others, JPI will pay $1,253,024,000 to resolve claims by the United States Medicaid and Medicare Trust Funds, and other federal agencies. This civil settlement also resolves four pending qui tam actions. Along with the civil settlement, Johnson & Johnson is executing a five-year Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services, Office of the Inspector General, which includes JPI being placed under that agreement. This agreement will impose a strict compliance program to ensure that the conduct does not recur, and penalties for any non-compliance by JPI.

IV. ELEMENTS OF THE OFFENSE

A. Misbranding

The information charges one count of misbranding under the FDCA, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1). Section 331 lists prohibited acts, including:

> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

Section 352 of the FDCA defines a drug as "misbranded" under several circumstances, including (as relevant here):

> A drug or device shall be deemed to be misbranded –
>
> * * *
> (f) Directions for use and warnings on label
> Unless its labeling bears (1) adequate directions for use . . . .

Section 333 sets forth misdemeanor and felony penalties for violations of Section 331:

> (a) Violation of section 331 of this title; second violation; intent to defraud or mislead
>
> (1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.
>
> (2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

The information in this case charges a misdemeanor under 21 U.S.C. § 333(a)(1). In order to prove this crime, the government must establish the following elements beyond a reasonable doubt:

1. that Risperdal is a drug

2. that Risperdal was misbranded in that it lacked adequate directions for the uses intended by JPI, and

3. that JPI caused Risperdal, while misbranded, to be introduced into interstate commerce.

It is not illegal for a doctor, using good medical judgment, to prescribe a drug for an off-label use. However, it constitutes criminal misbranding for a drug manufacturer to introduce its drug into commerce for a new intended use which has not been approved by the FDA, and for which the label did not provide adequate directions.

B. Forfeiture

The forfeiture component of the information and plea agreement arises from the FDCA's provision for seizing misbranded drugs. 21 U.S.C. § 334 (allowing proceedings on libel of information, for condemnation, against drugs that are misbranded or adulterated so that the government can seize, destroy or sell them). These proceedings are by their nature classic civil

forfeiture proceedings. Under federal forfeiture law, the government can pursue criminal forfeiture in any case where the defendant is charged with a violation of an Act of Congress which contains a civil forfeiture remedy. See 28 U.S.C. § 2461(c) (allowing criminal forfeiture where the defendant is charged "in a criminal case with a violation of an Act of Congress for which the civil or criminal forfeiture of property is authorized . . . ."). Thus, if civil forfeiture is authorized in a statute such as the FDCA, then criminal forfeiture is authorized as well.

Because the misbranded drugs here are no longer available for seizure or destruction, the government can seek substitute assets. See 18 U.S.C. § 2461(c) (the procedures set forth in 21 U.S.C. § 853 apply to this criminal forfeiture); 21 U.S.C. § 853(p) (allowing the forfeiture of substitute assets if the items subject to forfeiture are no longer available). Pursuant to the plea agreement, the government here seeks, and defendant has agreed to pay, a forfeiture judgment for substitute assets in the amount of $66,000,000.

V. THE MAXIMUM PENALTIES

The maximum penalty for this offense is a fine of $200,000 (under 18 U.S.C. § 3571(c)(5)), or twice the gross gain or gross loss, whichever is greater (18 U.S.C. § 3571(d)); a special assessment of $125 (18 U.S.C. § 3013(a)(1)(B)(iii)); and a five-year term of Court supervision (18 U.S.C. § 3561(c)(2)); in addition, forfeiture may be ordered.

VI. THE FACTS AT TRIAL

In the plea agreement, the parties have stipulated to a factual basis sufficient to support the entry of this plea. Plea Agreement, ¶ 8. These stipulated facts are set forth above.

In order to give the Court context for these stipulations, the government here sets forth some of the broader facts that it would prove if the case were to proceed to trial.

A. Regulatory Background

The government would show that the FDA approved Risperdal in December of 1993 to treat "the management of the manifestations of psychotic disorders." As it was used in the Risperdal labeling, this phrase meant management of hallucinations and delusions (i.e., psychotic symptoms) and behaviors or symptoms which were a consequence of hallucinations and delusions. Risperdal's pivotal clinical studies supporting its application for approval were short term trials with schizophrenia patients. The approved labeling also noted that there were insufficient studies on the use of Risperdal in the elderly to determine efficacy in that population, stating that "[c]linical studies of Risperdal did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients."

