

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

██████████ Individually and on Behalf
of All Others Similarly Situated,

Plaintiff,

vs.

JOHNSON & JOHNSON, WILLIAM C.
WELDON, DOMINIC J. CARUSO and PETER
LUTHER,

Defendants.

Civil Action No.

**COMPLAINT and
DEMAND FOR JURY TRIAL**

Plaintiff ██████████ individually and on behalf of others similarly situated, by way of
Complaint against Johnson & Johnson, William C. Weldon, Dominic J. Caruso, and Peter Luther,
say:

INTRODUCTION AND OVERVIEW

1. This is a class action for violations of the anti-fraud provisions of the federal securities laws on behalf of all purchasers of Johnson & Johnson (“JNJ” or the “Company”) publicly traded securities between October 14, 2008 and July 21, 2010 (the “Class Period”), who were damaged thereby.

2. JNJ is a healthcare company that sells, among other things, over-the-counter (“OTC”) drugs to consumers. During the Class Period, defendants repeatedly touted the success and revenue of OTC drug sales by its subsidiary McNeil-PPC, Inc. (“McNeil”). At the same time, defendants failed to disclose that a number of manufacturing facilities were failing to maintain current good manufacturing practices (“cGMPs”).

3. Specifically, defendants’ Class Period statements were materially false and misleading for failing to disclose the following:

(a) Starting in April of 2008, defendants received numerous consumer complaints that Tylenol products made at a manufacturing facility in Las Piedras, Puerto Rico exhibited a “musty” odor. Despite being aware of these complaints, defendants failed to conduct an adequate investigation and failed to notify the U.S. Food and Drug Administration (“FDA”) as required;

(b) Defendants failed to take corrective action when foreign materials and contamination were found in a manufacturing facility in Fort Washington, Pennsylvania from May 2009 to April 2010. Similarly, defendants ignored 46 separate complaints of foreign materials in products made at that facility from June 2009 to April 2010; and

(c) In late 2008, defendants learned of potential problems with one of its Motrin products. Rather than issue a public recall, defendants sent contractors out to stores to buy the product back and told the contractors not to mention any recall. After the FDA learned of this “phantom recall,” it pressured defendants to publicly recall the products.

4. As a result of the blatant, systemic, and repeated failure of defendants to maintain proper manufacturing practices at their facilities, defendants have been forced to issue over eight separate recalls including dozens of products and hundreds of millions of individual packages. Further, defendants are now under investigation by the U.S. House of Representatives, the U.S. Senate, the U.S. Attorney's Office for the Eastern District of Pennsylvania, and multiple state Attorneys General offices.

5. As a result of the gradual disclosure of defendants' conduct, the price of JNJ stock has declined significantly, causing damages to Plaintiff and the Class.

JURISDICTION AND VENUE

6. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("1934 Act"), 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5, 17 C.F.R. §240.10b-5, promulgated thereunder. Jurisdiction is conferred by §27 of the 1934 Act, 15 U.S.C. §78aa.

7. Venue is proper here pursuant to §27 of the 1934 Act. JNJ conducts business in this District, it is headquartered in this District, and acts giving rise to the violations complained of occurred in this District.

THE PARTIES

8. Plaintiff ██████████ purchased JNJ securities during the Class Period as set forth in the attached certification and was damaged thereby.

9. Defendant JNJ maintains operations at One Johnson & Johnson Plaza, New Brunswick, New Jersey. JNJ's stock traded on the NYSE, which is an efficient market.

10. Defendant William C. Weldon ("Weldon") was JNJ's Chairman and Chief Executive Officer ("CEO") at all relevant times.

11. Defendant Dominic J. Caruso ("Caruso") was JNJ's Chief Financial Officer ("CFO") and Vice President of Finance at all relevant times.

12. Defendant Peter Luther (“Luther”) was President of McNeil at all relevant times.

13. Defendants Weldon, Caruso and Luther are collectively referred to hereinafter as the “Individual Defendants.”

CLASS PERIOD EVENTS AND STATEMENTS

14. On October 14, 2008, JNJ issued a press release reporting the Company’s financial results for the third quarter of 2008, which stated in relevant part:

Johnson & Johnson continues to achieve solid earnings results despite the impact that generic products have had on our Pharmaceutical business,” said William C. Weldon, Chairman and Chief Executive Officer. “Of note was the strong sales performance of our Consumer segment and the solid sales results in our Medical Devices and Diagnostics segment.

Worldwide Consumer sales of \$4.1 billion for the third quarter represented a 13.1% increase over the prior year with operational growth of 9.4% and a positive impact from currency of 3.7%. Domestic sales increased 11.2%, while international sales increased 14.7%; 8.1% from operations and 6.6% from currency.

15. On January 20, 2009, JNJ issued a press release reporting the Company’s financial results for the full year and fourth quarter of 2008, which stated in relevant part:

The Worldwide Consumer segment achieved annual sales in 2008 of \$16.0 billion, an increase of 10.8% over the prior year with operational growth of 8.3% and a positive impact from currency of 2.5%. Domestic sales increased 8.3%, while international sales increased 12.8% (8.3% from operations and 4.5% from currency).

16. On February 20, 2009, JNJ filed its 2008 Annual Report on Form 10-K with the Securities and Exchange Commission (“SEC”). With respect to the Company’s Consumer Segment, the Form 10-K stated, in relevant part:

The Consumer segment includes a broad range of products used in the baby care, skin care, oral care, wound care and women’s health care fields, as well as nutritional and over-the-counter pharmaceutical products. The Baby Care franchise includes the JOHNSON’S® Baby line of products. Major brands in the Skin Care franchise include the AVEENO®; CLEAN & CLEAR®; JOHNSON’S® Adult; NEUTROGENA®; RoC®; LUBRIDERM®; Beijing Dabao Cosmetics Co., Ltd.; and Vendôme product lines. The Oral Care franchise includes the LISTERINE® and REACH® oral care lines of products. Major brands in the Women’s Health franchise are the CAREFREE® Pantiliners and STAYFREE® sanitary protection products. The

nutritional and over-the-counter lines include SPLENDA[®], No Calorie Sweetener; the broad family of TYLENOL[®] acetaminophen products; SUDAFED[®] cold, flu and allergy products; ZYRTEC[®] allergy products; MOTRIN[®] IB ibuprofen products; and PEPCID[®] AC Acid Controller from Johnson & Johnson • Merck Consumer Pharmaceuticals Co. These products are marketed principally to the general public and sold both to wholesalers and directly to independent and chain retail outlets throughout the world.

* * *

Consumer segment sales in 2008 were \$16.0 billion, an increase of 10.8% over 2007 with 8.3% of this change due to operational growth and the remaining 2.5% due to positive currency fluctuations. U.S. Consumer segment sales were \$6.9 billion, an increase of 8.3%. International sales were \$9.1 billion, an increase of 12.8%, with 8.3% as a result of operations and 4.5% due to currency fluctuations over 2007.

The Over-the-Counter (OTC) Pharmaceuticals and Nutritionals franchise sales were \$5.9 billion, an increase of 14.6% from 2007.

17. On April 14, 2009, JNJ issued a press release reporting the Company's financial results for the first quarter of 2009, which stated in relevant part:

Worldwide Consumer sales of \$3.7 billion for the first quarter represented a decrease of 8.7% versus the prior year with a decline of 1.0% operationally and a negative impact from currency of 7.7%. Domestic sales decreased 5.1%, while international sales decreased 11.6%; which reflected an operational increase of 2.4% and a negative currency impact of 14.0%.

18. On July 14, 2009, JNJ issued a press release reporting the Company's financial results for the second quarter of 2009, which stated in relevant part:

Worldwide Consumer sales of \$3.9 billion for the second quarter represented a decrease of 4.5% versus the prior year with an increase of 3.1% operationally and a negative impact from currency of 7.6%. Domestic sales increased 0.8%, while international sales decreased 8.4%; which reflected an operational increase of 4.7% and a negative currency impact of 13.1%.

