Johnson & Johnson

Testimony of

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before the

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Chairman Towns, Congressman Issa, and Members of the Committee, my name is Colleen Goggins, and I serve as the worldwide chairman of the consumer group of Johnson & Johnson. In this position, which I have held since June 2001, I oversee all of Johnson & Johnson's consumer products and serve on the company's executive committee. The product lines in the consumer group include household names like Neutrogena, Aveeno, Listerine, Band-Aid, and Neosporin. I also oversee the over-the-counter products within the consumer group, which includes the pediatric Tylenol, Motrin, Zyrtec, and Benadryl products that were recalled by McNeil Consumer Healthcare on April 30, 2010. McNeil is one of the Johnson & Johnson operating companies. I am pleased to testify on behalf of Johnson & Johnson to present our understanding of the events.

All of the Johnson & Johnson family of companies realize that we have a responsibility to provide consumers with the highest quality products possible, and we have worked hard to fulfill that responsibility for more than a century. We are proud that our products help millions of people around the world improve their health and well-being. Across our organization, we believe our first responsibility is to the doctors, nurses, and patients, to mothers and fathers, and all others who use our products and services. In this instance, we have not lived up to that responsibility, and the recall is therefore a disappointment to our Chairman Bill Weldon, to me personally, and to the thousands of employees in the Johnson & Johnson family of companies.

The quality and process issues that we found at McNeil, those which led to the recall and others, are unacceptable. On behalf of McNeil and Johnson & Johnson, I apologize to the mothers, fathers, and caregivers for the concern and inconvenience caused by the recall. Johnson & Johnson embraces the work of this Committee, and we hope that today's hearing will be an important step in furthering public understanding of the recall.

Consistent with our goal of furthering public understanding, it is critical that the public understand that the recall was not undertaken on the basis of adverse medical events. Unfortunately, there has been some confusion in the media with respect to this recall. I would like to stress, therefore, four key points. First, as the FDA noted last month, the health risks to consumers from the recalled products were remote. Second, McNeil has no indication of a serious adverse medical event caused by any of the issues referenced in the recall announcement. Third, no raw materials that tested positive for objectionable bacteria were ever used in the manufacture of McNeil's pediatric products. And finally, McNeil rejected the products that it found had excess active ingredient.

Because the McNeil products are used by millions of sick children each year, we receive many questions and reports on possible adverse events. We take all of these seriously, assess all of them, and specifically investigate all serious adverse event reports, whether or not the events may have been caused by our products. The mere existence of these normal and expected reports does not alter the medical conclusions of the FDA and our doctors that the safety risk from the recalled products is remote.

The recall last month was implemented because of the presence of minute metal particles detected in a small percentage of products. To be clear, these quality issues, including the minute particles, are unacceptable to us. Johnson & Johnson and McNeil take these issues seriously, and we are committed to taking the steps necessary to bring McNeil's operations back to a level of quality that Johnson & Johnson demands of its companies, and that the public rightly expects of us.

A. The Health Risk to Consumers is Remote

McNeil implemented a broad, precautionary recall of liquid children's and infants' medicines on April 30, 2010, because quality process deficiencies produced tiny metal particles in a small amount of product. The recall was not prompted by adverse medical events, nor was it prompted by safety concerns regarding two additional quality issues referenced in the recall notice – excess concentration of active ingredient, and inactive ingredients that did not meet McNeil's testing requirements. Neither of these issues, nor the tiny particle issue, presented anything other than a remote patient safety issue. This conclusion rests on detailed health assessments that were performed by McNeil and shared with the FDA and that included a wide range of possible assumptions.

First, with respect to the minute particles that were discovered in some products, the health assessment concluded that even if those products were distributed and particles were ingested, the health risk was remote. The tiny particles were inert, small, and sparse. The particles did not present a risk for cuts or tears to the gastrointestinal tract, the assessment concluded. Still, the presence of these particles is unacceptable from a quality perspective.

Second, with respect to products with an excess concentration of acetaminophen, which McNeil rejected, McNeil's medical experts confirmed that even ingestion of the maximum labeled dose, over an extended period of time, with the highest identified level of excess acetaminophen would not present a medical concern.

