

**STATE OF CONNECTICUT**

RETURN DATE: JUNE 6, 2017	:	SUPERIOR COURT
	:	
STATE OF CONNECTICUT,	:	JUDICIAL DISTRICT
<i>Plaintiff,</i>	:	OF HARTFORD
	:	
v.	:	AT HARTFORD
	:	
JOHNSON & JOHNSON CONSUMER, INC.	:	
and JOHNSON & JOHNSON,	:	
<i>Defendants.</i>	:	MAY 24, 2017

**COMPLAINT**

1. Plaintiff, State of Connecticut, brings this action complaining of defendants Johnson & Johnson Consumer Inc. and Johnson & Johnson for violating Connecticut's Unfair Trade Practices Act (“CUTPA”), chapter 735 of the General Statutes, as follows:

**Jurisdiction**

2. This action is brought by George Jepsen, Attorney General, State of Connecticut, at the request of Michelle Seagull, Commissioner of Consumer Protection for the State of Connecticut, pursuant to General Statutes § 42-110m

3. This Court has jurisdiction over the Defendants pursuant to CUTPA because the Defendants have transacted business within the State of Connecticut at all times relevant to this complaint.

### **Parties**

4. Plaintiff is the State of Connecticut (the “State”), by George Jepsen, Attorney General of the State.

5. Defendant Johnson & Johnson is a New Jersey corporation and its principal place of business and executive offices are located at One Johnson & Johnson Plaza, New Brunswick, NJ, 08933.

6. Defendant Johnson & Johnson Consumer Inc., a wholly-owned subsidiary of Defendant Johnson & Johnson (“J&J”), is a New Jersey corporation with its principal place of business at 199 Grandview Road, Skillman, NJ 08558. McNeil-PPC, Inc., which subsequently merged into Johnson & Johnson Consumer Inc., manufactured, promoted, advertised, offered for sale, sold, and distributed over the counter (“OTC”) drugs, through its unincorporated McNeil Consumer Healthcare Division, headquartered at 7050 Camp Hill Road, Fort Washington, Pennsylvania. McNeil owned and/or operated, through its Consumer Healthcare Division, facilities in Fort Washington, Pennsylvania; Las Piedras, Puerto Rico; and Lancaster, Pennsylvania. McNeil Consumer Healthcare Division formerly a division of McNeil-PPC. Inc., is now a division of Johnson & Johnson Consumer Inc. (“McNeil”).

7. McNeil transacts business in Connecticut and nationwide by manufacturing, promoting, advertising, offering for sale, selling, and/or distributing adult, children, and infant OTC drugs, including but not limited to the following product brands: Tylenol, Motrin, Benadryl, St. Joseph Aspirin, Sudafed, Pepcid, Mylanta, Roloids, Zyrtec, and Zyrtec Eye Drops with different formulations of these drugs for adults, infants, and children.

### **Trade and Commerce**

8. McNeil was at all times relative hereto, engaged in trade or commerce in the State as defined in CUTPA, specifically in General Statutes § 42-110a(4).

### **McNeil's Conduct**

9. McNeil represented that quality and safety were a top priority and that McNeil complied with current Good Manufacturing Practices ("cGMP").

10. Between 2009 and 2011, McNeil announced voluntary recalls of certain lots of over-the-counter medicines, including but not limited to the following:

a. On September 11, 2009, McNeil announced a voluntary recall of 57 product lots of Infants' and Children's Tylenol liquid products manufactured at its Fort Washington, Pennsylvania facility.

b. On November 6, 2009, December 18, 2009, and January 15, 2010, McNeil announced voluntary recalls of 595 product lots of Tylenol, St. Joseph, Benadryl, Roloids, and Motrin products manufactured at its Fort Washington, Pennsylvania and Las Piedras, Puerto Rico facilities.

c. On April 30, 2010, McNeil announced a voluntary recall of approximately 1,200 product lots of Infants' and Children's Tylenol, Motrin, Benadryl, and Zyrtec liquid products manufactured at its Fort Washington, Pennsylvania facility.

