# Johnson & Johnson recalls more over-the-counter medicines

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For the past several months, a recall crisis has been developing at the Johnson & Johnson company over serious quality control problems in over-the-counter medicines. Since last September, the Food and Drug Administration (FDA) has received hundreds of complaints concerning Johnson & Johnson medicines, which have involved seven fatalities.

The recalls have centered on such well-known brands as Tylenol, Motrin, Benadryl and Zyrtec, as well as children's version of some of these products, which possibly contain metal particles and chemicals used to treat plywood.

The most recent product recalls began in December 2009 when McNeil Consumer Healthcare, a division of Johnson & Johnson, received consumer complaints of "an unusual moldy, musty or mildew-like odor that, in a small number of cases, was associated with temporary and non-serious gastrointestinal events. These include nausea, stomach pain, vomiting, or diarrhea," in Tylenol brand arthritis medicines.

On January 15, 2010, McNeil issued a press release announcing the recall of several other medicines, including Motrin products, Benadryl Allergy Ultratabs, Rolaids antacid tablets and Simply Sleep products. The press release states that the unpleasant odor comes from trace amounts of a chemical called 2,4,6-tribromoanisole (TBA), a derivative of a pesticide and fire-retardant used in the manufacture of packaging materials.

According to a warning letter from the FDA to the president of J&J subsidiary McNeil Consumer Healthcare dated January 15, 2010, the company began receiving complaints of the unpleasant odor in its products in 2008. The company did nothing for four months, during which period additional complaints were received. Then, after J&J determined that the odor's cause was not microbial, it closed the investigation in August of that year.

By August 2009 the company had received 112 complaints of the odor. By September internal testing pointed to TBA contamination, but the result was not made available to the FDA even after several requests. The letter concludes that J&J was possibly in violation of federal pharmaceutical manufacturing regulations for failure to report abnormalities to the FDA within three working days and for failure to conduct a timely and thorough investigation of contaminated batches of product.

The FDA recently disclosed that it had issued a warning in March to a Johnson & Johnson subsidiary, Advanced Sterilization Products, for failing to correct problems with sterilizing devices.

In another press release on April 30, McNeil announced a recall of children's and infants' Tylenol and Motrin products, as well as children's Zyrtec and Benadryl allergy medicine, which did not meet quality control standards. Some included too much of the active ingredient, while others contained "tiny particles." The company issued yet another recall announcement in June, for more Benadryl and Extra Strength Tylenol Gels the company had "failed to include" in the January recall.

A May 27 article in the *Los Angeles Times* used local tax documents to show huge layoffs at McNeil's Fort Washington, Pennsylvania, plant, which produces the Children's Tylenol affected by the recall. The company cut at least 478 jobs from the end of 2005 to the end of

2009. The article also noted an FDA report that contract employees and temporary workers were not properly trained. Thus, the decline in product quality standards has coincided with layoffs and other attacks on company workers.

A May 27 hearing of the House Committee on Oversight and Government Reform revealed the enormity of the recall, as well as the company's cover-up efforts. The scale of the recall, which J&J had repeatedly put at 6 million bottles of products, now appears to be more than 20 times larger, at 136 million bottles. Over the course of the committee's investigation of J&J, the company was repeatedly admonished for failure to produce relevant documents and to otherwise fully cooperate with investigators.

One particularly egregious facet of the McNeil recalls is the company's handling of the situation when top executives knew about the tainted products. According to company emails, executives decided in 2009 against a recall of Motrin vials and instead hired "mystery shoppers"—private contractors posing as regular consumers—to simply purchase the products back from retailers.

At the May 27 hearing, Johnson & Johnson Chairman Colleen Goggins stated that she had no knowledge of the "phantom recall." But the *New York Times* reports that in just one 2009 purchase order, an outside contractor received $487,500 for visiting 5,000 US stores to purchase the tainted products.

One document produced to the House committee was an instructional memo for "mystery shoppers." Titled "CSCS Motrin Purchase Project June, 2009," the document highlights the deceptive and ultimately unsafe methods by which Johnson & Johnson's contractors bought up questionable products.

The following excerpt largely speaks for itself:

"**OBJECTIVE**: to visit all the stores on your schedule; locate and purchase all of the Motrin IB Caplet 8ct Vial product in the store, bagging the product by store (with receipt)…and returning to the manufacturer…. 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!** If asked, simply state that your employer is checking the distribution chain of this product and needs to have some of it purchased for the project."

The obvious danger that some products had been purchased already, and that others, no doubt, would be absent a public recall announcement, was thus outweighed by the company's financial interest in protecting its brand name.