UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA ex rel
Camille McGowan and Judy Doetterl,

Plaintiffs,

v.

Civil No.:

JANSSEN PHARMACEUTICA, INC.; JANSSEN PHARMACEUTICA PRODUCTS, L.P.; and JOHNSON & JOHNSON, INC.,

FILED IN CAMERA AND UNDER SEAL

Defendants.

COMPLAINT

Plaintiffs-Relators Camille McGowan and Judy Doetterl, by and through their attorneys Hodgson Russ LLP, for their Complaint, allege as follows:

PARTIES

1. Plaintiffs-Relators Camille McGowan and Judy Doetterl commence this action on their own and on behalf of the United States of America against defendant Janssen Pharmaceutica, Inc., Janssen Pharmaceutica Products, L.P. (collectively "Janssen"), and Johnson & Johnson, Inc. under the qui tam provisions of the False Claims Act, 31 U.S.C. §§ 3729 et seq.

2. Camille McGowan is a resident of the State of New York and a former employee of Janssen. Ms. McGowan was employed as a contract Sales Manager in Janssen's Eldercare Division, Central Region from about April 2001 until about May 2002. She was

employed directly by Janssen as a District Manager in Janssen's Eldercare Division, Eastern Region from about May 2002 until about November 2004.

3. While an employee of Janssen, Camille McGowan personally learned information and came in contact with many documents that form the basis of the allegations in this Complaint.

4. Camille McGowan is an "original source" within the meaning of the False Claims Act, 31 U.S.C. § 3730(e)(4)(B), because she is an individual who has direct and independent knowledge of the information on which the allegations in this Complaint are based and will voluntarily provided such information to the United States government.

5. Judy Doetterl is a resident of the State of New York and a current employee of Janssen. Ms. Doetterl has worked for Janssen's Eldercare Division as a sales representative in the Division's Eastern Region since about October 2001 to the present.

6. During the course of her employment with Janssen, Judy Doetterl has personally learned information and has come in contact with many documents that form the basis of the allegations in this Complaint.

7. Judy Doetterl is an "original source" within the meaning of the False Claims Act, 31 U.S.C. § 3730(e)(4)(B), because she is an individual who has direct and independent knowledge of the information on which the allegations in this Complaint are based and will voluntarily provide such information to the United States.

8. Upon information and belief, Janssen Pharmaceutica, Inc. is a New Jersey corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica, Inc. is a wholly owned subsidiary of Johnson & Johnson, Inc. and is principally engaged in the manufacture and sale of pharmaceuticals including prescription pharmaceuticals falling under the jurisdiction and regulation of the U.S. Food and Drug Administration ("FDA").

9. Upon information and belief, Janssen Pharmaceutica Products, L.P. is a New Jersey business entity with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Products, L.P. is a wholly owned subsidiary of Johnson & Johnson, Inc. and is principally engaged in the manufacture and sale of pharmaceuticals including prescription pharmaceuticals falling under the jurisdiction and regulation of the FDA.

10. Upon information and belief, Johnson & Johnson, Inc. is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331; 28 U.S.C. §1345; and 31 U.S.C. § 3732.

12. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732(a).

13. The defendants regularly conduct substantial business within the State of New York, maintain permanent employees and offices in the State of New York, and have made and are making significant sales within the State of New York.

14. Venue is proper under 31 U.S.C. § 3732(a) because the defendants can be found and/or transact business within the Western District of New York and because some of the violations of 31 U.S.C. § 3729 alleged in the complaint occurred within this judicial district.

15. Venue is also proper pursuant to 28 U.S.C. § 1391(b) and (c).

SUMMARY OF THE ACTION

16. This action challenges Janssen's unlawful promotion of the brand name prescription drug Risperdal and the foreseeable consequences of such promotion — the submission of false claims to the United States for reimbursement and/or payment.

17. In or around 1993, Janssen obtained approval from the FDA to market Risperdal, the brand name for the generic drug risperidone. The FDA initially approved Risperdal for use as an antipsychotic for the management of the manifestations of psychotic disorders.

18. In 2002, the indicated use for Risperdal was changed to include only the treatment of schizophrenia. Risperdal has never been approved by the FDA for the treatment of dementia.