11. During this time period, McNeil delivered for introduction into commerce certain batches of over-the-counter medicines that were not manufactured, processed, packed, or held in

conformance with certain federal current Good Manufacturing Practices.

12. McNeil stipulated in a Guilty Plea and Sentencing Memorandum with the United States that some of its OTC drugs were not manufactured, processed, packed, labeled, held, or distributed in conformance with cGMP requirements, and therefore were deemed adulterated as a matter of federal law, without any showing of actual defect, and that the Federal Food, Drug, and Cosmetic Act prohibited the introduction or delivery for introduction into interstate commerce of any drug that was deemed adulterated.

13. McNeil also stipulated that it did not initiate any Corrective Action Preventive Action plans ("CAPA Plans") for multiple batches of OTC drugs between May 2009 and April 2010 when foreign material, particulate matter and/or contamination were observed, even though its own operating procedures required CAPA Plans. Failure to initiate CAPA Plans did not comply with McNeil's operating procedures, and therefore, did not comply with cGMP requirements for these drugs.

14. McNeil stipulated that it delivered for introduction into interstate commerce certain batches of OTC drugs that were deemed adulterated as a matter of federal law and cGMP requirements.

#### **Violations of the CUTPA – Count I**

15. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 14.

16. McNeil promoted, advertised, offered for sale, sold, and/or distributed OTC drugs in Connecticut that were deemed adulterated because these OTC drugs were not manufactured, processed, packed, held, or distributed in compliance with cGMP. McNeil violated CUTPA when they

misrepresented the quality of their OTC drugs and compliance with cGMP.

17. McNeil violated CUTPA when they represented that these OTC drugs had sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they did not have. McNeil engaged in trade or commerce that was unfair, false, deceptive, or misleading and therefore unlawful under General Statutes § 42-110b(a).

### **Violations of the CUTPA– Count II (Willfulness)**

18. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 17.

19. Defendants have engaged in acts or practices alleged herein when they knew, or should have known, that their conduct was unfair or deceptive in violation of General Statutes § 42-110b(a).

### **Prayer for Relief**

WHEREFORE, the State respectfully requests that:

A. Pursuant to CUTPA, specifically General Statutes § 42-110m, the Court permanently enjoin and restrain 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 false, misleading, or deceptive practices in the manufacturing, promotion, advertising, offering for sale, selling, and distributing of their OTC drugs.

B. Pursuant to CUTPA, specifically General Statutes § 42-110o, the Defendants be ordered to pay civil penalties in the amount of FIVE THOUSAND and 00/100 DOLLARS (\$5,000.00)

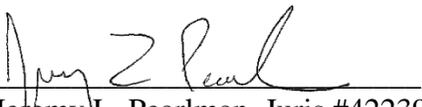
for each and every willful violation of CUTPA;

C. Pursuant to CUTPA, specifically General Statutes § 42-110m, the Defendants be ordered to pay costs and reasonable attorneys' fees incurred by the State in connection with the investigation and litigation of this matter; and

D. That the Court grant such further relief as the Court deems necessary or appropriate to remedy the effects of McNeil's unlawful trade practices.

Dated at Hartford, Connecticut this 24th day of May, 2017.

PLAINTIFF,  
STATE OF CONNECTICUT,  
GEORGE JEPSEN,  
ATTORNEY GENERAL

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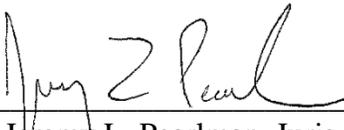
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<i>Defendants.</i>	:	MAY 24, 2017

**AMOUNT IN DEMAND**

The amount in demand herein exceeds Fifteen Thousand Dollars (\$15,000.00), exclusive of interest and costs.

PLAINTIFF,  
STATE OF CONNECTICUT,  
GEORGE JEPSEN,  
ATTORNEY GENERAL

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