Third, with respect to raw materials, McNeil tested the raw materials and rejected any containers of raw materials that tested positive for objectionable bacteria. No raw materials that tested positive for objectionable bacteria were ever used in production. In addition, McNeil tested its final products for bacteria and has not identified any products placed on the market that contained objectionable bacteria. Indeed, the McNeil liquid products are specifically designed to resist bacteria, with both a low water activity level and a preservative system that preclude bacteria growth. McNeil tested these attributes and confirmed that the product killed bacteria.

Even though we were relieved that the medical risks were remote, we recognize that quality process deficiencies are important and must be remedied. Tylenol and the other brand

names produced by McNeil are some of the most trusted names in over-the-counter medicine. Millions of families rely on our products to treat those dearest to them.

B. McNeil Implemented a Broad, Precautionary Recall

McNeil acted quickly to implement a broad recall after its discovery of the fine black particles in a one-ounce bottle of a Tylenol product on a production line of the plant in Fort Washington, Pennsylvania. The products with the fine particles were withheld from distribution, and McNeil commenced an immediate internal investigation.

After receiving the results of an outside laboratory analysis, McNeil issued a field alert to the FDA and suspended production of liquid products on all four of the Fort Washington production lines. This field alert provided details on the particles found and the results of the laboratory tests. This field alert was issued several days before the FDA commenced a site inspection of McNeil's Fort Washington facility. Working closely with the FDA during this inspection, McNeil decided voluntarily to recall all of the unexpired liquid products, even though the just-completed health hazard evaluations concluded the recalled products presented a "remote probability" of a serious adverse medical event.

McNeil's records show that no product packaged after the discovery of the fine black particles was released or distributed into the market.

C. McNeil Acted Rapidly in Pulling Products from Shelves and Informing Consumers and Doctors of the Recall

Immediately upon commencing the recall on April 30, 2010, McNeil acted quickly and decisively to work with wholesalers and retailers to ensure that recalled products were removed from shelves, to inform the public of the recall, and to make sure that parents and caregivers stopped giving the recalled products to children.

Even as McNeil was preparing the materials to announce the recall publicly, its personnel began the process of notifying major retail customers. On April 30, 2010, McNeil's personnel reached out to major customers such as Wal-Mart, Target, CVS, Walgreens, Costco, Sam's Club, Rite Aid, and Kroger. That evening, McNeil began to receive confirmations that retailers were taking action, including confirmation that recall information was received by Duane Reade, Rite Aid, CVS (which indicated that it was already in the process of removing inventory from shelves), Wal-Mart (which indicated that it imposed a "PULL AND HOLD" order), and Family Dollar. To reach smaller retailers, McNeil distributed its notices to wholesalers and brokers that specialize in serving small retail outlets. We understand that substantial amounts of recalled products were removed from store shelves that evening and over the ensuing weekend.

To assist retailers and wholesalers, McNeil prepared and distributed numerous documents for the recall. These included a press release, a warehouse and retail customer letter, a recall authorization form and business reply card, shelf signs in multiple digital formats, health care professional questions and answers, and trade questions and answers. McNeil directed warehouses and retail customers to identify all retail and warehouse inventory of the recalled products, remove them from the shelves, and return them to McNeil. In addition, McNeil requested that retailers institute immediate "stop sell" procedures on the recalled products. The

"stop sell" is designed to prevent the UPC code from an individual product being scanned for sale at a retail register.

McNeil's communications also contained toll-free telephone numbers for the recall shipping coordinator and McNeil's customer service. The questions and answers provided information on identifying the recalled products and returning them to McNeil. Similarly, McNeil distributed question and answer information for pharmacists that contained information on returning the recalled products for a refund.

In parallel to its efforts to inform retail customers and wholesalers of the recall, and to remove the products from store shelves, McNeil worked quickly and broadly to announce the recall to the public, provide information to consumers, and ensure that parents discontinued using the recalled products.