19. The FDA prohibits manufacturers of prescription drugs from promoting or marketing drugs for uses not approved by the FDA (*see* 21 U.S.C. § 331(a), (d), and 21 U.S.C. § 352). Such promotion or advertising is commonly referred to as "off-label" or "off-indication."

20. Beginning no later than January 2001 and continuing up to the present time (the "Relevant Period"), the defendants have sought to increase the sales and market share of Risperdal in the burgeoning elderly population. To accomplish this objective, the defendants have systematically and aggressively promoted Risperdal for the treatment of dementia in elderly patients.

21. The defendants' off-label marketing scheme has included, among other things:

- Use of Janssen's Eldercare Division as a principal selling agent of Risperdal;
- An elaborate training program that instructed Janssen Eldercare sales personnel how to effectively promote Risperdal for the treatment of dementia;
- Financial incentives that rewarded Janssen Eldercare sales personnel who successfully promoted the use of Risperdal in long-term care settings;
- Regular and continuous sales calls by Janssen Eldercare sales representatives to nursing homes, primary care physicians who treat the elderly, and neurologists who treat patients suffering from dementia;
- Regular and continuous sales calls by Janssen Eldercare sales representatives to physicians whose prescribing behavior demonstrated a pattern of off-label use of anti-psychotics;
- Regular and continuous sales calls by Janssen Eldercare sales representatives to "closed pharmacies" who supply prescription drugs primarily to long-term care facilities and institutions; and
- Widespread distribution of articles by Janssen Eldercare sales representatives discussing the efficacy of Risperdal for the treatment of dementia.

22. Sales of Risperdal have exceeded $5 billion from 2001 through 2003.

23. A large portion of these sales, and most of the sales made by Janssen's Eldercare division, are attributable to the use of Risperdal for the treatment of dementia.

24. Many patients who have been prescribed Risperdal to treat dementia have had their prescriptions paid for, directly or indirectly, by the United States through reimbursements under Medicaid or through Medicare.

25. The use of Risperdal for the treatment of dementia is not recognized as a medically accepted indication under applicable federal laws and regulations. Such use is not eligible for coverage under Medicare and Medicaid.

26. Through its off-label marketing and promotion, Janssen knowingly caused medical personnel and pharmacists to submit claims to the United States for payment and/or reimbursement to cover the use of Risperdal for the treatment of dementia.

27. The United States has paid these false claims and has therefore suffered substantial financial damages, which have inured to the benefit of the defendants.

JANSSEN'S ELABORATE OFF-LABEL MARKETING SCHEME

28. Beginning no later than January 2001 and continuing up to the present time, Janssen has directed its sales and marketing programs for Risperdal to medical personnel who treat elderly patients suffering from dementia. Janssen has instructed its Eldercare sales

representatives to make regular sales visits to medical personnel in nursing homes, primary care physicians, and neurologists.

29. Janssen has collected and maintained data on the prescribing behavior of physicians and has directed its Eldercare sales representatives to make sales visits to those physicians whose prescribing behavior demonstrates a propensity to prescribe antipsychotics for off-label use.

30. Janssen has directed its sales representatives to make sales visits to "closed pharmacies," such as Omnicare of Western New York and NCS of Rochester, who supply prescription drugs primarily to long-term care facilities that house and treat the elderly.

JANSSEN TRAINED ITS SALES REPRESENTATIVES TO SELL RISPERDAL OFF-LABEL

31. Beginning no later than January 2001 and continuing up to the present time, Janssen has managed an elaborate Eldercare training program that is designed to teach Eldercare sales representatives how to effectively promote Risperdal for the treatment of dementia.

32. For example, in its sales manual, "Handling the Most Common Objections Voiced by Prescribers," which Janssen distributed in or around the spring of 2001, Janssen directed Eldercare sales personnel to tell physicians that "Risperdal has an excellent combination of efficacy and safety, which is supported by Csernansky, Conley, and Katz's superior results."

"Katz's superior results" refers to a study conducted by Ira R. Katz which concluded that Risperdal (in low dosages) was effective for the treatment of dementia in elderly patients.

33. In its "Primer on Dementia," which Janssen distributed in the spring of 2001, Janssen provided its Eldercare sales representatives with an overview of the diagnostic criteria and the etiologies of dementia so that sales representatives could speak intelligently about dementia when making sales visits.

