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SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION, MERCER COUNTY
DOCKET NO. C-75-12

JEFFREY S. CHIESA, Attorney General of the State of New Jersey, and ERIC T. KANEFSKY, Acting Director of the New Jersey Division of Consumer Affairs, Plaintiffs, v. JANSSEN PHARMACEUTICALS, INC.; and JOHNSON & JOHNSON, Defendants.	Civil Action **COMPLAINT**

1. Plaintiffs Jeffrey S. Chiesa, Attorney General of the State of New Jersey ("Attorney General"), with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, and Eric T. Kanefsky, Acting Director of the New Jersey Division of Consumer Affairs ("Director"), with offices located at 124 Halsey Street, Seventh Floor, Newark, New Jersey (collectively, "Plaintiffs") bring this action against Janssen Pharmaceuticals, Inc. and Johnson & Johnson (collectively, "Defendants") for violating the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1et seq. ("CFA"), as follows:

JURISDICTION AND VENUE

2. This action is brought for and on behalf of the People of the State of New Jersey, by the Attorney General and Director, pursuant to the provisions of the CFA, N.J.S.A. 56:8-1 et seq.

3. This Court has jurisdiction over the Defendants pursuant to the CFA, N.J.S.A. 56:8-1 et seq., because the Defendants have transacted business within the State of New Jersey ("New Jersey") at all times relevant to this Complaint.

4. Venue for this action properly lies in Mercer County pursuant to R. 4:3-2(b) because Defendants transact business in or some of the transactions upon which this action is based occurred in Mercer County.

PARTIES

5. The Attorney General is charged with enforcing the CFA. The Director is charged with administering the CFA on behalf of the Attorney General. By this action, the Attorney General and Director seek injunctive and other relief for violations of the CFA, pursuant to N.J.S.A. 56:8-8, 8-11, 8-13 and 8-19.

6. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation with its principal place of business at 1125 Trenton Harbourton Road, Titusville, New Jersey, and is a wholly-owned subsidiary of Johnson & Johnson. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Defendant Janssen and Defendant Johnson & Johnson, through its wholly-owned subsidiary Janssen, transacts business in New Jersey and nationwide by manufacturing, marketing, promoting, selling and distributing atypical

antipsychotic prescription drugs containing risperidone or paliperidone, the most popular product is known by the trade name Risperdal (which includes Risperdal Consta and Risperdal M-Tab).

ADVERTISEMENT AND SALE OF MERCHANDISE

7. The CFA, N.J.S.A. 56:8-1, defines "advertisement" as:

> . . . the attempt directly or indirectly by publication, dissemination, solicitation, indorsement or circulation or in any other way to induce directly or indirectly any person to enter or not enter into any obligation or acquire any title or interest in any merchandise or to increase the consumption thereof . . .

8. The CFA, N.J.S.A. 56:8-1, defines "merchandise" as "any objects, wares, goods, commodities, services or anything offered, directly or indirectly to the public for sale."

9. The CFA, N.J.S.A. 56:8-1, defines "sale" as "any sale, rental or distribution, offer for sale, rental or distribution or attempt directly or indirectly to sell, rent or distribute."

10. Defendants were at all times relative hereto, engaged in the advertisement and sale of merchandise in New Jersey, to wit: selling, promoting and distributing Risperdal and other atypical antipsychotics containing risperidone or paliperidone.

BACKGROUND

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

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

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

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

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

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

JANSSEN'S MARKETING OF RISPERDAL

17. Federal and state laws allow physicians to prescribe FDA-approved drugs for conditions or diseases for which specific FDA approval has not been obtained when, through the exercise of independent professional judgment, the physician determines the drug in question is

an appropriate treatment for an individual patient. This practice is referred to as prescribing for an "off-label" use.

18. However, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, pharmaceutical manufacturers may not promote or market their products for any use not specifically approved by the FDA. This prohibited practice is known as "off-label marketing."

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

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

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

22. To expand Risperdal's use in the geriatric population, for example, Janssen created and deployed an "ElderCare" sales force in mid-1998, the purpose of which was to focus specifically on Risperdal's use to treat dementia in the elderly.

