



STATEMENT OF

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

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U.S. HOUSE OF REPRESENTATIVES

HEARING ON

“JOHNSON & JOHNSON’S RECALL OF CHILDREN’S

TYLENOL AND OTHER CHILDREN’S MEDICINES & THE

PHANTOM RECALL OF MOTRIN (PART 2)”

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Introduction

Mr. Chairman and Members of the Committee, I am Dr. Joshua M. Sharfstein, Principal Deputy Commissioner of the Food and Drug Administration (FDA or the Agency), an agency of the Department of Health and Human Services. Thank you for the opportunity to discuss the McNeil Consumer Healthcare, LLC (McNeil) recalls and the Agency's role with respect to recalls.

In May, your Committee's hearing focused on the serious quality lapses at two McNeil production facilities, which led to several large recalls of over-the-counter (OTC) medications for children and adults. Today, I would like to provide a brief update on FDA's investigation of these problems and then address what some have called the "phantom recall."

First, FDA has continued to investigate whether any serious illnesses or deaths have been linked to the recalls. Since the last hearing, FDA has extensively investigated adverse events reported to FDA and McNeil citing the products that were subject to the recall. This investigation, which covers over 2,400 reports received by FDA for the two-year period immediately preceding the recall, as well as for the two-month period immediately following the recall, does not, overall, establish a direct link to any serious adverse event, including death, and a recalled product.

Second, FDA has worked with McNeil to improve the two facilities at the center of the previous recalls.

- In Puerto Rico, FDA became aware that McNeil had received reports of products from its Las Piedras facility having a musty, moldy odor and that McNeil did not conduct a thorough, timely investigation of the issue or file timely reports. After FDA personnel urged McNeil to conduct a more complete investigation, the firm identified the cause of the odor to be a chemical, called 2, 4, 6-Tribromoanisole or TBA, a pesticide used to treat wooden pallets. FDA issued McNeil a warning letter on January 15, 2010, related to their failure to conduct a thorough, timely investigation of the issue. Since that time, FDA issued guidance and a letter to industry explaining the potential for TBA contamination, inspectional guidance to ensure coverage of the potential for TBA contamination from treated wooden pallets, and a letter providing guidance to specific customers who used components that may have been exposed to TBA. Subsequent investigations by customers contacted by FDA led to additional recalls. McNeil has informed us that the firm has stopped using wooden pallets, cleaned its facilities, and increased its oversight and qualification standards of its suppliers, and FDA has reviewed and commented on these changes. FDA is currently conducting a follow-up inspection of the facility.
- In Pennsylvania, FDA found that McNeil's facility in Fort Washington had not conducted adequate investigations of product problems and complaints. During the April 2010 inspection, the firm announced that it had stopped manufacturing liquid products and would conduct a recall of liquid products associated with excessive particulate matter, potency variability, and possible microbial

contamination. Subsequent to the inspection, the firm held a series of meetings with FDA and identified a series of corrective actions that the company would take across all McNeil facilities. These corrective actions included ceasing all manufacturing and renovation of the Fort Washington facility, remediation of its quality systems, and using a third-party expert consulting firm to review all aspects of the firm's manufacturing and quality changes. FDA is continuing to review and provide feedback to the company concerning these remedial actions.

Third, FDA has inspected additional McNeil facilities in the time since the last hearing. This includes facilities associated with McNeil in Lancaster, Pennsylvania; Lititz, Pennsylvania; and Guelph, Ontario, Canada. As I just mentioned, FDA is currently conducting a follow-up inspection of McNeil's facility in Las Piedras, Puerto Rico. All facilities associated with McNeil have been inspected at least once within the last year. FDA has found inspectional deficiencies of varying degrees of seriousness at all of these facilities. One common concern the Agency has found across these facilities is the failure to investigate and correct product problems in a prompt and thorough manner. McNeil has responded to these observations with a large-scale corrective action plan. FDA is currently reviewing and investigating this plan to ensure that corrective actions are actually effective.

Fourth, FDA has had continued discussions with Johnson & Johnson, the parent company of McNeil, to address the breakdowns in leadership and oversight that led to these serious compliance problems. We recognize that the company is taking the Agency's concerns

seriously, and many changes have been made. FDA intends to keep a close eye on these facilities until the company earns back our confidence.

In February of this year, FDA called an extraordinary meeting with senior executives of Johnson & Johnson. At that meeting, the Agency discussed a number of serious compliance problems at McNeil. More broadly, FDA confronted these executives about whether McNeil's corporate culture supported a robust quality system to ensure the purity, potency, and safety of its products.

As part of that meeting, the Agency raised concerns about what some have called the “phantom recall” of subpotent Motrin tablets in the Spring of 2009. FDA raised this concern because it seemed strange that the company had paid a contractor to go into retail stores across the country to purchase all available product while acting like a regular customer, and not disclosing whether it was a recall. In the Summer of 2009, the Agency told the company that a real recall needed to occur.

Over the last several months, the Committee has investigated this event further, using its authority to gather additional information from the company and the Agency.

Because of this Committee’s investigation, we now understand much more about the events. My understanding comes from documents that have been provided to the Committee by McNeil and FDA. I have not had access to all of the relevant materials gathered in the related criminal investigation.

Based on what we now know, the “phantom recall” raises important questions for Johnson & Johnson, FDA, and Congress.

The current voluntary system of drug recall depends on companies providing accurate and complete information to the Agency, and recalling adulterated or otherwise violative products in a prompt and appropriate manner. As you and other members of the Committee have stated, the new documents raise serious questions about whether the company’s actions met this standard.

Regardless of the behavior of a company, it is FDA’s job to do everything possible to protect the public. It was clear in November 2008 that the Motrin lots did not meet specifications. Yet the actual recall did not happen until early August of the following year. This took too long. Part of this delay can be attributed to several months spent checking whether or not any remaining product was on the shelves. Then, in April 2009, the company sent a report to FDA indicating that it was purchasing product from the shelves of retailers. This communication did not fully disclose the likely scale of the action or the way that the company was intending to proceed. From this point, it took until July for FDA to tell the company that a recall should be conducted. In my opinion, that message should have been given sooner.

FDA has no legal authority to require a manufacturer to recall a drug product that is unsafe or is not in compliance with current Good Manufacturing Practice. The recall

system depends on full and open disclosure, trust, and the industry's acceptance of its responsibilities to protect the public from violative products.

FDA urges and expects firms to notify the Agency when initiating a drug recall, but firms have no legal requirement to provide this type of notification. If a firm does initiate a drug recall, the Agency does not have legal authority to approve the manner in which the firm conducts the recall or to direct the firm to adopt a different recall strategy.

Although the Agency is able to accomplish most drug recalls with the cooperation of the manufacturer, there are instances in which firms are reluctant or unwilling to conduct a recall, or to do so in the time frame that FDA believes necessary and appropriate to protect public health. If a firm refuses to recall violative product, FDA may pursue a remedy in Federal court, such as a seizure, but this can be time-consuming and cumbersome. Under current authorities, when the product has already been widely distributed to hundreds of retail stores, the Agency would need to undertake hundreds of separate seizures in order to ensure that all violative product has been removed from the marketplace.

The events of the "phantom recall" raise important questions about the current voluntary recall system. In this case, if FDA had the authority simply to order a recall to be done in the right way, I do not believe these events would have occurred.

Thank you for the opportunity to testify today, and I look forward to your questions.