19. On October 13, 2009, JNJ issued a press release reporting the Company's financial results for the third quarter of 2009, which stated in relevant part:

Worldwide Consumer sales of \$4.0 billion for the third quarter represented a decrease of 2.7% versus the prior year with an increase of 1.1% operationally and a negative impact from currency of 3.8%. Domestic sales decreased 4.4%;

international sales decreased 1.4%, which reflected an operational increase of 5.2% and a negative currency impact of 6.6%.

20. On November 6, 2009, McNeil issued a press release which stated in relevant part:

In consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is initiating a voluntary recall of a limited number of product lots of **TYLENOL[®] Arthritis Pain Caplet 100 count bottles, with the distinctive red EZ-OPEN CAP**. McNeil is initiating the recall after identifying an uncharacteristic smell or taste associated with these lots that led to a small number of consumers reporting nausea and related symptoms. This recall includes five product lots only [], and does not include any other lots of **TYLENOL[®] Arthritis Pain Caplet 100 count with EZ-OPEN CAP** or any other **TYLENOL[®] Arthritis Pain** products. McNeil is implementing this recall as a precaution.

Consumers who purchased **TYLENOL[®] Arthritis Pain Caplet 100 count bottles with the distinctive red EZ-OPEN CAP** from the lots included in this recall should stop using the product and contact McNeil for instructions on a refund or replacement.

21. On December 18, 2009, McNeil issued a press release which stated in relevant part:

In consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is expanding its voluntary recall to include all available product lots of ***TYLENOL[®] Arthritis Pain Caplet 100 count bottles, with the distinctive red EZ-OPEN CAP*** []. In November 2009, 5 lots of this product were recalled due to consumer reports of an unusual moldy, musty, or mildew-like odor that was associated with nausea, stomach pain, vomiting and diarrhea. The recall is being expanded, as a precaution, to include all **TYLENOL[®] Arthritis Pain Caplet 100 count bottles with the distinctive red EZ-OPEN CAP**.

The uncharacteristic smell is caused by the presence of trace amounts of a chemical called 2,4,6-tribromoanisole. The source of 2,4,6-tribromoanisole is believed to be the breakdown of a chemical used to treat wooden pallets that transport and store packaging materials. The health effects of this compound have not been well studied, and to date all of the observed events reported to McNeil were temporary and non-serious.

Consumers who purchased **TYLENOL[®] Arthritis Pain Caplet 100 count bottles with the distinctive red EZ-OPEN CAP** from the lots included in this recall should stop using the product and contact McNeil for instructions on a refund or replacement. (Emphasis in original).

22. On January 8, 2010, FDA investigators sent McNeil a report memorializing violations at the Puerto Rico manufacturing facility regarding, among other things, musty odors associated with

some Tylenol products. As a result of that report, on January 15, 2010 the FDA sent defendant Luther a letter stating the following:

We are aware of the complaint information available to your company, the sequence of events, and the extent of your firm's follow up measures during this period. We have concluded that your company did not conduct a timely, comprehensive investigation.

Your initial investigation into the root cause of the odor was unjustifiably delayed and terminated prematurely. Numerous complaints were received over a four month period in 2008 before they were considered a trend and before actions were initiated to determine the root cause. When microbiological testing in August 2008 did not support an initial speculation that microbial contamination was the root cause of the odor, the investigation was closed. No other possible root causes were pursued. ***Your firm lacked adequate justification for this decision.***

Complaints of uncharacteristic odor were reported again in April 2009. Approximately 112 similar complaints were received by August 3, 2009. Although your firm had test results indicative of contamination with TBA as the source of the off odor on the complaint samples since September 2009, these results were not shared with FDA until after the initiation of the inspection and following several requests for this information made by the district office.

In October 2009, you concluded that the most probable root cause of the odor in the Tylenol Arthritis Relief caplets was the exposure of drug product bottles to wood pallets chemically treated with TBP. You did not expand the scope of the investigation to other lots and products potentially affected by this deviation. This would include, for example, products packaged in bottles from the same supplier that used the same type of wooden pallets, and other products manufactured by your facility for which odor complaints were received.

* * *

[T]he timing and depth of your investigative efforts regarding uncharacteristic odor complaints were insufficient to meet good manufacturing practice. Your firm's management, including the Quality Control Unit, was not proactive in response to consumer complaints. In addition, during the 2008 examination of complaint samples, your firm's analysts noted that the tablets, once removed from the bottle, did not have an unusual odor but the bottle retained a strong odor. Nonetheless, you did not pursue chemical testing at that time.

Your firm's quality management should have ensured the start of chemical testing far earlier. Failure to do so prolonged identification and resolution of the problem, resulting in continued consumer exposure. Quality problems must be thoroughly investigated, root cause determined, and appropriate corrective and preventive

actions implemented as quickly as possible to limit exposure of the public to substandard drugs.

* * *

Your firm received numerous uncharacteristic odor consumer complaints during the period of April 2008 through September 2008 for your product Tylenol Arthritis Relief caplets. Nevertheless, you failed to submit a FAR to FDA within three working days to inform the Agency of the nature of the problem and the steps that you were taking to address it. You did not submit the FAR until September 18, 2009, after again noting an adverse, continuing trend of numerous complaints over the course of a several month period.

The Agency is concerned about the response of Johnson & Johnson (J&J) to this matter. It appears that when J&J became aware of FDA's concerns about the thoroughness and timeliness of McNeil's investigation, whether all potentially affected products had been identified, and whether the recall was adequate in scope, J&J did not take appropriate actions to resolve these issues. Corporate management has the responsibility to ensure the quality, safety, and integrity of its products. Neither upper management at J&J nor at McNeil Consumer Healthcare assured timely investigation and resolution of the issues. (Emphasis added).

23. On January 26, 2010, defendants held a conference call with investment analysts, during which defendant Weldon stated:

We are very conscious of the bar we set for ourselves and that consumers expect more from us than from others because of our history and reputation. A recent consumer product recall and FDA warning letter were important reminders of this expectation and the vigilance it requires. I want to assure you that we take these matters very seriously and nothing is more important to us than the health and safety of the people who use our products. We are undertaking a thorough review of our procedures to ensure that we identify potential improvements we could make moving forward. We believe these and other actions we are taking will address the concerns of the FDA raised in its warning letter, and we will be working in close consultation with them.

When McNeil Consumer Healthcare first received some complaints on a musty odor associated with our products in 2008, the company conducted a microbiological investigation to check for the presence of bacteria and mold, which would be consistent with the presence of the odor. No bacteria or mold was found down, and it was believed that the complaints were likely an isolated issue.

When similar complaint trends were identified in 2009, the company initiated further investigation and novel forensic testing. McNeil determined that the reported uncharacteristic odor was caused by trace amounts of a chemical byproduct

originating from the treatment of wood pallets used to transport and store product packaging materials. Subsequently, we initiated a voluntary product recall based on broad precautionary criteria, recalling numerous product lots that had not been the subject of any customer complaints.

Even as we continue our investigation, we have taken additional actions beyond the recall to assure product quality. We have required suppliers who ship materials to our plants to discontinue the use of the type of wood pallets associated with the recall. We are conducting full inspections of all materials coming into our facilities and have had outside experts evaluate our plants. We are confident in moving forward with production, and we will continue to monitor and evaluate the situation and consult with the FDA.