In mid-1994, Janssen asked the FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) – the unit that reviewed marketing and promotional materials – for opinions in two areas. One concerned whether Janssen could list specific psychotic disorders in its promotional claims, and the second was whether it needed to have additional clinical studies to support a promotional campaign for geriatric use of Risperdal. In response, DDMAC told Janssen it could mention specific psychotic disorders in advertising if it also stated that its pivotal trials were in schizophrenia, and said that "a focused marketing campaign targeting specific non-schizophrenic psychoses would be misleading." DDMAC also told Janssen that additional data from clinical trials would be required to support the promotion of Risperdal specifically for geriatric use. DDMAC stated that until such data was available, it would be misleading to suggest that the safety and efficacy of Risperdal had been established specifically in the elderly.

In August of 1995, Janssen wrote to the FDA concerning its intentions to use the results of a proposed study, if successful, to revise Risperdal's labeling regarding "behavioral disturbances associated with dementia." The Director of the FDA's review division advised Janssen that if its interest had been in targeting the population of dementia patients with psychosis, it would not really be an expansion of Risperdal's current basic claim. However, Janssen's proposal was exploring "a much broader and more diffuse clinical target" which would extend to clinical findings such as "anxiety, depression, agitation, aggressiveness, verbal outbursts, wandering, etc." that would not necessarily be considered psychotic manifestations. The Director advised Janssen that the FDA would consider a claim of "behavioral disturbances in demented patients" to be misleading because it was so broad as to be misinterpreted by physicians, and the FDA would not consider that claim.

In August of 1997, Janssen met with FDA review officials about its efforts to obtain approval for labeling changes to allow Janssen to promote Risperdal for use in treating dementia patients' symptoms. The FDA told Janssen that it could not promote Risperdal for use specifically with demented patients until the FDA approved a change to the Clinical Trials section of the label to include results supporting such promotion. The FDA also told Janssen that it was opposed to any indication for "aggression associated with dementia."

In January of 1999, DDMAC, after receiving a complaint, found that Janssen had conducted a campaign marketing Risperdal specifically for geriatric patients, and in doing so had used materials which were "false, misleading, and/or lacking in fair balance." DDMAC found that this campaign, with a theme of "Hostile Outside, Fragile Inside," used material which stated or implied that Risperdal had been found to be safe and effective for the elderly and in specifically

treating hostility in the elderly, but in fact the elderly had not been specifically studied in the clinical trials for Risperdal.

On January 20, 1999, the FDA made a "not approvable" finding on Janssen's application to include in its labeling the use of Risperdal for treatment of psychotic and behavioral disturbances in dementia. The FDA said that Janssen had failed to fully evaluate the safety of Risperdal for the proposed use in the elderly. The FDA said that the data Janssen submitted showed a slight excess of deaths for patients using Risperdal compared to those using a placebo, finding it to be a "relatively weak signal," and determined that it needed further exploration before the FDA could reach a decision about approving Janssen's proposed labeling change for treatment of psychotic and behavioral disturbances in dementia.

In 2003, as a result of incidences of deaths in clinical trials of Risperdal in the elderly, the FDA required a new warning to be placed on Risperdal's label concerning the risk of cerebrovascular adverse events (strokes). The warning cautioned that "Cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, were reported in patients (mean age 85 years; range 73-97) in trials of risperidone in elderly patients with dementia-related psychosis."

By 2005, the FDA had available further studies in Risperdal and in other drugs in its same class. Based on a meta-analysis of these studies, the FDA determined that there was in fact an increased risk of mortality for elderly dementia patients taking Risperdal and other atypical antipsychotics compared to such patients taking a placebo. In April, 2005, the FDA required that each manufacturer of an atypical antipsychotic, including Janssen for Risperdal, include in its labeling a "black box" warning stating that "Elderly patients with dementia-related psychosis

treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo."