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

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

COUNT I

VIOLATION OF THE CFA BY DEFENDANTS (UNCONSCIONABLE COMMERCIAL PRACTICES AND DECEPTION)

25. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 24 as if more fully set forth herein.

26. The CFA, N.J.S.A. 56:8-2, prohibits:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing[] concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of merchandise. . .

27. Defendants, in the course of marketing, promoting, selling, and distributing the prescription drug Risperdal have engaged in the advertisement or sale of merchandise through unconscionable commercial practices and deception in violation of the CFA, specifically by promoting Risperdal for uses that have not been shown to be safe or effective and by failing to adequately disclose the risks associated with the use of Risperdal.

28. Each unconscionable commercial practice and act of deception by Defendants constitutes a separate violation of the CFA, N.J.S.A. 56:8-2.

COUNT II

VIOLATION OF THE CFA BY DEFENDANTS (FALSE PROMISES AND/OR MISREPRESENTATIONS)

29. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 28 as if more fully set forth herein.

30. Defendants, in the course of marketing, promoting, selling, and distributing the prescription drug Risperdal have engaged in the advertisement or sale of merchandise through false promises and/or misrepresentations in violation of the CFA, specifically by representing that Risperdal has sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

31. Each false promise and/or misrepresentation by Defendants constitutes a separate violation of the CFA, N.J.S.A. 56:8-2.

PRAYER FOR RELIEF

WHEREFORE, based upon the following allegations, Plaintiffs respectfully request that the Court enter judgment against Defendants:

(a) Finding that the acts and omissions of Defendants constitute unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 et seq.;

(b) Permanently enjoining and restraining Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in deceptive practices in the promotion and marketing of its pharmaceutical products in violation of the CFA, N.J.S.A. 56:8-1 et seq., including, but not limited to, the acts and practices alleged in this Complaint;

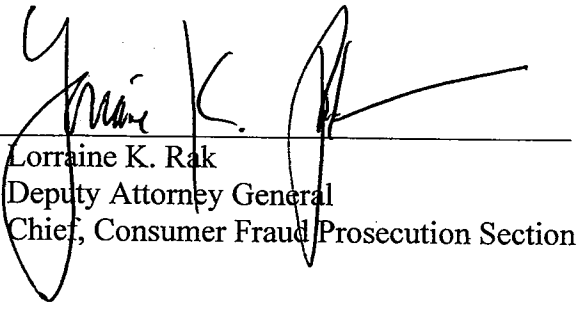
(c) Directing the assessment of restitution amounts against Defendants to restore to any affected person, whether or not named in this Complaint, any money or real or personal property acquired by means of any alleged practice herein to be unlawful and found to be unlawful, as authorized by the CFA, N.J.S.A. 56:8-8;

(d) Assessing the maximum statutory civil penalties against Defendants for each and every violation of the CFA, in accordance with the CFA, N.J.S.A. 56:8-13;

(e) Directing the assessment of costs and fees, including attorneys' fees, against Defendants for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56:8-11 and N.J.S.A. 56:8-19; and

(f) Granting such other relief as the interests of justice may require.

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: 
Lorraine K. Rak
Deputy Attorney General
Chief, Consumer Fraud Prosecution Section

Dated: August 30, 2012
Newark, New Jersey

RULE 4:5-1 CERTIFICATION

I certify, to the best of my information and belief, that the matter in this action involving the aforementioned violations of the CFA, N.J.S.A. 56:8-1 et seq., is not the subject of any other action pending in any other court of this State. I am aware that private actions have been brought against the Defendants, but have no direct information that any such actions involve consumer fraud allegations. I further certify that the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated. I certify that there is no other party who should be joined in this action at this time.

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: _____
Lorraine K. Rak
Deputy Attorney General
Chief, Consumer Fraud Prosecution Section

Dated: August 30, 2012
Newark, New Jersey

RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with Rule 1:38-7(b).

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: _____
Lorraine K. Rak
Deputy Attorney General
Chief, Consumer Fraud Prosecution Section

Dated: August 30, 2012
Newark, New Jersey

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Deputy Attorney General Lorraine K. Rak is hereby designated as trial counsel for the Plaintiffs in this action.

JEFFREY S. CHIESA
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: _____
Lorraine K. Rak
Deputy Attorney General
Chief, Consumer Fraud Prosecution Section

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