24. On March 1, 2010, JNJ filed its 2009 Annual Report on Form 10-K with the SEC.

With respect to the Company's Consumer Segment, the Form 10-K stated, in relevant part:

The Consumer segment includes a broad range of products used in the baby care, skin care, oral care, wound care and women's health care fields, as well as nutritional and over-the-counter pharmaceutical products, and wellness and prevention platforms. The Baby Care franchise includes the JOHNSON'S[®] Baby line of products. Major brands in the Skin Care franchise include the AVEENO[®]; CLEAN & CLEAR[®]; JOHNSON'S[®] Adult; NEUTROGENA[®]; RoC[®]; LUBRIDERM[®]; Dabao; and Vendôme product lines. The Oral Care franchise includes the LISTERINE[®] and REACH[®] oral care lines of products. The Wound Care franchise includes BAND-AID[®] brand adhesive bandages and PURELL[®] instant hand sanitizer products. Major brands in the Women's Health franchise are the CAREFREE[®] Pantliners; STAYFREE[®] sanitary protection products; and Vania Expansion products. The nutritional and over-the-counter lines include SPLENDA[®], No Calorie Sweetener; the broad family of TYLENOL[®] acetaminophen products; SUDAFED[®] cold, flu and allergy products; ZYRTEC[®] allergy products; MOTRIN[®] IB ibuprofen products; and PEPCID[®] AC Acid Controller from Johnson & Johnson • Merck Consumer Pharmaceuticals Co. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world.

* * *

Consumer segment sales in 2009 were \$15.8 billion, a decrease of 1.6% from 2008 with 2.0% of this change due to operational growth and negative currency impact of 3.6%. U.S. Consumer segment sales were \$6.8 billion, a decrease of 1.4%. International sales were \$9.0 billion, a decrease of 1.7%, with growth of 4.7% achieved by operations and a decrease of 6.4% resulting from the negative impact of currency fluctuations.

The Over-the-Counter (OTC) Pharmaceuticals and Nutritionals franchise sales were \$5.6 billion, a decrease of 4.5% from 2008 . . . In December 2009, the Company

announced a voluntary recall of all lots of TYLENOL[®] Arthritis Pain 100 count with EZ-OPEN CAP following reports of an uncharacteristic smell; however, there was an insignificant impact on sales. In January 2010, the Company has undertaken a broader voluntary recall of TYLENOL[®] and certain OTC products as a precautionary action.

25. On April 20, 2010, JNJ issued a press release reporting the Company's financial results for the first quarter of 2010, which stated in relevant part:

Worldwide Consumer sales of \$3.8 billion for the first quarter represented an increase of 1.5% versus the prior year consisting of a decrease of 3.7% operationally and a positive impact from currency of 5.2%. Domestic sales decreased 9.6%; international sales increased 11.1%, which reflected an operational increase of 1.4% and a positive currency impact of 9.7%.

Positive contributors to operational results were NEUTROGENA[®], AVEENO[®] and LE PETIT MARSEILLAIS[®] skin care products; ZYRTEC[®] over-the-counter allergy treatment; international sales of LISTERINE[®] antiseptic mouthrinse; and women's sanitary protection products. These operational sales increases were more than offset by the impact of the previously announced recall of selected OTC products as well as the devaluation of the Venezuelan currency.

26. On April 20, 2010, defendants held a conference call with investment analysts, during which defendant Caruso, JNJ's CFO, engaged in the following colloquy:

[Analyst]: Okay. And then the recall in OTC, could you quantify the impact in the first quarter and I assume that we should see a catch-up in the second quarter, is that correct?

[Caruso]: Well, maybe the best way to quantify the impact in the first quarter, the overall consumer business was down 3.7% operationally. Without that, the consumer business would have been about flat for the first quarter. So that gives you sort of an overall impact and you can see that the OTC business in the first quarter in the US was down 25% from the prior year. So they are the two best indicators to assess the overall impact.

As I mentioned earlier, Larry, we are now resuming production levels and shipments are now resuming to more normal levels. So I think there will be some improvement obviously in the second quarter, but we still will see some impact from not being on the market in the early part of the second quarter. So we will have to wait and see how that plays out during the second quarter.

27. On April 30, 2010, FDA investigators sent the Company an inspection report regarding the Fort Washington facility that identified several violations of cGMP. Most troublingly, the April 30, 2010 report noted that required corrective actions were not taken when foreign material, particulate matter, and/or contamination were observed in at least 21 separate drug batches from May 2009 to April 2010. Similarly, required corrective actions were not taken after 46 consumer complaints regarding foreign materials consisting of black or dark specks from June 2009 through April 2010.

28. Also on April 30, 2010, McNeil issued a press release which stated in relevant part:

McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., in consultation with the U.S. Food and Drug Administration (FDA), is voluntarily recalling all lots that have not yet expired of certain over-the-counter (OTC) Children's and Infants' liquid products manufactured in the United States and distributed in the United States, Canada, Dominican Republic, Dubai (UAE), Fiji, Guam, Guatemala, Jamaica, Puerto Rico, Panama, Trinidad & Tobago, and Kuwait. []

McNeil Consumer Healthcare is initiating this voluntary recall because some of these products may not meet required quality standards. This recall is not being undertaken on the basis of adverse medical events. However, as a precautionary measure, parents and caregivers should not administer these products to their children. Some of the products included in the recall may contain a higher concentration of active ingredient than is specified; others may contain inactive ingredients that may not meet internal testing requirements; and others may contain tiny particles. While the potential for serious medical events is remote, the company advises consumers who have purchased these recalled products to discontinue use.

The company is conducting a comprehensive quality assessment across its manufacturing operations and has identified corrective actions that will be implemented before new manufacturing is initiated at the plant where the recalled products were made.

29. On this news, shares of the Company's stock declined \$0.71 per share, or 1.1 percent, to close on April 30, 2010 at \$64.30 per share, on heavy trading volume.

30. On May 4, 2010, McNeil issued a press release which stated in relevant part:

We have no higher concern than providing parents with the highest quality products for their children. The quality issues that the FDA has observed, many of which we

had recently identified in our own quality reviews and communicated to the FDA, are unacceptable to us, and not indicative of how McNeil Consumer Healthcare intends to operate. While the chance of serious adverse medical reaction is remote, we apologize to those who rely on our medicines for the concern and inconvenience this recall may have caused. We will provide a detailed response to the FDA on their observations, and work diligently to ensure that they are addressed.

We have temporarily suspended production at our Fort Washington, PA plant, where the observations were made. We will not restart operations until we have taken the necessary corrective actions and can assure the quality of products made there.

This step comes on top of others we already have taken to ensure quality compliance. Early this year we initiated a comprehensive assessment of quality and manufacturing systems across our operations. We have committed extensive internal resources to this effort, and brought in independent outside experts to assist us.

We will continue to work in close consultation with the FDA to take corrective action and ensure that our quality operations meet the high standards that consumers expect from us.

31. On May 5, 2010, the House Committee on Oversight and Government Reform issued a press release that stated in relevant part:

Chairman Edolphus ‘Ed’ Towns (D-NY) and Ranking Member Darrell Issa (R-CA) today announced that the committee has opened an investigation into the circumstances surrounding a major recall of children’s medication. McNeil Consumer Healthcare (a subsidiary of Johnson & Johnson), the manufacturer and marketer of well known over-the-counter and prescription pharmaceuticals including Children’s Tylenol, Infants’ Tylenol and Children’s Motrin, recently announced a voluntary recall of more than 40 over-the-counter medications as Food and Drug Administration (FDA) inspectors were completing a nearly two-week long inspection of the facility where the medication is produced.

Towns and Issa want to bring attention to the recall particularly due to the fact that children could be adversely impacted if they were to take any of the medicine that was covered by the recall. The oversight leaders are seeking clarification on the recall based on a Washington Post article that contains conflicting accounts about the existence of raw materials in the medication and the significance of their contamination effect. FDA and McNeil Consumer Healthcare have given conflicting accounts of the circumstances surrounding the recall, including what prompted the recall and how serious the recall is. ***In addition, as this is the third recall of Tylenol products in less than a year, the lawmakers are questioning the adequacy of FDA’s inspection procedures and whether McNeil failed to investigate consumer complaints that could have identified the contamination problems.***

Chairman Towns and Ranking Member Issa said, ‘We are deeply concerned about the recall of popular pediatric medications widely used by infants and children across the country. When a recall of this nature occurs, it is our responsibility to bring attention to the issue as a public service and to fulfill our oversight responsibility by asking tough questions about the conditions of the manufacturing plant and controls put in place by the drug company’s management, and about whether FDA’s inspection and recall procedures were sufficient. In the coming days we will be asking both McNeil Consumer Healthcare and the FDA to provide this committee with information about the recall and we expect a hearing will follow in the coming weeks. This is an issue we cannot afford to ignore.’ (Emphasis added).