B. Janssen's Misbranding of Risperdal

From December 1993 until March 3, 2002, Risperdal's FDA-approved indication was "the management of the manifestations of psychotic disorders." Janssen was not permitted to distribute Risperdal (i.e. introduce Risperdal into interstate commerce) for any other intended use, and Janssen was also required to limit its marketing of Risperdal to promoting this use and only this use. Under this indication, Janssen could promote Risperdal for treatment of patients who had psychotic symptoms, which meant it could promote Risperdal for treatment of delusions or hallucinations or behaviors or symptoms which were a consequence of delusions or hallucinations. Janssen could not promote Risperdal for behaviors or symptoms which did not arise from psychotic symptoms, and Janssen could not promote Risperdal specifically for the elderly. The restriction on promotion specifically for the elderly meant that Janssen could promote Risperdal generally for treating psychotic symptoms – even if the doctor's patients were elderly – but it could not promote Risperdal specifically for treatment of psychotic symptoms in the elderly, because Risperdal had not been shown to be safe and effective in studies specifically in the elderly. Off-label promotion can be – and here is – evidence of an unapproved intended use.[3]

In May of 1998, Janssen launched its ElderCare sales force. This purpose of this sales force was to promote Risperdal and two other drugs to physicians who saw primarily older and elderly patients (65 years old and above). These sale representatives also sought out physicians who were medical directors for nursing homes, and other prescribers who treated

[3] 21 C.F.R. § 201.128; Wisconsin v. Mitchell, 508 U.S. 476, 489 (1993); Whitaker v. Thompson, 353 F.3d 947, 953 (D.C. Cir. 2004).

patients in nursing homes. The purpose of ElderCare was summarized in early 1999 by a member of Janssen's sales management, a district manager, who advised one of his sales representatives, with respect to the promotion of Risperdal, that "I was glad to see that you are keeping your discussions around dementia, because we are a geriatric sales force that focuses on treatment of behavioral disturbances associated with dementia."

Janssen's ElderCare sales force consistently promoted Risperdal for treatment of behavioral disturbances in dementia patients, and did not limit its promotion to patients with psychotic symptoms. This showed Janssen's intent to distribute Risperdal for this new intended use. The government would offer into evidence numerous Field Conference Reports (FCRs), which were written reports of district sales managers' "ride-along" sessions with sales representatives which occurred every few months. In preparing FCRs, the district managers reported on these "ride-along" sessions, and sometimes described the actual promotion by a sales representative to a doctor. The FCRs the government would offer described promotion which was off-label marketing of Risperdal and evidence of a new intended use. These reports set forth Janssen's sales management commending sales representatives for promoting Risperdal for use in behaviors and symptoms of dementia, without any limitation (pre March of 2002) to those dementia patients who had psychotic symptoms (i.e. delusions or hallucinations). The district managers also submitted these to Janssen's Regional Business Directors, the next higher level of management supervision of the sales force, and it was part of those directors' jobs to review the Field Conference Reports.

In these FCRs reporting on sales visits between early 1999 and late 2001, Janssen's district sales managers repeatedly commended and encouraged sales representatives for promoting

Risperdal to doctors for long-term treatment of behavioral disturbances in the demented patient and for the treatment of agitation and aggression due to dementia. The FCRs represent the comments from Janssen sales force managers from many parts of the country. In no FCR produced to the government did any manager during this period caution any sales representative to limit promotion of Risperdal for treatment of dementia patients to those patients with psychosis or psychotic symptoms.

On September 25, 2000, the FDA wrote to Janssen and requested that it change Risperdal's indication in its label to "treatment of schizophrenia" and to submit the proposed change within 3 months. This narrowed indication more accurately reflected the patient population which was the subject of Risperdal's clinical trials upon which the FDA originally approved Risperdal in 1993. The FDA made the same request of the other manufacturers of atypical antipsychotic drugs. On March 3, 2002, the FDA gave final approved to this change in Risperdal's labeling, based on Janssen's submissions on January 28, 2002.

Janssen's sales management continued to encourage and direct the ElderCare sales force to promote Risperdal for treatment of symptoms in dementia patients after the label changed to "treatment of schizophrenia" in March 2002. After this label change, Janssen was not permitted to introduce Risperdal into commerce for any use with non-schizophrenic dementia patients because Risperdal was then only indicated for treatment of schizophrenia. Specifically, after the label change Janssen was not permitted to introduce Risperdal for use for treatment of psychotic symptoms or any other symptoms in non-schizophrenic dementia patients. Schizophrenia affected approximately 1% of the general population, and because of the lower life expectancy of schizophrenics, it affected an even lower percentage of elderly patients.

