

The Truth  About Health

Once Again, a Pharmaceutical Company Risks Your Health to Maintain its Profits

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In early May 2010, The Food and Drug Administration announced a voluntary recall of Johnson & Johnson products manufactured by their McNeil Consumer Healthcare Division.

Covered by the recall were liquid infant's and children's Tylenol ®, Motrin ®, Zyrtec ®, and Benadryl®.

In the 11 months prior to the recall, the company had received 46 consumer complaints about black specks or foreign material in these drugs. The FDA met with the manufacturer in February 2010 and in April, FDA inspectors walked into the manufacturing plant for an investigation. The day the investigation's report was issued, Johnson & Johnson announced its "voluntary" recall.

Tests showed that mixing equipment performed inadequately to completely distribute ingredients, meaning that some bottles of medication would contain more or less active ingredients than others.

Not only that, but the FDA inspectors also found manufacturing equipment covered with dirt, dust and grime, a hole in the ceiling and poor and unsanitary maintenance practices in the facility that made 40 of the recalled products. The McNeil plant in Pennsylvania has been shut down until all manufacturing issues have been handled.

The FDA criticized Johnson & Johnson for not doing all it could to promptly investigate reports of contaminants, eliminate any manufacturing conditions that could produce contamination and not ensuring that contaminated ingredients were kept out of any other products than those covered by the recall.

On May 4, 2010, the FDA held a telephone conference with media representatives, during which the press could ask direct questions. One after another, reporters asked what the contaminants were and how much risk for consumers they presented. Again and again, the FDA only responded that the contaminants were "gram-negative bacteria" and that tests to identify which bacteria were not yet conclusive. FDA staffers also repeatedly stated that the risk to consumers was "remote." But the list of gram-negative bacteria include these well-known and dangerous bacteria: E.coli, Salmonella, Shigella, Pseudomonas, Helicobacter, Legionella and organisms that cause gonorrhea and meningitis.

Not such insignificant bacteria!!

If you are curious about what an FDA investigation report looks like, visit this web page:
[http://www.fda.gov/downloads/AboutFDA/Centers
Offices/OR/ORAElectronicReadingRoom/UCM
210772.pdf](http://www.fda.gov/downloads/AboutFDA/CentersOffices/OR/ORAElectronicReadingRoom/UCM210772.pdf)

Source: Transcript for the FDA Media Briefing on the McNeil Product Recall, May 4, 2010, [http://www.fda.gov/downloads/NewsEvents/News
room/MediaTranscripts/UCM211061.pdf](http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM211061.pdf)

Source: Wikipedia, Gram-Negative Bacteria, April 29, 2010, <http://en.wikipedia.org/wiki/Gram->

negative bacteria

Source: Food and Drug Administration, FDA provides consumer advice following recall of products for infants and children, May 1, 2010, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210441.htm>

Source: Food and Drug Administration, Inspection report, April 30, 2010, <http://www.fda.gov/downloads/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/UCM210772.pdf>