32. On the evening of May 5, 2010, several news organizations extensively reported on the House Committee’s investigation. For example, as reported by *The Wall Street Journal Online* that evening:

The House Committee on Oversight and Government Reform is opening an investigation into conflicting accounts of what prompted a Johnson & Johnson unit’s recent recall of children’s over-the-counter medicines, as well as how the company handled consumer complaints about foreign matter in the bottles.

The committee will seek a chronology of events leading up to the recent recall, a spokesman for Rep. Darrell Issa, the ranking Republican on the committee, said Wednesday. It will also seek copies of investigation reports by the Food and Drug Administration and J&J’s McNeil Consumer Healthcare unit, the spokesman said.

The committee will examine the ‘adequacy of FDA’s inspection procedures,’ according to a statement issued by Rep. Edolphus Towns, the Democratic chairman, and Rep. Issa. It plans to ask the FDA for its procedures governing routine inspections of over-the-counter drug makers and recalls, said Kurt Bardella, Rep. Issa’s spokesman.

J&J declined to comment. The FDA said in a statement it recognizes ‘the committee’s interest in this case’ and looks forward to cooperating[] with the investigation.

The recall over the weekend involved more than 40 different Tylenol, Benadryl, Motrin and Zyrtec products for children and infants.

Some of the medicines had higher concentrations of the active ingredient than specified, according to the company, and some products may contain tiny metallic particles left as a residue from the manufacturing process.

It was the latest in a string of recalls at the McNeil unit.

J&J's McNeil made the liquids at a Fort Washington, Pa., plant that the company has temporarily shut down until it fixes the manufacturing problems and can assure quality production.

The company said it launched the recall after consumer complaints spurred an internal investigation that discovered manufacturing problems. An FDA spokeswoman gave a different account, saying a routine inspection last month found problems at the plant and the company decided to issue a recall after the regulators reported their findings.

FDA inspectors said bacteria contaminated raw materials to be used to make several lots of Tylenol products for children. FDA also said that the J&J unit received 46 complaints from consumers between June 2009 and April 2010 regarding 'foreign materials, black or dark specks' in the medicines.

33. News reports about the extent of the House Committee's investigation continued the following day. For example, on May 6, 2010, *Bloomberg* reported:

House lawmakers questioned whether U.S. regulators kept a close enough watch over Johnson & Johnson's production of children's medicines before a company unit last week recalled more than 40 types of drugs.

The Food and Drug Administration was asked to produce records of inspections of McNeil Consumer Healthcare, the J&J unit that manufactured the recalled medicines, in a letter the top two members of the House Oversight and Government Reform Committee sent today to Commissioner Margaret Hamburg. Lawmakers want the agency to describe its interactions with J&J and its review of the Fort Washington, Pennsylvania, plant that produced the medicines. It was McNeil's third major recall in the past eight months because of quality concerns, the committee said.

'Taken together, these recalls point to a major problem in the production of McNeil products, and raise questions as to the adequacy of FDA's response to repeated problems with McNeil's manufacturing practices,' Representatives Edolphus Towns, a New York Democrat and the committee's chairman, and Darrell Issa of California, the top committee Republican, wrote in the letter.

J&J on April 30 recalled some types of infant and children's Tylenol, Motrin, Zyrtec and Benadryl. The FDA said May 1 the recall was the result of 'manufacturing deficiencies' and warned consumers to stop using the medicines. FDA inspectors found tainted raw materials at the plant last month and the company failed to protect drugs from possible contamination or correct manufacturing deficiencies, agency officials said in a May 4 conference call.

'Most Vulnerable'

‘Infants and children represent the most vulnerable of our society and it is imperative that we aggressively pursue every oversight avenue available to us to ensure the products given to our children meet the highest threshold for safety and reliability as possible,’ Issa said today in an e-mail. ‘There is no acceptable margin of error’ when it comes to product safety for children’s medicines, he said.

* * *

In January, J&J recalled over-the-counter medicines including Roloids, Motrin, some Tylenol brands, Benadryl, St. Joseph Aspirin and Simply Sleep caplets after receiving complaints about musty odors in Tylenol caplets and reports of nausea, vomiting and diarrhea after use.

J&J failed to respond to 46 consumer complaints about the children’s medicines in the 10 months leading to last week’s recall, according to an FDA report posted on its website. Inspectors saw debris, dusty conditions and a hole in a laboratory ceiling among their findings at the plant, according to the report.

‘Black Eye’

‘It’s a black eye’ for J&J, the world’s largest health products company, said Jeff Jonas, an analyst with Gabelli & Co. in Rye, New York. ‘How dusty and dirty everything was is quite embarrassing.’

34. On this news, shares of the Company’s stock declined \$1.14 per share, or 2.7 percent, to close on May 6, 2010 at \$63.40 per share, on heavy trading volume.

35. On May 24, 2010, Senator Tom Harkin, Chairman of the U.S. Senate Committee on Health, Education, Labor, and Pensions, sent the FDA a letter that stated in relevant part:

I am writing to express deep concern over the recent recall of more than 40 medications for infants and children manufactured by Johnson & Johnson’s McNeil Consumer Healthcare unit . . . I am especially concerned because so many of the drugs at issue in this recall were intended for infants and children.

This recall is only the most recent in a series of disturbing events associated with products sold by the company since September 2009.

- September 2009: McNeil recalled products contaminated with bacteria.
- October 2009: McNeil products were stolen from a cargo terminal in Jacksonville, Florida, and the public was advised not to use the products.
- December 2009: After consumer complaints reaching as far back as 2008, McNeil recalled products due to a musty odor.

- May 2010: McNeil recalled children's products because they were sub- and super-potent, contained particles, included base ingredients that did not meet internal testing requirements, and were contaminated with gram-negative bacteria. According to the Centers for Disease Control and Prevention, the bacteria, later identified as *B. cepacia*, are often transmitted by contaminated medical products and are often resistant to common antibiotics. Despite at least 46 consumer complaints in the last year, McNeil did not initiate the recall until May, following an inspection by FDA.

36. On May 27, 2010, the House Committee on Oversight and Government Reform held a hearing regarding the JNJ scandal. At that hearing, Committee Chairman Edolphus Towns made an opening statement that included the following:

Less than a month ago a Johnson & Johnson company known as McNeil Consumer Healthcare recalled over 40 variations of children's medicine, including such widely used products as Children's Tylenol, Children's Motrin, Children's Benadryl and Tylenol Infants' Drops.

This recall was carried out because of production problems at McNeil that affected the quality, purity and potency of the medicine. McNeil received dozens of consumer complaints about foreign particles in children's medicine, which were later confirmed by McNeil.

In addition, tests at the plant show that three batches of Infant's Tylenol were found to be 'super potent,' meaning that they contained an overdose of the active ingredient.

McNeil's production of children's medicine was shut down by the company and a month later it is still shut down. The FDA is currently investigating any possible links between the recalled medicine and adverse health effects on children who took that medicine.

The FDA is also currently reviewing reports of children who died to determine if there is any connection between those deaths and this recall. At this point, the FDA is not aware of any connection between the recalled medicine and the death of any child.

One document the Committee received from the FDA refers to the case of a 1 ½ year old girl who died. That document reads, 'coroner's office called to report the death of a 1 ½ year old female that is suspected to be related to a Tylenol product.'