When Janssen announced the March 2002 labeling change to its sales representatives, Janssen advised them that they would not change their symptom-based message. Janssen made no effort to instruct its sales force to change the way it promoted Risperdal to limit such promotion to only symptoms which arose from schizophrenia and to promote it only for treatment of schizophrenics.

Field Conference Reports for sales calls after March 3, 2002, from April 2002 through February 2005, show that Janssen's sales force management continued to commend and encourage the sales representatives to promote Risperdal for treatment in dementia patients for behaviors and symptoms of dementia, evidencing this as a new intended use. District sales managers continued to commend sales representatives for and encourage sales representatives to promote Risperdal to doctors for controlling the symptoms associated with dementia. The district managers told sales representatives that Risperdal was for the geriatric nursing home patient with psychosis and agitation. The district managers also urged sales representatives to present and discuss key points from a study which had been done on the use and proper dosing of Risperdal in dementia patients, and which was not limited to dementia patients with schizophrenia or even with psychosis. The managers commended sales representatives for discussing with doctors why Risperdal was a better alternative than its competitors in the patients that were experiencing anxiety, agitation and behavioral disturbances associated with dementia. These FCRs also came from district managers in many parts of the country. Only in late 2004 were there any efforts by district managers or regional business directors to caution that selling for dementia was off-label, and there were only two of these cautions in 2004 and one in 2005. Further, sales representatives would testify that they continued to sell for use with dementia patients through the end of

ElderCare (which was in November 2005).

Janssen management also supported this off-label promotion, evidence of a new intended use. Janssen's 2000 Risperdal business plan stated that part of the focus for Risperdal for 2000 would be for "first line treatment" of several "psychotic and non-psychotic disorders," including dementia. In August, 2001, the Janssen Vice President for Marketing stated in a document that "Risperdal /Dementia is the primary focus of the ElderCare Sales force." The Director of Marketing for all CNS (with management responsibility for Risperdal) noted in June 1999 that one of the major goals for Risperdal in 2000 was to "strengthen our leadership position in dementia." A member of the Risperdal Brand Team communicated Janssen's intent to focus on dementia in a July 2001 e-mail, referring to the dementia market: "I don't think we should test positioning statements per se but you should be aware that this is an issue for us and that we need to find a way achieve [sic] a positioning to ensure we maintain our strong lead in this market–despite not having the indication." The leadership of the Risperdal Brand Team advised a new employee in February 2002 that the focus of the ElderCare Division was dementia. Indeed, the Risperdal 2002 Business Plan identified the labeling change to schizophrenia as a "threat." It set out as a "key tactic" for 2002 to "Minimize impact of new schizophrenia label" and cited one way of doing this was by using a "Symptom focused messages in sales aids."

Janssen institutionalized its support for off-label promotion for behaviors and symptoms of dementia in several ways. Bonuses paid to sales representatives encouraged off-label promotion of Risperdal. Until 2005, Janssen awarded a bonus to its sales representatives which was based largely on Risperdal sales in the representative's area, whether the sales were for on-label or off-label use of Risperdal. This bonus was, or could be, approximately 20% of a sales

representative's monetary compensation. Janssen's established compensation system provided an institutionalized incentive for ElderCare sales representatives to promote and sell Risperdal for off-label uses, resulting in Janssen distributing misbranded Risperdal.

According to data provided by IMS, a third-party provider of prescription information, a high percentage of Risperdal use in the elderly was for off-label uses. Only approximately 10% of Risperdal prescriptions in the elderly were for schizophrenia. Approximately 60% of Risperdal prescriptions were off-label among elderly patients before the March 2002 label change, approximately 90% of such prescriptions were off-label from March of 2002 until December of 2003, and after the FDA approved the bipolar indication in December of 2003 approximately 80-85% of Risperdal prescriptions to the elderly were off-label.

