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ATTORNEY GENERAL OF NEW JERSEY  
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Attorney for Plaintiffs

By: Patricia Schiripo (014441990)  
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MAY 24 2017

SUPERIOR COURT OF NJ  
MERCER VICINAGE  
CIVIL DIVISION

SUPERIOR COURT OF NEW JERSEY  
CHANCERY DIVISION, MERCER COUNTY  
DOCKET NO. \_\_\_\_\_

CHRISTOPHER S. PORRINO, Attorney General  
of the State of New Jersey, and STEVE C. LEE,  
Director of the New Jersey Division of Consumer  
Affairs,

Plaintiffs,

v.

JOHNSON & JOHNSON CONSUMER INC.;  
JOHNSON & JOHNSON; JANE AND JOHN  
DOES 1-20, individually and as owners, officers,  
directors, shareholders, founders, members,  
managers, employees, servants, agents,  
representatives and/or independent contractors of  
JOHNSON & JOHNSON CONSUMER INC.  
and/or JOHNSON & JOHNSON; and XYZ  
CORPORATIONS 1-20,

Defendants.

Civil Action

COMPLAINT

Plaintiffs Christopher S. Porrino, Attorney General of the State of New Jersey  
("Attorney General"), with offices located at 124 Halsey Street, Fifth Floor, Newark,  
New Jersey, and Steve C. Lee, Director of the New Jersey Division of Consumer Affairs

(“Director”) (collectively, “Plaintiffs”), with offices located at 124 Halsey Street, Seventh Floor, Newark, New Jersey, by way of Complaint state:

### **PARTIES AND JURISDICTION**

1. The Attorney General is charged with the responsibility of enforcing the Consumer Fraud Act (“CFA”), N.J.S.A. 56:8-1 et seq. The Director is charged with the responsibility of administering the CFA on behalf of the Attorney General.

2. By this action, the Attorney General and Director (collectively, “Plaintiffs”) seek injunctive relief and other relief for violations of the CFA. Plaintiffs bring this action pursuant to their authority under the CFA, specifically N.J.S.A. 56:8-8, 56:8-11, 56:8-13 and 56:8-19.

3. Venue is proper in Mercer County, pursuant to R. 4:3-2, because it is a county in which the Defendants have conducted business or in which some of the transactions upon which this action is based have occurred.

4. 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, New Jersey 08933.

5. 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, New Jersey 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”).

6. McNeil transacted business in New Jersey 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.

7. John and Jane Does 1 through 20 are fictitious individuals meant to represent the owners, officers, directors, shareholders, founders, members, managers, agents, servants, employees, representatives and/or independent contractors of Johnson & Johnson Healthcare Inc. and/or Johnson & Johnson who have been involved in the conduct that gives rise to this Complaint, but are heretofore unknown to Plaintiffs. As these defendants are identified, Plaintiffs shall amend the Complaint to include them.

8. XYZ Corporations 1 through 20 are fictitious corporations meant to represent any additional business entities who have been involved in the conduct that gives rise to the Complaint, but are heretofore unknown to Plaintiffs. As these defendants are identified, Plaintiffs shall amend the Complaint to include them.

**GENERAL ALLEGATIONS COMMON TO ALL COUNTS**

9. McNeil was at all times relative hereto, engaged in the sale of merchandise, including OTC drugs, in the New Jersey as defined in N.J.S.A. 56:8-1 of the CFA.

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 OTC 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.

12. During this time period, McNeil delivered for introduction into commerce certain batches of OTC medicines that were not manufactured, processed, packed, or held in conformance with certain federal cGMP.

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.

### COUNT I

#### **VIOLATION OF THE CFA (UNCONSCIONABLE COMMERCIAL PRACTICES AND DECEPTION)**

16. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 to 15 as if more fully set forth herein.

17. The CFA, N.J.S.A. 56:8-2, prohibits:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing[] concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby...

18. The CFA defines “merchandise” as including “any objects, wares, goods, commodities, services or anything offered, directly or indirectly to the public for sale.”

N.J.S.A. 56:8-1(c).

