

**IN THE COURT OF COMMON PLEAS  
FRANKLIN COUNTY, OHIO**

STATE OF OHIO, <i>ex rel.</i>	)	CASE NO.
MICHAEL DeWINE,	)	
ATTORNEY GENERAL	)	JUDGE
30 East Broad Street	)	
State Office Tower – 14 <sup>th</sup> Floor	)	
Columbus, Ohio 43215	)	
	)	
Plaintiff,	)	<b><u>COMPLAINT FOR</u></b>
	)	<b><u>DECLARATORY JUDGMENT,</u></b>
v.	)	<b><u>INJUNCTIVE RELIEF, CIVIL</u></b>
	)	<b><u>PENALTIES AND COSTS</u></b>
JOHNSON & JOHNSON	)	
CONSUMER INC.	)	
199 Grandview Road	)	
Skillman, NJ 08558	)	
	)	
and	)	
	)	
JOHNSON & JOHNSON	)	
One Johnson & Johnson Plaza	)	
New Brunswick, NJ, 08933	)	
	)	
Defendants.	)	

**COMPLAINT**

1. Plaintiff, State of Ohio, by and through the Attorney General of Ohio, Michael DeWine and his Consumer Protection Section brings this action to enjoin Defendants Johnson & Johnson Consumer Inc. and Johnson & Johnson (“Defendants”) from engaging in unfair or deceptive trade practices in the course of offering and selling consumer goods and services, and to obtain relief for consumers as a result of Defendants’ unfair or deceptive trade practices.

**PARTIES**

2. Plaintiff is the State of Ohio, by and through the Attorney General of Ohio, Michael DeWine and his Consumer Protection Section, who brings this action in the public interest and on

behalf of the State of Ohio under the authority vested in him pursuant to Ohio Revised Code (R.C.) 1345.07 of the Consumer Sales Practices Act.

3. 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.

4. 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”).

5. McNeil transacts business in Ohio 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.

## **JURISDICTION AND VENUE**

6. Plaintiff, State of Ohio, by and through the Attorney General of Ohio, Michael DeWine and his Consumer Protection Section, having reasonable cause to believe that violations of Ohio's consumer laws have occurred, brings this action in the public interest and on behalf of the State of Ohio under the authority vested in him pursuant to R.C. 1345.07 of the Consumer Sales Practices Act.

7. The actions of McNeil, hereinafter described, have occurred in the State of Ohio, County of Franklin and various other counties, and as set forth below, are in violation of the Consumer Sales Practices Act, R.C. 1345.01 et seq.

8. McNeil, is a "supplier" as that term is defined in R.C. 1345.01(C) as McNeil was, at all times relevant herein, engaged in the business of effecting "consumer transactions" by advertising, soliciting, selling, promoting and and/or distributing adult, children, and infant OTC drugs in the State of Ohio for purposes that were primarily for personal, family or household use within the meaning specified in R.C. 1345.01(A) and (D).

9. Jurisdiction over the subject matter of this action lies with this Court pursuant to R.C. 1345.04 of the Consumer Sales Practices Act.

10. This Court has venue to hear this case pursuant to Ohio Civ. R. 3(B)(3), in that some of the transactions complained of herein and out of which this action arose, occurred in Franklin County.

## **ALLEGATIONS**

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

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

### **CAUSE OF ACTION**

#### **COUNT ONE**

#### **UNFAIR OR DECEPTIVE CONSUMER SALES PRACTICES**

17. Plaintiff adopts, incorporates herein and re-alleges paragraphs 1 through 16 as if fully set forth below.

18. McNeil has engaged in transactions that constitute unfair or deceptive acts or practices, and is therefore unlawful under R.C. 1345.02(A). McNeil has:

- a. promoted, advertised, offered for sale, sold, and/or distributed OTC drugs in Ohio as manufactured, processed, packed, held, or distributed in compliance with cGMP;
- b. represented that these OTC drugs had sponsorship, approval, characteristics, ingredients, uses, and benefits that they did not have in violation of R.C. 1345.02(B)(1); and
- c. represented that these OTC drugs were of a particular standard and quality that they were not in violation of R.C. 1345.02(B)(2).

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests that this Court:

1. Adjudge and decree that Defendants have engaged in acts or practices in violation of the Consumer Sales Practices Act., R. C. 1345.01 *et seq.*, as previously set forth.
2. Permanently enjoin and restrain the Defendants from engaging in unfair or deceptive consumer sales practices set forth herein and from violating the Consumer Sales Practices Act.
3. Adjudge and decree that the Defendants are liable to the State for the reasonable costs and expenses of the investigation and prosecution of the Defendants' actions.
5. Assess, fine and impose upon Defendants a civil penalty pursuant to R. C. 1345.07(D) of Twenty-Five Thousand Dollars (\$25,000.00) for each unfair or deceptive act or practice alleged herein.
6. Order that all costs in this cause be taxed against Defendants.
7. Grant Plaintiff such other and further relief as this Court deems just, equitable and appropriate.

Respectfully Submitted,

MICHAEL DeWINE  
Attorney General

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