



Testimony of
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Chairman and Chief Executive Officer, Johnson & Johnson
before the
Committee on Oversight and Government Reform
U.S. House of Representatives

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Chairman Towns, Congressman Issa, and Members of the Committee, my name is Bill Weldon, and I am the Chairman and Chief Executive Officer of Johnson & Johnson. I appreciate the opportunity to appear before you today to describe our efforts over the last several months to address the serious quality issues at McNeil Consumer Healthcare. McNeil is one of the approximately 250 companies in the Johnson & Johnson family of companies.

As you know, I was unable – because of back surgery – to testify at the Committee’s hearing in May. I was grateful for the opportunity to meet with both the Chairman and Congressman Issa, shortly after recovering from surgery, to discuss our response to the recalls. Over the past several months, we have kept you informed about the progress we have been making and the milestones that have been achieved, as well as the challenges that we continue to confront. It is essential that we work closely with Congress, the FDA, and others to restore the public’s confidence in McNeil Consumer Healthcare’s products. This Committee has played an important role in focusing attention on the McNeil issues.

Mr. Chairman, I know that we let the public down. We did not maintain our high quality standards, and as a result, children do not have access to our important medicines. I accept full accountability for the problems at McNeil, and I will take full accountability for fixing them.

After we found a substantial quality issue at McNeil, we instituted a broad and precautionary recall of all liquid children’s products manufactured in Fort Washington, which we did in the interest of protecting consumers. Although our medical experts and the FDA agreed that the health risk was remote, we believed the right course of action was to proceed with a broad precautionary recall and commence a complete reexamination of McNeil’s manufacturing processes. We recognized then, and we recognize now, that we need to do better, and we will work hard to restore the public’s trust and faith in Johnson & Johnson, and strive to ensure that something like this never happens again.

I have spent my entire professional career at Johnson & Johnson. I started with the company in 1971 – right out of college. I began in the sales force before moving into an executive position. I was honored and humbled to be appointed, in 2002, Chairman and Chief Executive Officer of the company. I am very proud to lead Johnson & Johnson, its family of

companies, and its more than 100,000 employees. Our employees are some of the most dedicated, hard working, and committed professionals in the industry. I have given them my personal commitment that we will do whatever is necessary to address the quality concerns at McNeil, bring our important pediatric products back to the market responsibly, and restore the public's confidence in our products.

Indeed, I am pleased to announce that consumers will soon begin to see McNeil liquid pediatric products back on shelves. During the week of October 4, we will begin shipping one of McNeil children's medicine products to our customers. Although it will be available only in limited quantities at first, we have been able to achieve this step by working closely with the FDA and our Canadian affiliate. Almost 1 million bottles will be available for release next week, and we expect to distribute a total of 4 million bottles in the United States by the end of the year.

It is critical that the public have accurate information about what transpired at McNeil and how we came to have a string of product recalls. As Colleen Goggins testified in May, it is important for consumers to know that the April 2010 recall was not undertaken on the basis of reports of adverse medical events. We recalled these products because of Johnson & Johnson's commitment to consumers and its belief that the serious manufacturing issues it uncovered needed to be addressed even though the health risks to consumers were remote.

Today, I would like to describe for the Committee Johnson & Johnson's efforts to address the quality issues that it found at McNeil, and then address two issues raised in your letter inviting me to testify today.

A. Actions Taken To Fix the Problems at McNeil

After we first found the issues that led to the April 2010 recall, we stopped shipping the products, shut down the plant, and issued a broad precautionary recall of all liquid medicines made at Fort Washington. During the hearing in May, Ms. Goggins described the many steps that Johnson & Johnson and McNeil then took to address the issues that led to the recall. First and foremost, we kept McNeil's Fort Washington facility shut down, and we are completely revamping the facility to bring both equipment and procedures up to the high standards that we set for ourselves around the world.

When complete, it is fair to say that the Fort Washington facility will represent the state-of-the-art in medicine production. The facility will not open until we are confident that we can make McNeil products to the high quality standards that the public, Congress, and the FDA rightly expect from us. Across McNeil, Johnson & Johnson is investing more than \$100 million on facilities, equipment, and other improvements to our operations.

Even before the April 2010 recall, McNeil began working with an independent, third-party consulting firm with expertise in manufacturing and quality systems. This third-party expert has assisted McNeil in identifying issues with, and improving, McNeil's manufacturing methods, supply chain management, and overall quality practices. As Ms. Goggins testified, McNeil also made significant organizational changes in the quality and operations leadership on the management team in all McNeil facilities. Already by May, McNeil had appointed a new vice president of quality assurance, appointed a new vice president of operations, appointed a

new plant manager at Fort Washington, and appointed a new head of quality for the Fort Washington plant.

Since the hearing in May, these efforts have only accelerated. We have undertaken significant improvements at McNeil's facilities. We have taken further actions more broadly across McNeil. As Ms. Goggins promised during the May hearing, we submitted a "Comprehensive Action Plan" to the FDA in July. The Comprehensive Action Plan, which applies to all the manufacturing facilities McNeil operates to supply the U.S. market, addresses governance and management controls, training programs, process assessments, and process improvements. We have brought in outside experts to examine our production and quality practices, and they are examining and validating the way we make our products. We have called on our internal experts and brought them into the effort to improve quality across McNeil's facilities. We have improved our supply chain management and oversight to address issues identified in our overall review. And perhaps most importantly, we have committed to regular and detailed communications with the FDA throughout the implementation of the plan. We have been consistently meeting the remediation milestones we set for ourselves with the FDA.

