OPENING STATEMENT

CHAIRMAN EDOLPHUS TOWNS
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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"Johnson & Johnson's Recall of Children's Tylenol and other Children's Medicines and the Phantom Recall of Motrin" (Part 2)

Good morning and thank you for being here.

This is our second hearing on the disturbing recall of children's medicine by Johnson and Johnson.

At our first hearing we learned that J&J's April 30th recall of Children's Tylenol, Children's Motrin, Children's Benadryl and Tylenol Infants' Drops was the largest recall of children's medicine in history. More than 135 million bottles of children's medicine were recalled.

We also learned that there wasn't just one recall. We heard testimony about rolling recalls, a phantom recall, a plant shut-down, and management firings.

Since then, we have obtained additional documents which raise troubling questions about both the accuracy of J&J's earlier testimony and the extent of the "phantom recall."

When Johnson & Johnson learned it had a problem with one of its adult Motrin products in 2008 and 2009, the company hired contractors to go into stores and buy the product off the shelves – without saying it was a recall – so that the public and the news media wouldn't know what was really happening.

When J&J was asked about this phantom recall at our first hearing and about the behavior of its contractors, we were basically told that J&J didn't know what the contractors were doing.

However, documents subsequently obtained by the Committee show that J&J dictated how the phantom recall would be carried out. Internal emails and other documents indicate that J&J clearly knew what it was doing and why.

For example:

Referring to the problems with Motrin that resulted in the phantom recall, one McNeil executive said, "we are just trying to prevent a recall and a lot of expended $."

In another email, a McNeil executive refers to the phantom recall and says, "this was a major win for us as it limits the press that will be seen."

Finally, it appears the president of the company gave the go-ahead for the phantom recall, saying: "Let's make this happen asap."

Perhaps we can clear up this apparent discrepancy between J&J's testimony in May and the documents that have come to light since.

J&J has said the FDA knew about and approved the phantom recall, but the FDA says that isn't true. Both sides will have an opportunity to tell their sides of the story today.

But even if the FDA was technically aware of it, that does not excuse what Johnson & Johnson did. Johnson & Johnson had both the legal and moral obligation to do the right thing, and they did not. And the FDA does not have the legal authority to force a recall.

There are also new questions. Our investigation has uncovered documents that show J&J hired the phantom recall contractors to perform work related to Children's Tylenol. In light of

what we now know about the phantom recall of adult Motrin, I think J&J has a duty to fully explain how it handled problems with children's medicine.

Finally, the troubling issues about rolling recalls and phantom recalls that this hearing examines makes one point very clear: Even if the FDA had been notified about the Motrin problem, the agency did not have the legal authority to order a recall.

This needs to be rectified. **The FDA needs mandatory recall authority**.

I think most people would be surprised to learn that the FDA – the agency that is responsible for ensuring drug safety – has no power to order a company to recall its defective drugs. This is why I introduced a bill that would give the FDA mandatory recall authority. Hopefully we can avoid future phantom recalls and empower the FDA to take action to protect the American people.

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

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