DOCKET NO.:

STATE OF CONNECTICUT *Plaintiff*	:	SUPERIOR COURT
	:	JUDICIAL DISTRICT OF HARTFORD
v.	:	
JANSSEN PHARMACEUTICALS, INC, and JOHNSON & JOHNSON	:	
	:	AUGUST 30, 2012
Defendants	:	

COMPLAINT

FIRST COUNT

1. This is an action under the Connecticut Unfair Trade Practices Act ("CUTPA"), Chapter 735a of the Connecticut General Statutes (Conn. Gen. Stat.), to secure injunctive relief against the Defendants' alleged unfair or deceptive acts and practices which violate Conn. Gen. Stat. § 42-110b(a), to obtain relief as is necessary to redress injury to consumers resulting from the Defendants' violations of law, to obtain appropriate equitable relief, and for civil penalties.

THE PARTIES

2. Plaintiff, the State of Connecticut, represented by George C. Jepsen, Attorney General of the State of Connecticut, acting at the request of William M. Rubenstein, Commissioner of Consumer Protection, pursuant to Conn. Gen. Stat. § 42-110m(a).

3. Defendant Janssen Pharmaceuticals, Inc. 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 is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Defendant Johnson & Johnson, through its wholly-owned subsidiary Janssen, transacts business in the State of Connecticut 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).

4. The Defendants, Janssen and Johnson and Johnson through its wholly-owned subsidiary Janssen, at all relevant times has transacted business in the State of Connecticut.

5. The violations of law alleged herein have been and are being carried out within Connecticut.

DEFENDANTS' COURSE OF CONDUCT

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.

10. 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.

11. 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."

12. 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.

13. 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.

14. 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.

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."

DEFENDANTS' VIOLATION OF CUTPA

17. Defendants' course of conduct, as alleged herein, has been under taken in the conduct of trade or commerce, as defined in Conn. Gen. Stat. § 42-110a(4) .

18. Defendants' engaged in unfair or deceptive acts or practices in the course of marketing, promoting, selling, and distributing the prescription drug Depakote for uses for which Depakote was not effective, by engaging in improper off-label product promotion, and by failing to adequately disclose Depakote's characteristics, uses, benefits, and qualities thereof as follows:

a. 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.

b. 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.

c. 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.

d. 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

e. 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.

f. 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.

19. By doing the aforesaid acts or practices, Defendant engaged in unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b(a).

SECOND COUNT

1-19. The allegations of paragraphs 1 through 19 of the FIRST COUNT are incorporated herein as paragraphs 1 – 19 of the SECOND COUNT.

20. Defendant engaged in the aforementioned acts or practices alleged herein when it knew or should have known that its conduct was unfair or deceptive in violation of Conn. Gen. Stat. § 42-110b(a).

PRAYER FOR RELIEF

WHEREFORE, the PLAINTIFF claims the following relief:

1. An order pursuant to Conn. Gen. Stat. §42-110m(a) enjoining Defendants from making any false, misleading or deceptive representations regarding any of its products in violation of all applicable laws and regulations.

2. An order pursuant to Conn. Gen. Stat. §42-110m(a) directing Defendants to comply with all applicable laws and regulations relating to the marketing, sale, and promotion of its products.

3. An order pursuant to Conn. Gen. Stat. § 42-110o(b) directing Defendants to pay civil penalties for each willful violation of Conn. Gen. Stat. § 42-11b(a).

4. An order pursuant to Conn. Gen. Stat. §42-110m(a) directing Defendants to disgorge all gains achieved in whole or in part through the unfair acts or practices alleged herein.

5. An award of Attorneys fees, pursuant to Conn. Gen. Stat. § 42-110m(a).

6. Cost of suit.

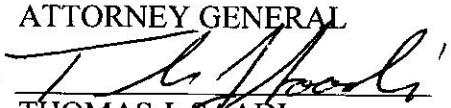
7. Such other relief as this Court deems appropriate.

HEREOF FAIL NOT, BUT OF THIS WRIT, MAKE DUE SERVICE AND RETURN ACCORDING TO LAW.

Dated at Hartford, Connecticut this 30th day of August, 2012

PLAINTIFF
STATE OF CONNECTICUT

GEORGE C. JEPSEN
ATTORNEY GENERAL

BY: 

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