Just last night, the Committee obtained from the FDA even more disturbing information. According to an FDA document, McNeil knew there was a potential problem with one of its Motrin products that was on the market in 2008, but rather

than issue a public recall, McNeil allegedly sent contractors out to stores to buy the product back and told the stores ‘not to mention’ a recall.

After the FDA confronted McNeil about this, McNeil announced a recall of the affected products.

This ‘phantom recall’ warrants further investigation by this Committee. *Who at McNeil and Johnson & Johnson knew about this scheme? How high up in the corporate suite was this scheme hatched? Is this a standard operating practice for McNeil?* (Emphasis added).

37. At the same hearing, Joshua M. Sharfstein, M.D., Principal Deputy Commissioner for the FDA, testified in relevant part as follows:

Spring/Summer 2009. At its Fort Washington facility, McNeil makes a wide variety of OTC products, including a large number of OTC liquid products for children.

In May and June 2009, FDA identified several cGMP violations, including McNeil’s failure to meet its own standard for quality in one of the ingredients in OTC liquids. McNeil’s standard for this ingredient, known as microcrystalline cellulose, required that there be no gram-negative bacteria. McNeil purchased the cellulose in partial lots that had not tested positive for this objectionable bacteria. The vendor tested other partial lots from the same large master lot and found a certain gram negative bacteria called *B. cepacia*. According to cGMP standards, McNeil should not have used any partial lots from this master lot.

* * *

Yet, because the company had not kept to its standard, it represented a cGMP violation, and the company initiated a recall of almost eight million bottles of finished product in August 2009.

Fall 2009. At its Las Piedras, Puerto Rico, facility, McNeil makes a large number of OTC pills for the U.S. market.

In the fall of last year, FDA became aware that McNeil had received reports of products from this facility having a musty odor. Yet, McNeil had not fully investigated these reports for about a year and did not notify FDA despite the requirement that such reports be referred to the Agency within three days.

FDA inspectors urged McNeil to conduct a complete investigation, which eventually identified the source of the odor to be a chemical, called 2,4,6-Tribromoanisole or TBA, which was in the air because of a pesticide used on the wood of the pallets used to store empty medication bottles. McNeil initiated a series of recalls as the scope of the problem became clear.

The risk posed to the public by this problem included potential temporary, non-serious gastrointestinal reactions – including nausea, stomach pain, vomiting, or diarrhea. Very little is known about the chemical TBA, but in the small quantities transferred to the products, it is not thought to pose a serious risk for long-term health problems.

On January 15, 2010, FDA issued a warning letter to McNeil expressing serious concerns about the company's control over the quality of its drugs and the company's failure to aggressively investigate and correct quality problems. This letter identified significant violations of the cGMP regulations. FDA noted that neither upper management at Johnson & Johnson nor at McNeil assured timely investigation and resolution of the issues.

* * *

February 2010. On February 19, 2010, senior compliance staff from FDA's Center for Drug Evaluation and Research and from FDA's field organization met with senior officials from McNeil and its parent company, Johnson & Johnson. Attendees included the President of McNeil, the Company Group Chairman for OTC at Johnson & Johnson, as well as a number of Quality Assurance executives from both companies.

This was an extraordinary meeting. FDA requested that senior officials from Johnson & Johnson attend the meeting so they would be on notice regarding FDA's rising concerns about whether McNeil's corporate culture supported a robust quality system to ensure the purity, potency and safety of its products. FDA also raised concerns about Johnson & Johnson's oversight of McNeil due to recent multiple recalls of McNeil products and recent warning letters FDA had issued to both McNeil and its parent company, Johnson & Johnson. Based on the Fort Washington and Las Piedras inspections in 2009 as well as the firm's recent compliance history, FDA expressed its significant concern that there was a pattern of conduct including failure to report material information to FDA in a timely manner, miscalculating and/or misstating risks and benefits of their products, and reactive vs. proactive approaches to product quality problems. FDA told the company's leadership that significant, immediate steps were needed to address issues of compliance and quality, especially in investigating product quality issues so that the company could take preventive action to avoid problems.

The Agency learned that McNeil was taking several major steps to address these issues, including implementing management reporting structure changes, hiring new managers, and engaging a third party manufacturing consultant. FDA indicated that it would continue to monitor closely and consider further action, and that it was concerned about whether the company's corporate culture was appropriately focused on product quality issues.

April 2010. In April, FDA inspectors returned to McNeil's Fort Washington facility. This inspection was scheduled sooner than usual due to McNeil's recent history of compliance problems, including numerous recalls and cGMP deficiencies discovered in the June 2009 Fort Washington inspection, which had a significant impact on the scheduling of the April 2010 inspection.

Days before the inspectors arrived, McNeil shut down manufacturing because of manufacturing issues, including particulates found in a number of liquid medications. These particulates included acetaminophen, cellulose, nickel, and chromium. FDA inspectors identified a range of cGMP violations. These included the company failing to meet its own specifications for bacteria and particulates and, for one Tylenol product, the possibility of higher than expected concentrations of Tylenol per dropper.

* * *

Although the public health risk from these quality problems is low, these problems should never have occurred, and the cGMP failures at the facility that caused them were unacceptable. Following cGMP requirements assures that products are consistent in their safety and effectiveness and failure to follow those procedures undermines consumer confidence. On April 30, 2010, McNeil announced a voluntary recall of over 136 million bottles of liquid infants' and children's products.

38. At the end of the hearing, Chairman Towns stated as follows:

Frankly, what we have heard today is not reassuring.

The initial story was bad enough: On April 30, Johnson & Johnson announced the largest recall of children's medicine in history. But it turns out there wasn't just one recall. ***What we have heard about today is rolling recalls, a phantom recall, a plant shut down, and management firings.***

I was hoping that J&J would be completely forthcoming today, but I think there are still unanswered questions.

J&J told the Committee staff that this most recent recall involved only 6 million bottles. That's a huge number. But ***today we learned from the FDA that it was more than 20 times that***, namely 136 million bottles. Regarding the phantom recall, J&J testified that there was no attempt to hide anything. But we uncovered a J&J document showing that they told their contractor not to say this was a recall.

J&J says that none of its contaminated products has had any adverse health effects. But the FDA testified today that the issue of whether any of these products caused deaths is still being investigated.

* * *

At this point, there are still many unanswered questions. We intend to pursue this further. (Emphasis added).

39. In light of the evidence presented at the May 27, 2010 hearing that the Company used third party contractors to effectuate a “silent recall” of Motrin in 2008, the Committee on Oversight and Government Reform expanded its inquiry on June 3, 2010, by issuing letters to two such contractors that stated in part:

In the course of our investigation, we discovered that in late 2008 Johnson & Johnson learned it had problems with a certain type of Motrin. Rather than announcing a recall, J&J allegedly hired a contractor to go to retail stores and surreptitiously purchase the suspect Motrin. The contractor’s employees were allegedly instructed to act as though they were ordinary customers. It wasn’t until this activity was discovered by the Food and Drug Administration that J&J announced a recall of the affected medication.

According to a document obtained by the Committee, WIS [International] was recruited by CSCS ‘on behalf of Johnson & Johnson’ to purchase the suspect Motrin. The WIS document states that the ‘objective’ is, ‘To visit all the stores on your schedule; locate, and purchase all of the MOTRIN....’ In addition, the document provides the following instructions:

‘You should simply ‘act’ like a regular customer while making these purchases. THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!’ []

We have expanded our investigation to include the issue of Johnson & Johnson’s phantom recall of Motrin.

40. On this news, shares of the Company’s stock declined \$1.76 per share, or almost 3 percent, to close on June 4, 2010 at \$58.01 per share, on heavy trading volume.

41. On June 11, 2010, Pharmalot.com, a website devoted to the pharmaceutical industry, posted as follows:

The Johnson & Johnson recall scandal is threatening to envelope the healthcare giant in ways that, just a few months ago, no one could imagine. The latest twist involves a series of emails that appear to lend further credence to what a Congressional committee is calling a ‘phantom recall,’ which was allegedly undertaken to obscure serious problems with widely used over-the-counter pediatric medications. The

episode is part of a long-running chain of events may prompt the FDA to consider criminal charges.