34. In a spring 2001 presentation to Eldercare sales personnel entitled "The Competitive Edge," a Janssen sales representative, under the direction of Janssen's brand management group, summarized the key findings of the 1999 Katz study and discussed the efficacy of Risperdal for treating dementia in the elderly population.

35. At Janssen's October 2001 Cycle 3 Meeting for Team Pittsburgh, Janssen instructed its sales representatives to "focus on symptoms instead of diagnosis" when selling Risperdal. Janssen described this as its "key promotional message."

36. At this same meeting, Janssen provided its Eldercare sales representatives with a hypothetical question and answer dialogue between a Janssen Eldercare sales representative and a physician. The sample dialogue instructed Eldercare representatives to "Bridge to Risperdal" with the following sales pitch:

> Doctor, as your patient's disease progresses into the moderate to later stages of AD [Alzheimer's Disease], and behavioral type symptoms become more prevalent. [sic] Risperdal offers you superior efficacy, an unparalleled safety profile, and dosing flexibility tailored to the geriatric patient.

37. In or around February 2002, the label indication for Risperdal was changed from "Risperdal is indicated for the treatment of the manifestations of psychotic disorders" to "Risperdal is indicated for the treatment of schizophrenia."

38. Despite this change, which limited the approved use of Risperdal to a diagnosis-based indication, Janssen continued to direct its Eldercare sales representatives, including Camille McGowan and Judy Doetterl, to promote Risperdal for the treatment of dementia.

39. For example, at a January 2002 Eldercare sales meeting, Janssen made a presentation to its some of its sales representatives about the change in Risperdal's label indication. In this presentation, Janssen concluded:

> Beginning February 2002 the indication for Risperdal will be schizophrenia vs. management of psychosis . . . . We will not change our focus on a symptom driven message . . . .We do not believe this will impact prescriber perceptions . . . .Core Message remains.

40. In August 2002, Janssen distributed a manual on sleep disorders — a "Sleep Backgrounder" — to some of its Eldercare sales representatives. In this manual, the author stated that "Risperdal is an effective treatment for sleep disruptions associated with dementia . . . ."

41. In or around the spring of 2003, the Risperdal package insert was modified to include a new warning regarding adverse events in elderly patients with dementia. The warning provided:

> **Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients with Dementia**: 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. In placebo-controlled trials there was a significantly higher incidence of cerebrovascular adverse events in patients treated with risperidone compared to patients treated with placebo. RISPERDAL has not been shown to be safe or effective in the treatment of patients with dementia-related psychosis.

42. In April 2003, Janssen sent letters to healthcare providers ("Dear Doctor Letters") informing them of the new warning on the Risperdal product insert.

43. Despite the new warning on the Risperdal product insert and the distribution of Dear Doctor Letters, Janssen continued to direct its Eldercare sales representatives to promote Risperdal for the treatment of dementia. Janssen refined its sales training programs to teach Eldercare sales personnel how to minimize the significance of the new warning during sales calls.

44. In its April 1, 2003 "CAE Package Insert Revision Backgrounder," Janssen instructed its Eldercare sales representatives to respond to a doctor's question, "Can I still use Risperdal when treating dementia patients?," with the following answer:

> Doctor, currently no atypical antipsychotics, including Risperdal, are FDA-approved for the treatment of dementia. Physicians should assess whether to prescribe Risperdal based upon a patient's condition, symptoms and individual risk factors. The safety and efficacy of Risperdal in treating the behavioral and psychological symptoms of dementia patients has been discussed in several publications.

45. In or around April 2003, Janssen called an emergency meeting of regional directors, district managers, and sales representatives in the Eldercare Division to discuss sales tactics in light of the new product insert warning. Riley Smith, then a high-ranking member of Janssen's brand management group, also attended.

46. At this April 2003 meeting, Mike Monaghan, then Regional Director for the Eastern Region, instructed the sales managers and representatives in attendance not to worry about the new label warning or the Dear Doctor Letters. He instructed the sales personnel to continue promoting the off-label use of Risperdal because Janssen was going to eventually secure a dementia indication.