McNeil prepared and distributed a press release that was sent to dozens of media outlets, including major broadcast and print media outlets. Many of these media outlets broadcast the recall widely; some news outlets distributed an e-mail alert on the recall, such as *The New York Times*. McNeil's media tracking indicates that there have been more than 2,300 media stories about the recall and dozens of reports on national broadcast television and cable. In the first three days of the recall, April 30 to May 3, our tracking shows that there were more than 143 million media impressions concerning the recall; and from April 30 to May 21, an estimated 362 million impressions.

The McNeil press release advised parents and caregivers that they should not administer these products to their children. The press release also contained a toll-free telephone number and address of the recall website for further information, and it encouraged parents and caregivers to speak with a doctor or pharmacist about alternative treatments.

McNeil established a website dedicated to the recall (www.mcneilproductrecall.com) where consumers could review the press release, request a refund or coupon, learn more about individual products recalled, and read frequently asked questions. The website contains guidance on obtaining additional information over the phone, through e-mail, or with a call back from a McNeil representative. The website has received approximately 3.5 million unique visitors, and it links to individual product sites that provide detailed information about the individual products recalled, including pictures of the products and UPC bar codes.

In addition, the websites for each of the recalled products – Tylenol, Motrin, Zyrtec, and Benadryl – contain prominent notices about the recall. And the Johnson & Johnson home page contains a dedicated box that links to recall information. McNeil even secured priority placement for recall information on Internet search results on likely recall-related search terms (e.g., Tylenol). A Johnson & Johnson company, BabyCenter, one of the most popular websites for new and expectant parents, communicated recall information though e-mail alerts and banner advertisements.

McNeil also used innovative technologies to distribute information about the recall. On "JNJ BTW," the company's blog, Chairman Bill Weldon posted an open letter to consumers with information on the recall, a link to the recall website, and the toll-free customer service telephone number. The Johnson & Johnson feed on Twitter provided a link to this information as well.

The company used Text4baby, a free mobile information service designed to promote maternal and child health, to distribute recall information.

In its press release McNeil broadly disseminated a toll-free telephone number where consumers could obtain information concerning the recall. The call center provided information about the recalled products, the disposal of recalled products, and a list of recalled products by name and code. Since April 30, 2010, the call center has fielded approximately 280,000 calls, and processed an additional 180,000 e-mails. In addition, McNeil has issued approximately 600,000 consumer refunds.

McNeil also distributed multiple letters to health care providers that provide detailed information about the recall, including a list of recalled products (including samples provided to health care professionals), a toll-free telephone contact number, and website addresses for further information. These letters include instructions to stop use of the recalled products. McNeil also sent e-mail alerts to the American Academy of Pediatrics, the American Association of Family Physicians, the American Association of Poison Control Centers, and the American Pharmacists Association concerning the recall. McNeil posted updated information on websites direct to health care professionals (www.tylenolprofessional.com and www.zyrtecprofessional.com).

McNeil's tracking indicates that distributions to health care professionals of its most recent notice included e-mails to 88,000 professionals who registered for communications; facsimiles to 325,000 locations of health care professionals; an electronic marketing alert to 645,000 health care professionals; and direct mail to 35,000 health care professionals not covered by the e-alerts and facsimiles. McNeil's press release and the letters to health care providers included information on reporting adverse medical reactions to the FDA. Health care professionals were also provided with a toll-free telephone number and website addresses to contact the Medical Affairs Department of McNeil.

D. Johnson & Johnson and McNeil are Committed to Improving Quality

Mr. Chairman, I want to stress that, even before the most recent recall, Johnson & Johnson and McNeil have been working together to improve the quality of McNeil's products. The Johnson & Johnson parent company is committed to providing McNeil with the resources and personnel needed to improve quality, work with the FDA, and ensure that the products meet our high standards. Indeed, over the past several years, McNeil's quality expenditures and investments relating to the Fort Washington plant have increased. Johnson & Johnson and McNeil will expend whatever resources are necessary to ensure that this facility provides, once again, high quality medicines.