At issue are quality-control failures that forced J&J to recently recall tens of millions of bottles of such venerable brands as Tylenol and Motrin, among others, which had been found to contain too much active ingredient or metallic specks. But instead of issuing a recall, J&J hired an outside contractor to buy Motrin from stores, and its employees were instructed to act like 'regular customers' and not discuss a possible recall []. This was disclosed at a May 27 Congressional hearing.

Since then, *internal J&J documents obtained by Pharnalot would appear to undercut some of J&J's contentions, such as the notion that its contractor's assignment was limited and transparent.* A J&J spokeswoman told The New York Times the contractor's memo was created without the knowledge of its McNeil Consumer Healthcare unit. *But e-mails suggest J&J employees were aware,* including Lily Vandermolen, an associate product director at McNeil, and Carolyn Parziale, a director of quality assurance at McNeil.

For instance, an April 1, 2009, email from Rob Small, director of field operations and transportation at Inmar, a J&J contractor, to various Inmar and J&J personnel, says: 'Some stores will not care, others will ask specifically what we are doing. *Initially, we are going to buy all product as mystery shoppers.* We will need to clarify to the field what the response will be if the store asks questions as we are reviewing products searching for specific lot codes.' Suggested responses to curious retailers? Say you are conducting random quality packaging checks or looking for packaging changes and need to purchase samples. Later, though, Inmar employees were told to say they were conducting an audit, but nothing else. Small did not return a call for comment.

Recently, Peter Luther, McNeil's president, told the committee that McNeil - which recently closed its Fort Washington, Pa., plant after a scathing FDA inspection - didn't make children's meds for other companies, according to a source close to the investigation. Yet, a few days later, the FDA announced Blacksmith Brands was recalling various PediaCare products made for the company at the same plant....

Meanwhile, J&J apparently was telling the FDA that its campaign was a product retrieval, not a recall. But in a July 16, 2009, e-mail from Neisa Alonso, an FDA investigator and recall emergency and coordinator, writes to Parziale that 'your company is doing a recall even though you are calling it a retrieval.' The FDA's position, she continued, is that J&J should do a recall, because it already appears that one is under way. A recent Motrin sampling, she added, failed a dissolution test and such failures 'typically' result in recalls. (Emphasis in original and added).

42. On June 14, 2010, *Bloomberg* reported as follows:

Johnson & Johnson's McNeil Consumer Healthcare president recommended a recall of faulty Motrin pills without notifying regulators or consumers, according to a person familiar with a congressional probe of the company.

Peter Luther, whose unit produced the Motrin tablets in 2008, told McNeil employees in an e-mail to go ahead with a 'market withdraw of Motrin,' writing, 'Let's make this happen ASAP.' The e-mail was obtained by Bloomberg from the person familiar with the investigation by the House Oversight and Government Reform Committee.

The probe into the Motrin tablets, which didn't dissolve properly, began in May as part of an inquiry into children's medicines recalled April 30 by McNeil because of manufacturing defects. Colleen Goggins, J&J's consumer group chairman, told a May 27 committee hearing that the company hadn't intended to mislead anyone about the Motrin incident. Contractors were hired to buy pills, emptying store shelves without announcing a recall, the person familiar with the investigation said.

'The FDA was kept fully informed of McNeil's plans and actions throughout the process,' Bonnie Jacobs, a spokeswoman for J&J's McNeil unit, said in a phone interview. 'The memo you referenced is consistent with what we have stated previously.'

* * *

A May 27, 2009, e-mail from Luther in response to a discussion among McNeil executives about whether to go ahead with the plan to buy the Motrin in stores expressed concern about the expense of the contractors hired by the company, the person said.

'Given our current financial situation, I hope we're not going to really double our cost to do this,' Luther said in the e-mail to six McNeil employees, according to the person familiar with the investigation.

The e-mails show that senior McNeil executives were involved with the plan to buy back the defective Motrin in large quantities, the person said, and not just perform a sampling of whether the product made it into stores, as Goggins said in testimony.

* * *

'The objective was to remove the affected product from a unique distribution channel, namely convenience stores and gas stations, with as little disruption and consumer confusion as possible,' Jacobs said. 'The FDA was kept informed of the survey and product retrieval, and after it was essentially complete, the FDA requested that we conduct an additional step, which was to conduct a formal recall, and we agreed.'

McNeil told the FDA it would ‘sample’ from stores where the Motrin had been sent, Meghan Scott, a spokeswoman for the agency, said on June 11.

‘They did not inform the agency that they would instruct contractors to go into stores, ‘act like a regular customer,’ and buy all of the product in question,’ Scott said in an e-mail. The agency didn’t respond immediately today to a new request for comment.

J&J fell 4 cents to \$58.42 in New York Stock Exchange composite trading. *The shares have fallen 9.1 percent since the New Brunswick, New Jersey-based company announced the April 30 recall of 40 children’s medicines.* (Emphasis added).

43. On June 15, 2010, McNeil issued a press release that stated in relevant part:

McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is recalling five product lots as an addition to the list of products included in the company’s January 15th, 2010 product recall. The additional lots involved are four product lots of BENADRYL® ALLERGY ULTRATAB™ TABLETS, 100 count, sold in the U.S.; and one product lot of EXTRA STRENGTH TYLENOL® Rapid Release Gels, 50 count sold in the U.S., Trinidad and Tobago, Bermuda, and Puerto Rico []. This recall is a follow-up to the product recall that McNeil Consumer Healthcare announced on January 15th, 2010 and is being taken because the products were inadvertently omitted from the initial recall action. McNeil Consumer Healthcare identified the omission and informed the U.S. Food and Drug Administration (FDA) of its decision to add these product lots to the recall list. All these products were produced before the January 15th, 2010 recall. Since January, McNeil Consumer Healthcare has continued to analyze and evaluate 2,4,6-tribromoanisole (TBA) and has shared that information with the FDA.

44. On June 23, 2010, *CNNMoney.com* published an article regarding the JNJ scandal that stated as follows:

Government safety inspectors pushed for a recall of popular children’s medicines at least three months before a Johnson & Johnson drugmaking unit removed the products from store shelves, according to documents obtained by CNNMoney.

In fact, Food and Drug Administration inspection reports going back to 2003 chronicle a build up of problems at the now-shuttered plant in Fort Washington, Pa., at the center of the widespread recall of Tylenol, Motrin, Benadryl and other over-the-counter drugs.

The FDA raised the recall issue this year after conducting an inspection of the Fort Washington facility from Jan 28 to Feb. 2. Inspectors questioned whether Johnson &

Johnson's McNeil unit had adequately tested a batch of raw materials that was used to make infant's and children's liquid Motrin in 2009.

McNeil told the FDA that it was satisfied with its own testing. It proceeded to make the Motrin drugs, and chose not to undertake additional testing of finished Motrin products.

But the lead FDA inspector was not satisfied and determined that 'the potential for contamination of the entire lot remains a possibility.'

'The most appropriate corrective action would have been to get control of all finished product,' the FDA said in the inspection report. 'Leaving potentially affected [Motrin] lots on the market did not appear to be in the best interest of infants and children who are the intended consumer.'

The FDA generally can recommend a recall, but does not have the authority to force one unless the product poses potential for serious injury or death.

On April 30, McNeil recalled 1,500 lots, or about 135 million bottles, of children's and infant's Motrin, Tylenol, Benadryl and Zyrtec drugs, saying that some of these products did not meet 'quality standards.' It noted the presence in the drugs of tiny metal particles and for the potential of bacterial contamination.

McNeil shut the Fort Washington plant on May 6, the same day that the FDA issued a scathing inspection report slamming conditions at the facility.

