STATEMENT OF
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COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

"Johnson & Johnson's Recall of Children's Tylenol and other Children's Medicines."

May 27, 2010

Good morning and thank you for being here.

Any time we give our children or grandchildren medicine, we expect it to be safe and we expect it to help our children get better.

When questions are raised about whether children's medicine is safe, parents need immediate answers. Almost every household in this country has these children's products in their medicine cabinets. And everyone has the same questions: Are these products safe, and what are we doing to ensure safety in the future.

While we do not want to cause unnecessary alarm, we also cannot ignore the troubling facts before us.

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?

We need to know what health risks are associated with this recall. We need to know whether this is an isolated issue, or part of a widespread problem with the safety and production of children's medicine at McNeil. We need to know what Johnson & Johnson is doing to get to the bottom of this. And we need to know what the FDA is doing to ensure the safety of children’s medicine and whether the FDA has the resources it needs to carry out its mission.

Both Johnson & Johnson and the FDA will be asked very difficult questions today and I hope they are prepared to give us the answers we need.

This is our first hearing on this issue, but there may be more. We will follow this road until we have all the answers the American people deserve.

There is nothing this Committee will investigate that is more serious than the health of our children. I can assure you that as Chairman of this Committee – and I know that I also speak for the Ranking Member when I say this – we will use all of our authority to find out what went wrong and do everything we can to ensure that it doesn't happen again.

Thank you.

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