We also want the public to understand that McNeil had a very detailed testing and quality assurance process even before the recent recall. The quality process included testing by raw material suppliers prior to shipment to McNeil, additional testing of raw materials upon receipt, numerous product testing cycles during production, and testing of final product samples before shipment to the consumer. For example, McNeil tested the levels of active ingredient from the beginning, middle, and end of the production and manufacturing process. These quality tests found the issues referenced in the April 30 press release, but better procedures were appropriate, as the FDA noted. McNeil has committed that it will not restart operations until it has taken the necessary corrective actions and can assure the quality of its products.

McNeil also has detailed processes for assessing and investigating consumer complaints and reports of possible adverse events from its products. McNeil has dedicated drug surveillance and safety groups that maintain detailed assessments of complaints and adverse event reports. Reports of possible serious adverse events, for example, are reported to the FDA quickly. Although the number of complaints and adverse event reports is very small when compared to the millions of liquid medicines produced by McNeil, the company takes each complaint and report seriously and seeks to investigate each one for potential quality improvements.

I would like to address the steps McNeil is now taking to bring its operation back to a level of quality that Johnson & Johnson demands of its companies, and that the public rightly expects of us.

First, even before the most recent recall was announced, McNeil retained an independent third-party expert to assist the Fort Washington facility in identifying immediate, interim, and long-term corrective actions that it needs to take. The third-party expert is a pharmaceutical consulting firm that has expertise in manufacturing and quality systems methodologies and practices.

Second, McNeil is improving processes and employee training in every part of the manufacturing and quality operations, and deploying new procedures and processes for the conduct of quality investigations.

Third, McNeil has also made significant organizational changes in order to augment the quality and operations leadership on the management team and in all McNeil facilities. McNeil appointed a new vice president of quality assurance, appointed a new vice president of operations, appointed a new plant manager at Fort Washington, and hired a new head of quality for the Fort Washington plant.

McNeil and its outside consultant are in the process of developing a comprehensive action plan on quality improvements, which McNeil will share with the FDA by July 15. The basic elements of the plan include the following:

Governance and Management Controls. Governance during the remediation period will include the establishment of a steering committee, which will include members of senior management, charged with guiding and overseeing remediation efforts across McNeil. Each plant will also have a remediation committee that will be responsible for implementing the plan for that plant and monitoring its effectiveness. Achieving long-term improved management control at each site is critical, and will require an evaluation and restructuring where needed of, among other things, the quality control unit, McNeil's development and manufacturing governance processes, and its quality management systems.

Training and Culture of Compliance. McNeil is committed to reinforcing and enhancing the culture of compliance throughout the company. McNeil has already taken actions to set higher expectations of employees and to increase employee focus on identifying underlying causes and finding lasting solutions to issues that arise during daily operations. Further actions to address the culture of compliance under the comprehensive action plan will include strengthened "good manufacturing practices" training program, the development of a leadership training program and enhanced supervisor training, and the establishment of quality goals for all

employees. McNeil also intends to implement measures to improve communications to and among personnel. Employees will be informed of the status of remediation and ongoing efforts on a regular basis through communications that enlist them in facilitating this transformation.

Full Assessment and Improvements. McNeil will conduct a full assessment of the processes, equipment, and facility in Fort Washington, and will assess McNeil's other facilities as part of the plan. McNeil and Johnson & Johnson are fully committed to providing the training, resources and capital investment needed to provide sustainable improvement of quality systems.

Product Assessments. McNeil will conduct in-depth quality assessments for each product McNeil manufactures to ensure each product's ability to meet specifications throughout its shelf life. Product assessments will review, among other things, testing results, stability data, investigation reports, out of specification findings, rejections, and process changes. McNeil will analyze whether additional controls are needed to support the release of products.

Communication with FDA and Interim Actions. McNeil will update the FDA about its progress implementing the plan at least once a month. McNeil also intends to use the support of a third party in making product release decisions during the first six months of operation. Third-party involvement may include review of investigations, complaints, completed batch records, and changes that have the potential to affect products or processes. McNeil is committed to continuing its cooperative and transparent dialogue with FDA.

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Mr. Chairman, I would like to close in the same manner that our company's chairman, Bill Weldon, concluded his letter to the people who use our products: "We will work hard to earn back your confidence."