IN THE CIRCUIT COURT OF THE FOURTH JUDICIAL CIRCUIT IN AND FOR DUVAL COUNTY, FLORIDA

16- 2012-CA-009579 -XXXX-MA

OFFICE OF ATTORNEY GENERAL, STATE OF FLORIDA, DEPARTMENT OF LEGAL AFFAIRS,

Plaintiff

v.

JANSSEN PHARMACEUTICALS, INC. and JOHNSON & JOHNSON

Defendants

Case No.:

DIVISION CV-H

COPY
ORIGINAL FILED ON
Date AUG 30 2012

COMPLAINT FOR INJUNCTIVE RELIEF, CIVIL PENALTIES AND OTHER RELIEF

COMES NOW, OFFICE OF ATTORNEY GENERAL PAM BONDI, STATE OF FLORIDA, DEPARTMENT OF LEGAL AFFAIRS, hereafter referred to as "Attorney General", and brings this action complaining of Defendants JANSSEN PHARMACEUTICALS, INC., hereafter referred to as "Janssen" and JOHNSON & JOHNSON for violating the for violating Florida's Deceptive and Unfair Trade Practices Act, Chapter 501 Part II, Florida Statutes (2010) and further states as follows:

Jurisdiction and Venue

1. Plaintiff Attorney General brings this action pursuant to the Florida Deceptive and Unfair Trade Practices Act, Chapter 501, Part II, Florida Statutes.
2. This is an action for injunctive relief, civil penalties and other relief in excess of $15,000.
3. This Court has jurisdiction pursuant to Sections 26.012, and 501.207, Fla. Stat., as Defendant Janssen and Defendant Johnson & Johnson, through its wholly-owned subsidiary Janssen, transacted business in Florida which affected multiple judicial circuits.

4. Venue is proper in this Court pursuant to Section 47.051, Fla. Stat., as Janssen and Johnson & Johnson, through its wholly-owned subsidiary Janssen, conducted business throughout the State of Florida including in Duval County, Florida. In addition, a portion of the cause of action accrued in Duval County.

5. The State has conducted an investigation of the matters alleged herein and Attorney General Pam Bondi has determined that this enforcement action serves the public interest, as required by Section 501.207(2), Florida Statutes (2010). See attached exhibit "A".

Parties

6. Plaintiff, Attorney General Pam Bondi, is an enforcing authority of Chapter 501, Part II, Florida Statutes (2010), and is authorized to seek the relief sought herein.

7. 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, transact business in Florida and nationwide by manufacturing, marketing, promoting, selling and distributing atypical antipsychotic prescription drugs containing risperidone or paliperidone. The most popular product version is known by the trade name Risperdal (which includes Risperdal Consta and Risperdal M-Tab).

Commerce

8. Section 501.203(8), Fla. Stat., defines Trade or Commerce as the advertising, soliciting, providing, offering, or distributing, whether by sale or rental, or otherwise, of any good or service, or any property.

9. Defendants were at all times relative hereto, engaged in trade or commerce in the State of Florida, to wit: advertising, selling, promoting and distributing 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 based upon studies involving schizophrenic patients.

12. In September 2000, the FDA clarified 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

16. 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.

17. 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."

18. 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, Janssen sent a form letter to thousands of health care providers throughout the United States and specifically within Florida 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 an increased 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." Janssen's letter prompted the FDA's Division of Drug Advertising, Marketing and Communications office to issue an official "Warning Letter" to Janssen on April 19, 2004, stating that Janssen's letter "misleadingly omits material 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 Florida's Deceptive and Unfair Trade Practices Act- Off Label Promotion

24. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 23.

25. Defendants, in the course of marketing, promoting, selling, and distributing the prescription drug Risperdal have engaged in a course of trade or commerce which constitutes deceptive or misleading practices, and is therefore unlawful under Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II (2010) 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.

Count II

Violation of Florida's Deceptive and Unfair Trade Practices Act - Misrepresentations

26. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 23.

27. Defendants, in the course of marketing, promoting, selling, and distributing the prescription drug Risperdal have engaged in a course of trade or commerce which constitutes [unfair,] deceptive, or misleading practices, and is therefore unlawful under Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II (2010) by representing that Risperdal has sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

Prayer for Relief

WHEREFORE, the Plaintiff prays that this honorable Court enter an Order:

A. Issuing a permanent injunction prohibiting Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair or deceptive conduct;

B. Ordering Defendant to pay all costs for the prosecution and investigation of this action, as provided by Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II (2010);

C. Impose civil penalties of Ten Thousand Dollars ($10,000) per violation of the Deceptive and Unfair Trade Practices Act pursuant to Section 501.2075, Fla. Stat. and civil penalties in the amount of Fifteen Thousand Dollars ($15,000) for per willful violation which victimized, or attempted to victimize a person who is 60 years of age or older, pursuant to Section 501.2077, Fla. Stat.;

D. Enter Judgment declaring Defendants' actions and practices unlawful under Chapter 501, Part II, Fla. Stat., pursuant to Section 501.207(1)(a), Fla. Stat.;

E. Award the Plaintiff costs and attorneys fees pursuant to 501.2105, Fla.Stat.; and

F. Award any and all such other relief as this Honorable Court deems just, equitable, and proper.

OFFICE OF THE ATTORNEY GENERAL, STATE OF FLORIDA,

DEPARTMENT OF LEGAL AFFAIRS

APPROVED:

PAMELA JO BONDI
ATTORNEY GENERAL

By: James Young

James D. Young
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Date: 8/23/12

By: Patrice S. Malloy

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Date: August 23rd, 2012

IN THE CIRCUIT COURT OF THE FOURTH JUDICIAL CIRCUIT, IN AND FOR DUVAL COUNTY, FLORIDA

THE STATE OF FLORIDA By PAMELA JO BONDI ATTORNEY GENERAL, Plaintiff v. JANSSEN PHARMACEUTICALS, INC, a Pennsylvania corporation, and JOHNSON & JOHNSON, a New Jersey corporation, Defendants	)	Case No.

DETERMINATION OF PUBLIC INTEREST

COMES NOW, PAMELA JO BONDI, ATTORNEY GENERAL, STATE OF FLORIDA, and states:

1. Pursuant to Section 20.11, Florida Statutes (1993), I am the Head of the Department of Legal Affairs, State of Florida (hereinafter referred to as the Department). In this matter, the Department seeks actual damages on behalf of one or more consumers caused by an act or practice performed in violation of Chapter 501, Part II, Florida Statutes.

2. I have reviewed this matter and I have determined that an enforcement action serves the public interest.

Pamela Jo Bondi

PAMELA JO BONDI
ATTORNEY GENERAL
STATE OF FLORIDA

Dated: 8/28/12

EXHIBIT
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