Following the label change in March of 2002, Janssen determined that it would continue its symptom-based message, and its sales aids avoided any emphasis on schizophrenia. Janssen completely failed to instruct its ElderCare sales representatives to only promote for use in elderly patients with schizophrenia. The first two ElderCare sales aids prepared after the March 2002 label change – aids that Janssen instructed every ElderCare sales representative to use on every call – listed symptoms prominently on the front cover. Some of these listed symptoms – such as agitation, confusion, hostility, impulsiveness – might be found in dementia patients. Nowhere on the covers of either of the first two sales aids did the word "schizophrenia" appear, nor was there any indication that treatment of these symptoms was being promoted only if they arose from schizophrenia.

Janssen directed its sales representatives to leave samples with its customer doctors. Although the average dose for treating schizophrenia was 3.8 mg. a day, and for

schizophrenia in the elderly the average dose was 2.4 mg. a day, the average daily dose for treating behaviors and symptoms of dementia was 0.9 mg. a day. The ElderCare representatives were provided principally with 0.25, 0.5 and 1 mg. samples to leave with physicians.

Janssen also promoted Risperdal in tandem with long term care pharmacy providers. This, in part, took the form of ElderCare sales representatives identifying prescribers who cared for elderly patients in nursing homes served by long term care pharmacy providers. Sales representatives also sought out and promoted to consultant pharmacists and directors of nursing at such facilities, who had influence with the prescribers as to what drugs the prescriber chose to prescribe. In other cases, Janssen Long Term Care account managers provided pharmacies with "Risperdal Preferred Letters." These letters were for the pharmacy to send to doctors saying that Risperdal was the pharmacy's preferred atypical antipsychotic, and the letters the Janssen representative provided touted Risperdal, saying "Risperdal has proven to be of benefit in geriatric patients with behavioral disturbances and aggression associated with dementia." This letter was provided to the pharmacy in February of 2003, well after the March, 2002, label change. The Janssen representative told the pharmacist that he could mail it to the physicians after he edited it and put it on his letterhead. A similar letter was provided to another pharmacy by a sales representative in late 2004, and that letter similarly said that "Risperdal has proven to be of benefit in patients with behavioral disturbances and psychosis," and recommended that the physician consider prescribing Risperdal for "patients exhibiting psychotic symptoms or behavioral problems." These form letters, provided by Janssen employees, were not limited to patients with schizophrenia (or, after December 2003, also bipolar disorder). Finally, Janssen noted that consultant pharmacists in Long Term Care facilities played an important role in

switching patients from one drug to another, such as Risperdal. In its 2001 Long Term Care business plan, Janssen noted that "Consultant Pharmacists are an important influencer in the LTC/EC [Long Term Care/Elder Care] segment and play a critical role in encouraging appropriate use of pharmaceuticals. If leveraged appropriately, they can act as an extension of our sales force."

Janssen spent significant resources on speakers and on funding CME programs. The CME programs often had off-label subject matter. In 2001 Janssen identified as part of its tactical planning to focus the CME dollars on off-label messages. At least in earlier years, the doctors were invited to CME presentations by the sales representatives. Prior to the March 2002 label change, Janssen Brand Team members had input into the look and feel of the CME presentations, into their content, and in selecting the core faculty who would present the CME programs.

In sum, Janssen's varied and sustained promotion of Risperdal for use with dementia patients, without regard to the absence of schizophrenia or bipolar disease (and before March 2002, without regard to the absence of psychosis), demonstrated intent to introduce Risperdal into commerce for this new intended use, without proper labeling.

The government would also present evidence that Janssen had a profit motive to maximize sales of Risperdal for new intended uses, which were off-label, with dementia patients. As one of the Risperdal brand managers noted in 2001, sales for use with elderly patients would be about $360 million in 2001, with higher financial targets for 2002 ($430 million). He noted that this "reflects more than sales in dementia; however, the majority of sales in elderly are in this use," and he added that the bulk of these sales fall to "the bottom line." Janssen executives knew that

the Risperdal patent was set to expire on December 27, 2007.[4] Sales of Risperdal and profits generated by Risperdal in fact dropped substantially when Risperdal faced generic competition.

In May 2005, the FDA found "not approvable" Janssen's revised application to add psychosis of Alzheimer's Disease to Risperdal's indication. The FDA concluded that Janssen had not provided substantial evidence of effectiveness for treatment of psychosis of Alzheimer's Disease. Subsequently, in November of 2005, Janssen disbanded its ElderCare sales force.