19. At all relevant times, McNeil have been engaged in the advertisement, offer for sale, sale and/or distribution of merchandise within the meaning of N.J.S.A. 56:8-1(c), including, OTC medications.

20. McNeil promoted, advertised, offered for sale, sold, and/or distributed OTC drugs in New Jersey that were deemed adulterated because these OTC drugs were not manufactured, processed, packed, held, or distributed in compliance with cGMP. McNeil violated the CFA 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 practices that were unconscionable, false, deceptive, or misleading and therefore unlawful under the CFA.

## COUNT II

### VIOLATION OF THE CFA (MISREPRESENTATIONS)

21. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 to 20 as if more fully set forth herein.

22. At all relevant times, McNeil promoted, advertised, offered for sale, sold, and/or distributed OTC drugs in New Jersey that were deemed adulterated because these OTC drugs were not manufactured, processed, packed, held, or distributed in compliance with cGMP. McNeil violated the CFA when they misrepresented the quality of their OTC drugs and their compliance with cGMP.

### **PRAYER FOR RELIEF**

**WHEREFORE**, based upon the foregoing allegations, Plaintiffs respectfully request that the Court enter judgment against Defendants:

- A. Finding that the acts and omissions of Defendants constitute multiple violations of the CFA, N.J.S.A. 56:8-1 et seq.;
- B. Permanently enjoining Defendants and their owners, officers, directors, shareholders, founders, managers, agents, servants, employees, representatives, independent contractors, corporations, subsidiaries, affiliates, successors, assigns and all other persons or entities directly under their control, from engaging in, continuing to engage in, or doing any acts or practices in violation of the CFA, including, but not limited to, the acts and practices alleged in the Complaint;
- C. Directing the assessment of restitution amounts against Defendants, jointly and severally, to restore to any affected person, whether or not named in this Complaint, any money or real or personal property acquired by means of any practice alleged herein to be unlawful and found to be unlawful, as authorized by the CFA, N.J.S.A. 56:8-8;
- D. Assessing the maximum statutory civil penalties against Defendants, jointly and severally, for each and every violation of the CFA, pursuant to N.J.S.A. 56:8-13;
- E. Directing the assessment of costs and fees, including attorneys' fees, against Defendants, jointly and severally, for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56:8-11 and N.J.S.A. 56:8-19; and

F. Granting such other relief as the Court deems equitable and just.

CHRISTOPHER S. PORRINO  
ATTORNEY GENERAL OF NEW JERSEY  
Attorney for Plaintiffs

By: Patricia Schiripo  
Patricia Schiripo  
Deputy Attorney General  
Consumer Fraud Prosecution Section

Dated: May 18, 2017  
Newark, New Jersey



**RULE 4:5-1 CERTIFICATION**

I certify, to the best of my information and belief, that the matter in this action involving the aforementioned violations of the CFA, N.J.S.A. 56:8-1 et seq., is not the subject of any other action pending in any other court of this State. I further certify, to the best of my information and belief, that the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated. I certify that there is no other party who should be joined in this action at this time.

CHRISTOPHER S. PORRINO  
ATTORNEY GENERAL OF NEW JERSEY  
Attorney for Plaintiffs

By: Patricia Schiripo  
Patricia Schiripo  
Deputy Attorney General  
Consumer Fraud Prosecution

Dated: May 18, 2017  
Newark, New Jersey

**RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE**

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with R. 1:38-7(b).

CHRISTOPHER S. PORRINO  
ATTORNEY GENERAL OF NEW JERSEY  
Attorney for Plaintiffs

By: Patricia Schiripo  
Patricia Schiripo  
Deputy Attorney General  
Consumer Fraud Prosecution Section

Dated: May 18, 2017  
Newark, New Jersey

**DESIGNATION OF TRIAL COUNSEL**

Pursuant to R. 4:25-4, Deputy Attorney General Patricia Schiripo is hereby designated as trial counsel for the Plaintiffs in this action.

CHRISTOPHER S. PORRINO  
ATTORNEY GENERAL OF NEW JERSEY  
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