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United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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<http://help.senate.gov>

May 24, 2010

Margaret Hamburg, M.D, Commissioner
U.S. Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Hamburg:

I am writing to express deep concern over the recent recall of more than 40 medications for infants and children manufactured by Johnson & Johnson's McNeil Consumer Healthcare unit. I commend you for FDA's leadership in responding to this crisis, both in terms of your outreach to the public and your increased regulatory activity. However, I am interested in ensuring that, as a public health agency whose mission is to protect the American public, you have sufficient authority to prevent and respond to contamination of the drug supply. I am especially concerned because so many of the drugs at issue in this recall were intended for infants and children.

This recall is only the most recent in a series of disturbing events associated with products sold by the company since September 2009.

- September 2009: McNeil recalled products contaminated with bacteria.
- October 2009: McNeil products were stolen from a cargo terminal in Jacksonville, Florida, and the public was advised not to use the products.
- December 2009: After consumer complaints reaching as far back as 2008, McNeil recalled products due to a musty odor.
- May 2010: McNeil recalled children's products because they were sub- and super-potent, contained particles, included base ingredients that did not meet internal testing requirements, and were contaminated with gram-negative bacteria. According to the Centers for Disease Control and Prevention, the bacteria, later identified as *B. cepacia*, are often transmitted by contaminated medical products and are often resistant to common antibiotics. Despite at least 46 consumer complaints in the last year, McNeil did not initiate the recall until May, following an inspection by FDA.

I appreciate that consumers were strongly advised to discontinue use and discard the products. However, the formulations recalled in May were intended for infants and children, who, depending on their age and cognitive development, may not be able to adequately communicate problems to their parents and caregivers. Parents and caregivers, in turn, may not be likely to attribute potential health problems to a product they use for colds, pain, and fevers.

In light of the manufacturing problems you have uncovered at McNeil and the particular vulnerability of populations who consume many of the products at issue, I am requesting responses to the following questions related to this situation:

Regarding inspection and recall:

- Does the contamination of McNeil's products present a safety risk to consumers? Could similar manufacturing failures result in situations that present a safety risk to consumers?
- Did FDA request that McNeil initiate the voluntary recall in May?
- Did McNeil object in any way to initiating the recall?
- Had McNeil refused to recall the products, could FDA have compelled a recall?
- Was there anything in this process that delayed your ability to inspect the facility or recall the products in a timely fashion?
- Does FDA need additional authority to respond to this sort of a situation?

Regarding adverse events reporting and consumer complaints:

- At what point was FDA notified of consumer complaints regarding children's products manufactured by McNeil?
- Are the systems for reporting adverse events and consumer complaints adequate?
- Does FDA need additional authority to improve these processes and respond to consumers' safety concerns regarding medical products?

Regarding internal testing requirements:

- Does McNeil have written procedures for production and process controls at its facility in Fort Washington, Pennsylvania?
- If so, did McNeil follow these procedures?
- Do you need additional authority in this area to ensure that drugs are made according to current Good Manufacturing Practice?
- CDC has indicated that *B. cepacia* are often resistant to common antibiotics. Does the presence of these bacteria in ingredients pose any health risk to consumers and are the bacteria, which were detected, resistant to antibiotics?

Regarding the safety of drug ingredients:

- On how many occasions did McNeil receive ingredients from FMC or any other vendor that had been associated with bacterial contamination?

- Is it true that McNeil identified bacterial contamination in ingredients received from FMC as early as 2009?
- What, if anything, did McNeil do to test incoming shipments from FMC for purity?
- Did McNeil's practices with respect to FMC comply with current Good Manufacturing Practice?
- What regulatory requirements apply to oversight of the ingredients used to make drugs?
- What requirements, if any, apply to oversight of the supply chain for ingredients?
- Does FDA need additional authority in this area to better protect the public health?

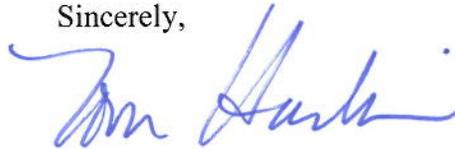
Regarding additional regulatory action:

- What additional action are you considering with regard to Johnson & Johnson, McNeil, or FMC?
- Does FDA have adequate penalties and remedies to respond to this situation or others like it?
- Do you perceive anything under your current authorities that delayed your ability to adequately respond to this situation?
- If so, what additional authorities do you need?

Please respond to these questions by June 11, 2010.

If you have any questions about this request, please contact Tom Kraus or Bill McConagha at 202-224-7675 or Beth Stein at 202-224-4493.

Sincerely,



Tom Harkin, Chairman
U.S. Senate Committee on
Health, Education, Labor and Pensions