Prior warnings

McNeil, which has issued five recalls of its cold and pain relief products over the past eight months, is currently being investigated both by the FDA and lawmakers.

At a congressional hearing last month, a senior FDA official spoke about the agency's 'growing concerns about the quality of the company's manufacturing process.'

'These concerns have led to a number of unsatisfactory inspections and consumer recalls,' said Joshua Sharfstein, principal deputy commissioner at the FDA.

Sharfstein said that in recent [] years the FDA identified several problems with manufacturing processes at facilities run by McNeil, including laboratory controls, equipment cleaning processes and a failure to investigate identified problems.

Some previous FDA inspection reports of the Fort Washington facility obtained by CNNMoney chronicle such problems – including repeat offenses.

The FDA typically conducts an inspection of a drug manufacturing facility once every two years, but the agency can increase the frequency.

In McNeil's case, safety inspections were on a routine cycle until 2008, after which the FDA stepped up its oversight of the Fort Washington plant.

An inspection report from December 2003 noted a mislabeling problem related to some lots of children's soft-chew Tylenol. The report said the packages of the product listed an incorrect amount of an ingredient per tablet. McNeil did not recall the affected products but destroyed and relabeled the products that had not yet been released into the market.

In January 2006, FDA inspectors noted that some equipment used to make drugs had not been properly cleaned.

Another report from February 2008 listed what appear to be more serious problems, such as insufficient follow-up and investigation of consumer complaints.

In May 2009, inspectors once again highlighted deficiencies including incomplete investigations into contamination of raw materials. More broadly, the report said that laboratory controls at the Fort Washington plant 'do not include the establishment of scientifically sound and appropriate sampling plans to ensure that components conform to appropriate standards of identity, strength, quality and purity.'

Additionally, the report said that procedures describing oral and written complaints against drug products made at the plant were not being followed.

Both of these issues are serious violations, according to drug manufacturing experts.

'It seems that from 2006 and 2009, quality and safety issues worsened at the plant,' said one expert who did not want to be named. 'It looks like there was a change in the quality assurance management at this facility during that time. Something as little as that can have a big impact on the entire operation.'

McNeil declined to comment for this article.

Since it temporarily shut production at the plant last month, the company said that it is taking steps to bring its operation 'back to a level of quality that Johnson & Johnson demands of its companies.'

McNeil also said the company has made significant organizational changes but did not provide details about the changes.

45. On June 24, 2010, McNeil issued a press release that stated in relevant part:

McNeil Consumer Healthcare, division of McNeil-PPC, Inc., a Johnson & Johnson company, today announced that it does not anticipate having sources of supply before the end of 2010 for most of the products that were produced at its Fort Washington, Pennsylvania manufacturing facility. Operations at the Fort Washington plant were suspended in connection with the recent recall of infants' and children's liquid over-the-counter (OTC) products manufactured there. The suspension of manufacturing also impacted adult OTC products manufactured at that facility. The majority of McNeil's U.S. OTC business is not impacted by the ongoing suspension of manufacturing at the Fort Washington plant.

As previously announced, the company is conducting a comprehensive quality assessment across its manufacturing operations, and has identified corrective actions that will be implemented before manufacturing resumes at the Fort Washington plant. McNeil has not yet finalized plans for resumption of production at the facility. The average annual sales of the products manufactured at this facility over the last three years were approximately \$650 million.

46. On July 8, 2010, McNeil issued a press release that stated in relevant part:

McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is recalling 21 lots of over-the-counter medicines. The lots involved ... are sold in the United States, Fiji, Guatemala, Dominican Republic, Puerto Rico, Trinidad & Tobago, and Jamaica. This action is a follow-up to a product recall that McNeil Consumer Healthcare originally announced on January 15, 2010, which was initiated following consumer complaints of a musty or moldy odor, which has been linked to the presence of trace amounts of a chemical called 2,4,6-tribromoanisole (TBA). The risk of serious adverse medical events is remote. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

These lots are being added to the list of recalled products as a precautionary measure after a continuing internal review determined that some packaging materials used in the lots had been shipped and stored on the same type of wooden pallet that was tied to the presence of TBA in earlier recalled lots. All lots involved in the recall were produced before the January 15, 2010 recall, after which McNeil stopped accepting shipments of materials from its suppliers on that type of pallet.

Consumers who purchased product from the lots included in this recall should stop using the product and contact McNeil Consumer Healthcare for instructions on a refund or replacement.

47. On July 19, 2010, *CNNMoney.com* reported as follows:

Johnson & Johnson, already under fire from the government over deplorable conditions at a Pennsylvania plant that makes children's pain and cold drugs, is now being cited for problems at another one of its drugmaking plants in the state.

A plant located in Lancaster, Pa., was recently inspected by the Food and Drug Administration and failed to receive a clean bill of health, according to the company.

The Lancaster facility received what is called a 'Form 483.' A Form 483 is issued after an FDA inspection yields unsatisfactory results for compliance with regulations or a violation of good manufacturing practices.

The FDA regional office in Philadelphia did not return calls seeking details about the observations made in the report. However, Johnson & Johnson confirmed that the company has received it.

48. On July 20, 2010, JNJ held a conference call for investors. On that call, JNJ's Vice President of Investor Relations, Louise Mehrotra, stated in relevant part:

For the second quarter of 2010 sales for the over-the-counter, or OTC, pharmaceuticals and nutritionals decreased 13.4% on an operational basis compared to the same period in 2009, with US sales down 27.5% and sales outside the US up 1.9% on an operational basis. Sales were impacted by the voluntary recalls announced earlier this year and suspension of production at the McNeil Fort Washington, Pennsylvania facility.

* * *

Regarding the Fort Washington facility, operations at this plant were suspended in connection with the recall of infants and children's liquid OTC products manufactured there. The suspension of manufacturing also impacted adult OTC products manufactured at that facility. As was previously announced, we do not anticipate having ultimate sources of supply before the end of 2010 for most of the products that were produced at this site.

Alternate supply of the remainder of these products is projected to start in the first quarter of 2011

* * *

[T]here are a variety of ongoing legal actions in connection with the recall, including the initiation of lawsuits against McNeil and the ongoing governmental investigation into circumstances regarding the recall. *We continue cooperating with the government's investigation and requests for information, including the receipt of a grand jury subpoena from the US Attorney's Office for the Eastern District of Pennsylvania.* (Emphasis added).

49. On the same call, defendant Caruso, JNJ's CFO, stated in relevant part:

While our estimates on healthcare reform have not changed, we now face new additional impacts from the McNeil Consumer product recalls and the suspension of production at McNeil's Fort for Washington, Pennsylvania facility, as well as pricing pressures primarily in the pharmaceutical sector that are accelerating in Europe. Two items that could not have been previously contemplated.

Let me explain the estimated impact of these two items. Turning to sales. While the majority of the McNeil's US OTC business has not been impacted by these recalls or the suspension of manufacturing at the Fort Washington facility, the negative impact on our annual sales from not shipping products produced at this facility is estimated at approximately \$600 million.

In the second quarter, as many of you have been noting, the healthcare industry has started to see the initial signs of additional pricing pressures resulting from increased cost containment efforts in Europe, which we expect to accelerate for the remainder of the year, with an estimated negative impact to sales of approximately \$200 million for 2010.

Given these two additional factors, we would be comfortable with your models reflecting an operational sales increase on a constant currency basis of approximately 1% for the year. This is lower than our previous guidance, reflecting the impact of the two new developments I just mentioned.

50. Also on the same call, defendant Caruso engaged in the following colloquy:

[Analyst]: A couple of questions. First, I know you don't give the product line detail, but when you look at the change in the guidance there is a lot of moving parts. I would assume that the gross margin is taking the majority of the pressure here from – obviously from the pharma pricing pressure in Europe, but also McNeil. Is that a fair assumption?

Caruso: Yes, that is a very fair assumption.