The government would also show that Janssen, through its promotion of Risperdal, caused the introduction of Risperdal into interstate commerce. Other subsidiaries of J&J manufactured Risperdal in Italy and Puerto Rico, packaged it in Puerto Rico, shipped it to a warehouse in New Jersey. From there it was shipped in interstate commerce to wholesalers and others who distributed it further in response to demand from prescriptions for Risperdal.

V. SENTENCING CONSIDERATIONS

The parties jointly request that JPI be sentenced on the day it enters its guilty plea. The parties have further agreed upon the appropriate sentence for the conduct pleaded to, and jointly urge the Court to accept the plea agreement and the agreed-upon sentence. The sentence the parties have agreed upon, and which they jointly propose to the Court, is a criminal fine of $334,000,000 and a forfeiture judgment of $66,000,000.

This agreed-upon fine and forfeiture reflect the factors set forth in 18 U.S.C. § 3353(a) and take into account the advisory sentencing guidelines here. The sentencing guidelines actually do not apply to this offense, but the parties have used as their point of reference the

[4] The FDA ultimately granted Janssen an additional six months of exclusivity and its Risperdal patent finally expired on June 29, 2008.

method set out in Chapter 8 of the sentencing guidelines as though they do.[5] In reaching the recommended penalties here, the parties have discussed the sentencing factors in the process of trying to identify the pecuniary gain realized by Janssen due to the relevant conduct of the offense. See U.S.C.G. §§8C2.4(a)(2) and 8A1.2, appl. note 3(H). The parties found that they had differing methods in attempting to identify such profit, but that there was agreement on the final fine and forfeiture numbers. These final agreed-upon numbers arose after each party engaged in the calculation of pecuniary gain, the calculation of a culpability score under section 8C2.5, after the selection of a multiplier number for the table at §8C2.6, and after the consideration of an amount for forfeiture.

The parties urge upon this Court that the proposed fine and forfeiture are appropriate under section 3553(a). Because the Chapter 8 guidelines do not apply to this case, section 8C2.10 directs the Court to determine the amount of the fine "by applying the provisions of 18 U.S.C. § 3553 and 3572." The proposed criminal resolution accomplishes the goals of sentencing under 18 U.S.C. § 3553(a). It is the product of extensive negotiations between the parties, addressing the seriousness, nature and circumstances of the offense, and the history and characteristics of the defendant. It also reflects the harm caused by the off-label marketing which undermined the drug approval process mandated by statute and posed risk to patients. This fine promotes respect for the law, and will deter JPI and other companies in the industry from further

[5] For a misdemeanor conviction, §§ 8C2.2 through 8C2.9 do not apply because of the absence of fraud (because §2N2.1, the guideline referenced by the statute here, is not on the list of statutes in the § 8C2.1 list and for a misdemeanor it does not invoke a guideline on the list). In the case of an offense whose guideline is not listed in § 8C2.1, section 8C2.10 directs the Court to determine an appropriate fine by applying 18 U.S.C. §§ 3553 (sentencing factors) and 3572 (relating to fines).

unlawful introduction of misbranded drugs. A criminal fine of this magnitude will also serve as general deterrence to others who might be tempted to engage in unlawful introduction of misbranded drugs.

All of the factors discussed in this section are difficult to quantify, but the United States believes the proposed criminal penalty is a just resolution of this matter.

Conclusion

For these reasons, the United States respectfully recommends that the Court accept the plea agreement and Janssen's plea of guilty to the Information, and sentence JPI to a criminal fine in the amount of $334,000,000, impose an asset forfeiture money judgment in the amount of $66,000,000, and require a special assessment of $125. The United States also asks that the Court impose this sentence following the company's plea of guilty at the conclusion of the plea hearing.

Respectfully submitted,

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Dated: November 4, 2013

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Memorandum was served upon defense counsel on the date below by email and U.S. Mail, and on the probation office by U.S. Mail, as follows:

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Dated: November 4, 2013

APPENDIX A

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

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Former Trial Attorney
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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

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DATE: _____

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SIGNATURE FOR JANSSEN PHARMACEUTICALS, INC.

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Attachment

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
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.