IN THE CIRCUIT COURT OF THE SEVENTEENTH JUDICIAL CIRCUIT, IN AND FOR BROWARD COUNTY, FLORIDA

OFFICE OF ATTORNEY GENERAL, STATE OF FLORIDA, DEPARTMENT OF LEGAL AFFAIRS,	)	
Plaintiff,	)	**Case no.**
Vs.	)	
JOHNSON & JOHNSON CONSUMER INC. and JOHNSON & JOHNSON	)	
Defendants.	)	

COMPLAINT

1. Plaintiff, the OFFICE OF ATTORNEY GENERAL, STATE OF FLORIDA, DEPARTMENT OF LEGAL AFFAIRS ("Florida") brings this action complaining of Defendants JOHNSON & JOHNSON CONSUMER INC. and JOHNSON & JOHNSON for violating the Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II as follows:

Jurisdiction and Venue

2. This action is brought for and on behalf of Florida, by Pamela Jo Bondi, Attorney General of the State of Florida, pursuant to the provisions of the Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II

3. This Court has jurisdiction over the Defendants pursuant to Sections 26.012 Fla. Stat. and Chapter 501.207 et seq, Fla. Stat. because the Defendants have transacted business within the State of Florida at all times relevant to this complaint.

4. Venue for this action properly lies in Broward County pursuant to the provisions of Section 47.051, Fla. Stat. and Chapter 501.207 et seq Fla. Stat. because Defendants transact business in Broward County or some of the transactions upon which this action is based occurred in Broward County.

Parties

5. Plaintiff is the OFFICE OF ATTORNEY GENERAL, STATE OF FLORIDA, DEPARTMENT OF LEGAL AFFAIRS, by Pamela Jo Bondi, Attorney General of the State of Florida.

6. 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.

7. 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").

8. McNeil transacts business in the State of Florida 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, Rolaids, Zyrtec, and Zyrtec Eye Drops with different formulations of these drugs for adults, infants, and children.

Trade and Commerce

9. McNeil was at all times relative hereto, engaged in trade or commerce in the State of Florida as defined in the Subsection 8 of the Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II:

> 'Trade' or 'commerce' mean the advertising, soliciting, providing, offering, or distributing, whether by sale, rental, or otherwise, of any good or service, or any property, whether tangible or intangible, or any other article, commodity, or thing of value, wherever situated. "Trade or commerce" shall include the conduct of any trade or commerce, however denominated, including any nonprofit or not-for-profit person or activity. "

Conduct

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

11. 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, Rolaids, 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.

12. 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.

13. 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.

14. 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.

15. 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.

Violation of the Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II Law – Count I

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

17. McNeil promoted, advertised, offered for sale, sold, and/or distributed OTC drugs in the State of Florida that were deemed adulterated because these OTC drugs were not manufactured, processed, packed, held, or distributed in compliance with cGMP. McNeil violated Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II when they misrepresented the quality of their OTC drugs and their compliance with cGMP.

Violation of the Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II Law – Count II

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

19. McNeil promoted, advertised, offered for sale, sold, and/or distributed OTC drugs in the State of Florida that were deemed adulterated because these OTC drugs were not manufactured, processed, packed, held, or distributed in compliance with cGMP. McNeil violated Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II 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 Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II.

Prayer for Relief

WHEREFORE, the State of Florida respectfully request that:

A. Pursuant to Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II, 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 Section 501.2075, Fla. Stat., the Defendants be ordered to pay civil penalties of not more than Ten thousand dollars ($10,000.00) for each such violation of Florida Deceptive and Unfair Trade Practices Act and civil penalties in the amount of not more than Fifteen thousand dollars ($15,000.00) for each such willful violation which victimized, or attempted to victimize a person who is 60 years of age or older or handicapped persons, pursuant to Section 501.2077 Fla. Stat.

C. Pursuant to Florida's Deceptive and Unfair Trade Practices Act, Florida Statutes Chapter 501, Part II, the Defendants be ordered to pay costs and reasonable attorneys' fees incurred by the State of Florida 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.

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OFFICE OF THE ATTORNEY GENERAL, STATE OF FLORIDA,

DEPARTMENT OF LEGAL AFFAIRS,

APPROVED:
PAMELA JO BONDI
ATTORNEY GENERAL

By: Patrice Malloy
Patrice Malloy
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Date: May 23, , 2017