51. On this news, shares of the Company's stock declined nearly \$1.00 per share, or 1.67 percent, to close on July 20, 2010 at \$58.58 per share, on heavy trading volume.

52. On July 21, 2010, the FDA issued another scathing report regarding JNJ. As reported and summarized by *Reuters*:

- Different Pepcid flavors found in same packages
- FDA cites test procedures, complaint handling
- Analyst cites remote risk plant could be shut down
- J&J shares down 2.5 percent

U.S. inspectors found problems with test procedures, record-keeping and handling of consumer complaints at a Johnson & Johnson and Merck & Co manufacturing plant in Lancaster, Pennsylvania, a report released on Wednesday said.

The U.S. Food and Drug Administration report noted numerous instances where consumers complained that different products were packaged together, for instance berry-flavored Pepcid chewable antacid tablets were mixed in with mint-flavored Pepcid tablets.

Shares in J&J, which runs the plant as part of a joint venture with Merck, fell 2.5 percent. Merck slipped 1.3 percent. The facility makes widely used consumer brands, including heartburn drugs Pepcid and Mylanta.

‘How do you get mint into berry if you’re controlling your manufacturing process?’ said Jan Wald, an analyst with Noble Financial Capital Markets who predicted it could be costly for J&J to fix the litany of quality control lapses cited in the new report.

J&J is grappling with quality control lapses at two of its other plants that have forced it to recall tens of millions of bottles of Tylenol and other popular consumer medicines.

On Tuesday, J&J said the massive recalls would trim its full-year earnings and said it was the subject of a criminal investigation by the U.S. prosecutor in Philadelphia.

Morningstar analyst Damien Conover said there is ‘a remote chance’ the problems at the Lancaster plant, enumerated by the FDA on Wednesday, could also force J&J to shut it down.

‘Today’s report highlights the problems, which make J&J’s situation a little more hairy,’ Conover said. ‘But it’s hard to tell if they will warrant suspension or closure of the Lancaster facility.’

FDA SAYS INFORMATION WAS HARD TO GET

The new FDA report listed 12 shortcomings uncovered by agency inspectors who visited the Lancaster site in late June and early July.

Records related to drug production ‘were not made readily available for authorized inspection,’ the report said. FDA inspectors said they had to request information on specific topics as many as 10 times before receiving full information.

‘Clearly the FDA doesn’t feel the responses to their questions were timely, or in some cases adequate and thinks the quality control processes were not effective,’ said Wald.

Overall, Wald said the FDA observations focus on the quality of documentation being performed at the plant, rather than dirt or contaminated products – more serious types of problems cited by FDA at the now-closed J&J Fort Washington, Pennsylvania plant.

J&J on Tuesday cut its 2010 profit forecast because of the repeated recalls of painkillers Tylenol and Motrin and the allergy drugs Benadryl and Zyrtec and the expense of revamping the deficient Fort Washington plant. J&J said the facility will be out of commission until the second half of 2011.

Johnson & Johnson on Monday confirmed it had been cited by regulators for problems at the Lancaster plant. On Wednesday, the company repeated an earlier statement that it ‘takes the issues raised by the agency seriously’ and will address the concerns as quickly as possible. (Emphasis added).

53. On this news, shares of the Company’s stock declined \$1.46 per share, or 2.5 percent, to close on July 21, 2010 at \$57.12 per share, on heavy trading volume.

54. In total, from the April 30, 2010 recall to the day before the July 20, 2010 conference call, JNJ’s stock price declined over 8.3 percent. On July 20, 2010, the day of the Company’s conference call, and the following day, the Company’s stock price declined another 4 percent.

55. On August 11, 2010, JNJ filed its Form 10-Q with the SEC for the second quarter of 2010. In the filing, JNJ disclosed that the Company was subject to civil investigative demands from multiple state Attorneys General offices regarding the recall of various products of McNeil Consumer Healthcare, and the FDA inspections of the Fort Washington, Pennsylvania and Lancaster, Pennsylvania manufacturing facilities.

56. Defendants’ Class Period statements were materially false and misleading for failing to disclose the following:

(a) Starting in April of 2008, defendants received numerous consumer complaints that Tylenol products made at a manufacturing facility in Las Piedras, Puerto Rico exhibited a

“musty” odor. Despite being aware of these complaints, defendants failed to conduct an adequate investigation and failed to notify the U.S. Food and Drug Administration as required;

(b) Defendants failed to take corrective action when foreign materials and contamination were found in a manufacturing facility in Fort Washington, Pennsylvania from May 2009 to April 2010. Similarly, defendants ignored 46 separate complaints of foreign materials in products made at that facility from June 2009 to April 2010; and

(c) In late 2008, defendants learned of potential problems with one of its Motrin products. Rather than issue a public recall, defendants sent contractors out to stores to buy the product back and told the contractors not to mention any recall. After the FDA learned of this “phantom recall,” it pressured defendants to publicly recall the products.

57. On August 19, 2010, defendant Weldon told *The Wall Street Journal* that the McNeil unit was an “outlier” and that the quality control problems that led to the recalls were localized to that unit. Just six days later, however, JNJ announced the recall of several million disposable soft contact lenses produced by Vision Care, a different division of JNJ.

SCIENTER

58. During the Class Period, defendants had both the motive and opportunity to conduct fraud. They also had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of JNJ securities during the Class Period.

LOSS CAUSATION/ECONOMIC LOSS

59. During the Class Period, as detailed herein, defendants made false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially

inflated the price of JNJ's securities and operated as a fraud or deceit on Class Period purchasers of JNJ securities by misrepresenting the Company's business. Later, when defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of JNJ's securities fell precipitously, as the prior artificial inflation came out of the price over time. As a result of their purchases of JNJ securities during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

NO SAFE HARBOR

60. JNJ's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

61. Defendants are also liable for any false FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false and the FLS was authorized and/or approved by an executive officer of JNJ who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

62. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- (b) The omissions and misrepresentations were material;
- (c) The Company's stock was traded in an efficient market;
- (d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock; and
- (e) Plaintiff and other members of the Class purchased JNJ stock between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

63. At all relevant times, the market for JNJ stock was efficient for the following reasons, among others:

- (a) As a regulated issuer, JNJ filed periodic public reports with the SEC;
- (b) JNJ regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services; and
- (c) JNJ stock was actively traded in an efficient market, namely the NYSE, under the symbol "JNJ."

CLASS ACTION ALLEGATIONS

64. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased JNJ securities during the Class Period (the "Class"). Excluded from the Class are defendants, directors and officers of JNJ and their families and affiliates.

65. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to

the parties and the Court. JNJ had more than 2.8 billion shares of stock outstanding, owned by thousands of persons.

66. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) Whether the 1934 Act was violated by defendants;
- (b) Whether defendants omitted and/or misrepresented material facts;
- (c) Whether defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;
- (e) Whether the prices of JNJ securities were artificially inflated; and
- (f) The extent of damage sustained by Class members and the appropriate measure of damages.

67. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

68. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

69. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

COUNT I
(For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants)

70. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

71. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

72. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- (a) Employed devices, schemes, and artifices to defraud;
- (b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

- (c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of JNJ securities during the Class Period.

73. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for JNJ securities. Plaintiff and the Class would not have purchased JNJ securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

74. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of JNJ securities during the Class Period.

COUNT II
(For Violation of §20(a) of the 1934 Act Against All Defendants)

75. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

76. The Individual Defendants acted as controlling persons of JNJ within the meaning of §20(a) of the 1934 Act. By virtue of their positions and their power to control public statements about JNJ, the Individual Defendants had the power and ability to control the actions of JNJ and its employees. JNJ controlled the Individual Defendants and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

WHEREFORE, plaintiff demands judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding plaintiff and the members of the Class damages and interest;
- C. Awarding plaintiff's reasonable costs, including attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

Dated: September 21, 2010

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all issues so triable.

Dated: September 21, 2010