47. On May 16, 2003, Robert Vaughn sent an email to Relator Camille McGowan and other Janssen sales personnel. The email was a summary of "action plans" for marketing Risperdal in the Syracuse sales area. In this message, Vaughn stated that Matthew Policare needed to "focus his message to move exponent share by not only selling for dementia related psychosis with the dementia patient still at home, but even more so for the patients with unresolved mod [sic.] & anxiety symptoms as an add on to SSRI therapy."

48. Shortly after the new warning was added to the Risperdal product insert, Janssen learned that medical personnel in certain nursing homes were no longer prescribing Risperdal for the treatment of dementia. In response, Janssen continued to maintain its focus on promoting Risperdal for use in the elderly population. For example, on June 27, 2003, Charles Gise, a Janssen sales representative, sent an email to Emily Harms and Stacy Zalewski. In the

email, he suggested that they needed to "quickly brainstorm how we are going to work together to stop the bleeding and turn these accounts back on to Risperdal."

49. In or around June 2003, Janssen held a sales meeting for the Eastern Region. Seven district managers attended, including Camille McGowan. Michael Monaghan, then Regional Sales Director for the Eastern Region, and Riley Smith, then a high-ranking member of Janssen's brand management group, also attended.

50. At this meeting, Michael Monaghan told the Eldercare sales managers in attendance that "we are selling dementia." One of the district managers asked Mr. Monaghan if selling for dementia constituted off-label promotion. Mr. Monaghan admonished the district manager for failing to "get it" and instructed him that Janssen sells Risperdal for dementia and doctors prescribe Risperdal for dementia.

51. Ed Hopwood, a sales representative who attended the June 2003 meeting as a substitute district manager, explained that he regularly promoted Risperdal for treatment of dementia during his sales visits. He showed his "detail book" (sales materials) to the others managers in attendance. The book contained materials on "off-label" use of Risperdal. Michael Monaghan openly approved of Hopwood's off-label sales. Monaghan told Hopwood (laughingly) not use his detail book in the upcoming days because representatives of Janssen's legal department were going to be accompanying him on sales visits.

52. In or around June 2003, at Janssen's Eldercare Cycle II sales meeting, Janssen made a presentation to some of its Eldercare sales personnel on how to respond to

doctors' concerns about increased legal liability in light of the new warning on the Risperdal product insert. Janssen instructed its Eldercare sales representatives to make the following sales pitch:

> Doctor, first it is important that you recognize this labeling change is not a box warning or a contraindication . . . .By law, drug companies are regulated by the Food and Drug Administration and cannot promote off label use. Physicians are not regulated by the FDA and are free to exercise their professional judgment in making prescribing decisions are therefore not confined to prescribe products for only FDA approved indications.

53. In September 2003, at Janssen's Eldercare Cycle III sales meeting, Janssen made a presentation to some of its Eldercare sales representatives on the practice trends of neurologists. A this presentation, Janssen informed its sales representatives that "while no atypical is indicated for dementia be aware that some neurologists are using them with dementia patients."

54. On September 15, 2004, Plaintiff-Relator Judy Doetterl had a conversation with Lisa Ferguson, an Eldercare Division District Manager responsible for sales regions throughout New York. Ms. Ferguson told Ms. Doetterl that Janssen Eldercare representatives could not explicitly promote the off-label use of Risperdal, but that they could continue to craft a symptom-driven message. For example, Ms. Ferguson explained that Eldercare sales representatives could present as a sales pitch the idea that some elderly patients in long-term care facilities who exhibit certain symptoms, like agitation and confusion, may have bipolar disease, but were never properly diagnosed.

55. At the present time, Janssen continues to direct its sales representatives to promote Risperdal for the treatment of dementia.

JANSSEN REAPED GREAT FINANCIAL REWARDS AS A RESULT OF ITS SUCCESSFUL OFF-LABEL MARKETING

56. Beginning no later than January 2001 and continuing up to the present time, Janssen Eldercare sales representatives in the Eastern Region (New York, New Jersey, parts of Pennsylvania, and New England) successfully promoted Risperdal for the treatment of dementia during sales visits to nursing homes, primary care physicians, and neurologists.

