IN THE IOWA DISTRICT COURT FOR POLK COUNTY

THE STATE OF IOWA, ex rel. THOMAS J. MILLER, ATTORNEY GENERAL 99AG25112 Plaintiff, v. JANSSEN PHARMACEUTICALS, INC.; and JOHNSON & JOHNSON, Defendants.	)	EQUITY NO. CE 72393 **PETITION**

Plaintiff, the State of Iowa ex rel. Attorney General Thomas J. Miller, by Special Assistant Attorney General William L. Brauch, brings this action against Defendants JANSSEN PHARMACEUTICALS, INC. and JOHNSON & JOHNSON, for violating the Iowa Consumer Fraud Act, Iowa Code section 714.16, as follows:

Jurisdiction and Venue

1. This action is brought by the State of Iowa ex rel. Attorney General Thomas J. Miller, pursuant to the provisions of the Iowa Consumer Fraud Act, Iowa Code section 714.16.

2. This Court has jurisdiction over the Defendants pursuant to Iowa Code section 714.16, because the Defendants have transacted business within the State of Iowa at all times relevant to this Petition.

3. Venue for this action properly lies in Polk County, Iowa, pursuant to Iowa Code section 714.16 (10), because Defendants transact business in Polk County, Iowa and/or some of the transactions out of which this action arose occurred in Polk County, Iowa.

Parties

4. Plaintiff is the State of Iowa ex rel. Attorney General Thomas J. Miller.

5. The Attorney General of Iowa is charged, inter alia, with the enforcement of the Consumer Fraud Act, Iowa Code section 714.16(7).

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.

7. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

8. Defendant Janssen and Defendant Johnson & Johnson, through its wholly-owned subsidiary Janssen, transacts business in the State of Iowa 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).

ADVERTISING AND SELLING MERCHANDISE IN IOWA

9. Iowa Code § 714.16(2)(a) applies to the sale, lease or advertisement of merchandise in the State of Iowa. Defendants were at all times relevant hereto, engaged in the advertisement and sale of merchandise in the State of Iowa to wit: advertising, soliciting, offering for sale and selling prescription drugs, Risperdal and other atypical antipsychotics containing risperidone or paliperidone.

Background

10. 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.

11. 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.

12. 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."

13. 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.

14. 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.

15. 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

15. 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.

16. 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."

17. 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.

19. 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, and post traumatic stress disorder.

20. 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.

21. 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.

22. 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.

23. 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.

APPLICABLE STATUTES

24. Iowa Code section 714.16(2)(a), states in relevant part as follows:

> The act, use or employment by a person of an unfair practice, deception, fraud, false pretense, false promise, or misrepresentation, or the concealment, suppression, or omission of a material fact with intent that others rely upon the concealment, suppression, or omission, in connection with the lease, sale, or advertisement of any merchandise or the solicitation of contributions for charitable purposes, whether or not a person has in fact been misled, deceived, or damaged, is an unlawful practice.

25. As used in the Consumer Fraud Act, the term "person" includes:

> any natural person or the person's legal representative, partnership, corporation (domestic and foreign), company, trust, business entity or association, and any agent, employee, salesperson, partner, officer, director, member, stockholder, associate, trustee or cestui que trust thereof.
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> Iowa Code section 714.16(1)(j).

26. Neither all nor any part of the application for injunctive relief herein has been previously been presented to or refused by any court or justice. Iowa R. Civ. P. 1.1504.

27. In an action by the state, no security shall be required of the state. Iowa R. Civ. P. 1.207.

VIOLATIONS OF LAW

IOWA CONSUMER FRAUD ACT

28. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 27.

29. Defendants, in the course of marketing, promoting, selling, and distributing the prescription drug Risperdal have engaged in unfair, deceptive, or misleading practices in connection with the sale of merchandise, and therefore, have engaged in practices that are unlawful under Iowa Code section 714.16(2)(a) 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.

30. Defendants, in the course of marketing, promoting, selling, and distributing the prescription drug Risperdal have engaged in unfair, deceptive, or misleading practices in connection with the sale of merchandise, and therefore, have engaged in practices that are unlawful under Iowa Code section 714.16(2)(a) by representing that Risperdal has sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

REMEDIES

31. Iowa Code section 714.16(7), in relevant part, provides:

> If it appears to the attorney general that a person has engaged in, is engaging in, or is about to engage in a practice declared to be unlawful by this section, the attorney general may seek and obtain in an action in a district court a temporary restraining order, preliminary injunction, or permanent injunction prohibiting the person from continuing the practice or engaging in the practice or doing an act in furtherance of the practice. The court may make orders or judgments as necessary to prevent the use

> or employment by a person of any prohibited practices, or which are necessary to restore to any person in interest any moneys or property, real or personal, which have been acquired by means of a practice declared to be unlawful by this section, including the appointment of a receiver in cases of substantial and willful violation of this section. . . . . .
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> . . . . . In addition to the remedies otherwise provided for in this subsection, the attorney general may request and the court may impose a civil penalty not to exceed forty thousand dollars per violation against a person found by the court to have engaged in a method, act, or practice declared unlawful under this section; provided, however, a course of conduct shall not be considered to be separate and different violations merely because the conduct is repeated to more than one person. In addition, on the motion of the attorney general or its own motion, the court may impose a civil penalty of not more than five thousand dollars for each day of intentional violation of a temporary restraining order, preliminary injunction, or permanent injunction issued under authority of this section. A penalty imposed pursuant to this subsection is in addition to any penalty imposed pursuant to section 537.6113. Civil penalties ordered pursuant to this subsection shall be paid to the treasurer of state to be deposited in the general fund of the state.

32. Iowa Code section 714.16(10) provides:

> In an action brought under this section, the attorney general is entitled to recover costs of the court action and any investigation which may have been conducted, including reasonable attorneys' fees, for the use of this state.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter an order:

A. Issuing a permanent injunction prohibiting 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 unfair, deceptive or misleading conduct, as provided by Iowa Code section 714.16(7);

B. Ordering Defendants to pay civil penalties of up to $40,000 for each violation of the Consumer Fraud Act, as provided by Iowa Code section 714.16(7);

C. Ordering Defendants to pay all costs, court costs, and attorney fees for the prosecution and investigation of this action, as provided by Iowa Code sections 714.16(10); and,

D. Granting such other and further relief as the Court deems equitable and proper.

Respectfully submitted,

STATE OF IOWA ex rel.
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