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## **Towns, Issa Ask FDA for Answers on Pediatric Medication Recall**

WASHINGTON – Chairman Edolphus “Ed” Towns (D-NY) and Ranking Member Darrell Issa (R-CA) are requesting information from the Food and Drug Administration (FDA) related to a recent major voluntary recall of popular over-the-counter pediatric medication by McNeil Consumer Healthcare (a subsidiary of Johnson & Johnson), the manufacturer and marketer of well known over-the-counter and prescription pharmaceuticals. Yesterday, Towns and Issa announced the committee’s investigation into the circumstances surrounding the recall of more than 40 over-the-counter medications including Children’s Tylenol, Infants’ Tylenol and Children’s Motrin, as Food and Drug Administration (FDA) inspectors were completing a nearly two-week long inspection of McNeil’s Fort Washington, Pennsylvania plant where the medication is produced.

This recall was the third major quality-related recall made by McNeil in the last eight months. The first recall occurred in September 2009 when McNeil recalled infant and children’s Tylenol products because an inactive ingredient did not meet quality standards. Then, in November 2009, five lots of over-the-counter Tylenol arthritic pain medication were recalled after an unusual moldy, musty, or mildew-like odor in these products caused reports of nausea, stomach pain, vomiting, and diarrhea. This recall was expanded in December 2009 to include all product lots of this medication. This recall was further expanded once again in January 2010 to include a variety of other over-the-counter products.

“Taken together, these recalls point to a major problem in the production of McNeil products,” said Towns and Issa. “Given McNeil’s questionable track record and consecutive recalls, we need to understand what prior actions the FDA took to address McNeil’s quality control problems and what events led the FDA to its April 2010 inspection of McNeil’s Fort Washington plant.”

It has been reported that FDA has been working with McNeil since May 2009 to address its manufacturing problems. According to one report, FDA met with McNeil in February to express its concerns about McNeil’s production practices and had assured FDA that it was addressing its problems. A clarification of the timing of the events that spurred the recall is important in understanding both McNeil’s and FDA’s response to the problem.

FDA's most alarming finding was that raw materials used to make these infant and children's products were contaminated with potentially harmful bacteria. According to FDA, the bacteria have not been found in any finished product and no illnesses or deaths have been reported.

Towns and Issa said, "We are deeply concerned about the recall of popular pediatric medications that millions of families have grown to rely on and stocked in their medicine cabinets. A recall of this nature, especially when it involves children, calls for swift action and cooperation from all parties. We look forward to receiving the FDA's response to our inquiry. The American people deserve answers and we intend to get to the bottom of this matter."

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### **Documents and Links**

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[Letter from Chairman Towns and Ranking Member Issa to the Hon. Margaret A. Hamburg, M.D.](#)

[Letter from Chairman Towns and Ranking Member Issa to Mr. William Weldon](#)