57. Upon information and belief, Janssen Eldercare sales representatives in sales regions throughout the United States successfully promoted Risperdal for the treatment of dementia during sales visits to nursing homes, primary care physicians, and neurologists.

58. In its 2001 Eldercare Sales Force update, "The Path to Excellence," Janssen congratulated its Eldercare sales force for helping to increase Risperdal's market share in the elderly population. Janssen noted that:

> [A]s a result of your focused efforts and dedications, Risperdal continues to be the market leader in the LTC/geriatric market. [ ] Risperdal continues to dominate the dementia market with a share of 52.5% for the 12 month ending February 2001.

59. At the fall 2001 Central Region sales meeting of Janssen's Eldercare division, Janssen presented financial data that showed an increase in Risperdal's market share for dementia from approximately 50% to approximately 53.4%. Janssen also presented data that

showed a market-share increase for Risperdal in the primary care segment of the dementia market from approximately 50% to approximately 60%.

Count I.

Substantive Violations Of The False Claims Act (31 U.S.C. § 3729(a)(1) and (a)(2))

60. Plaintiffs-Relators repeat and re-allege paragraphs 1 through 59 above.

61. Beginning at least as early as January 2001 and continuing up to the present time, the defendants have systematically and aggressively marketed Risperdal for the treatment of dementia.

62. Upon and information and belief, the defendants' sales representatives made false statements to medical personnel about the efficacy of Risperdal for the treatment of dementia.

63. The defendants' off-label marketing and false statements caused medical personnel to prescribe Risperdal for the treatment of dementia.

64. A significant percentage of the patients who have been prescribed Risperdal to treat dementia are persons whose prescriptions are paid for, in whole or in part, by medical assistance programs which are funded by the federal government, such as Medicare and Medicaid.

65. The statutes and regulations establishing the Medicare and Medicaid programs limit coverage to prescription drugs that are used in accordance with a medically

accepted indication (*see* 42 U.S.C. § 1396r-8). A medically accepted indication includes any use approved by the FDA or supported by the relevant medical compendia. Risperdal has never been approved by the FDA for the treatment of dementia, and the use of Risperdal for the treatment of dementia is not endorsed by the relevant medical compendia.

66. The defendants' off-label marketing of Risperdal and false statements caused medical personnel and pharmacists to submit off-label prescriptions for payment and/or reimbursement through Medicare or Medicaid.

67. The defendants caused these false and/or fraudulent claims to be presented to the United States or its agencies for the express purpose and with the intent to be paid for such claims and with full knowledge of their falsity.

68. The United States, through its agents or employees, paid such false and/or fraudulent claims or reimbursed states for paying such false and/or fraudulent claims. At the time of such payment, the United States was unaware of the false and/or fraudulent nature of the claims.

69. The United States has sustained substantial damages by reason of the unlawful marketing and fraudulent conduct of the defendants.

Count II.

False Claims Act Conspiracy
(31 U.S.C. § 3729(a)(3))

70. Plaintiffs-Relators repeat and re-allege paragraphs 1 through 69 above.

71. Beginning no later than January 2001 and continuing up to the present time, the defendants have knowingly conspired with others, including their employees and agents, to defraud the United States by causing false or fraudulent claims to be submitted and paid by the United States under Medicare and Medicaid health programs.

72. The United States, through its agencies, paid such false and/or fraudulent claims or reimbursed states for paying such false and/or fraudulent claims.

73. As a result, the United States has sustained substantial damages by reason of the knowing acts and fraudulent conduct of the defendants as described herein.

Jury Demand

74. Plaintiffs-Relators demand a jury on all issues and matters triable by a jury herein.

Relief Requested

WHEREFORE, the United States of America ex rel Camille McGowan and Judy Doetterl demand judgment against the defendants as follows:

a) On the first cause of action, for treble damages under 31 U.S.C. § 3729(a)(1) and (2) in an amount to be determined at trial, plus penalties, costs, interest, and attorney's fees;

b) On the second cause of action, for treble damages under 31 U.S.C. § 3729(a)(3) in an amount to be determined at trial, plus penalties, costs, interest, and attorney's fees;

c) On the first and second causes of action, for the damages sustained by the United States of America; and

d) Awarding such other and further relief as this Court deems proper as a matter of law or under the False Claims Act.

Dated: December 21, 2004

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