In addition, I have been traveling around the country visiting Johnson & Johnson's manufacturing sites and speaking with the employees on the front lines of our production facilities. Soon, I will be visiting our manufacturing sites around the world. Our employees must know, as I have told them in these meetings, that Johnson & Johnson is dedicated to manufacturing products to the highest standards. As trusted partners in our manufacturing process, I have stressed to our employees the importance of identifying and reporting any issues that they may observe at their facilities.

Finally, Mr. Chairman, we have completed the organizational restructuring of our quality and operations responsibilities across Johnson & Johnson. We began this reorganization prior to the events at McNeil, and those events highlighted the need for clear and effective oversight of our companies' operations. Under the reorganization, we have established new chief quality officers for each of our three business segments – consumer, pharmaceutical, and medical devices. The quality operations in each of the business segments now report to a chief quality officer for the company. Quality and manufacturing report to a single point, with oversight of our operating companies. This person reports directly to me.

B. The Retrieval and Subsequent Recall of Motrin Products

Mr. Chairman, at the May 27 hearing, and again in your recent letter to me, you raised questions about what you described as a "phantom recall" of two lots of 8-caplet Motrin vials that were distributed to certain retail establishments, primarily gas stations and convenience stores. Since that hearing, when the Committee raised this issue with us for the first time, we have provided the Committee with thousands of documents and information about the retrieval of Motrin products that took place in 2009.

Based on what I have learned since the May hearing about the way the Motrin retrieval was handled, including the points that this Committee brought to light, it is clear to me that in retrospect, McNeil should have handled things differently. And going forward, if similar situations arise, they will be handled differently.

As an initial matter, it is important to keep in mind that the Motrin retrieval and subsequent recall were not prompted by safety concerns about the product. Rather, the caplets were found not to dissolve as quickly as intended. McNeil reported this dissolution issue to the FDA, and made plans to assess how much, if any, of the product in question was still in stores. At the time the quality issue arose, McNeil reasonably believed that a small amount of these 8-count vials remained in convenience store locations. The company elected to use a third-party contractor, called Inmar, to visit stores and, if the Motrin product in question was found in a store, to purchase and destroy the product. In a March 23, 2009, field alert, which is a formal notice to the FDA, McNeil stated that “a third party has been contracted to perform an in store assessment. . . . If this assessment confirms that there is no product from [the affected Motrin batches] at the store level, a recall will be considered not necessary due to unavailability in the market; otherwise a recall of these Motrin batches will be recommended to be performed.” There were additional communications, as I understand it, between the FDA district office personnel and McNeil from April to July 2009.

On April 21, 2009, McNeil submitted a field alert stating that “a statistical sampling of approximately ten (10) percent of all stores across the US that received these batches were visited (250 stores out of 2000). The assessment performed demonstrated that, on a statistical basis, a low amount of product (approximately 1% of the batches) is potentially still at the retail level. The product from the subject lots found in the stores was removed during the visits. Visits to the remaining retailers will be completed by July 15, 2009 to remove any product from the subject lots that is found.” On May 5, 2009, McNeil informed its customers that it would “send in our own teams to remove the specific product lots from those retail outlets and reimburse the outlets for the cost of the product removed.”

In July 2009, after the retrieval had already been completed, and about two months after the April 21 field alert to the FDA, the FDA informed McNeil that the retrieval should be treated as a formal recall. McNeil appropriately agreed to the FDA’s request and submitted the necessary recall documentation to the FDA.

In response to the Committee’s requests, we produced to you internal McNeil correspondence, correspondence with the FDA, and the formal notices sent to the FDA reflecting McNeil’s communications with the agency regarding the use of a third-party contractor to purchase and remove the Motrin products from the retail locations. The documents that we provided to the Committee show that McNeil informed FDA officials about McNeil’s plans for an in-store assessment and then a retrieval of any of the 8-caplet Motrin vials that remained available for sale. McNeil believed that this was an expeditious way to remove the remaining caplets from the convenience store shelves.

I believe that McNeil acted with good intentions, and I do not view the use of a contractor to retrieve product, by itself, as inappropriate. The retrieval of product in this case was targeted and very comprehensive. But this episode was not a model for how I would like to see Johnson & Johnson companies approach problems with defective product when they arise, and I can assure the Committee that we are taking stock of the lessons learned.

C. The Children's Tylenol Assessment and September 2009 Recall

Mr. Chairman, your letter to me about today's hearing included a document – apparently an internal e-mail from a contractor – referencing a potential for a recall involving Children's Tylenol. As this is not a Johnson & Johnson or McNeil document, I cannot speak to it specifically. I can, however, tell you that in the summer of 2009, McNeil contracted with Inmar to assist with a recall that was announced publicly on September 24, 2009. The FDA was informed that McNeil would use Inmar to assist with the recall. The FDA specifically approved visits to retailers, and it approved communications to retailers that described the use of contractors to purchase and remove the recalled products. Prior to the recall, in July 2009, as I understand it, McNeil requested that Inmar conduct an in-store assessment to determine the extent to which product from the affected lots – which had been produced many months earlier – remained in the marketplace. A document provided to the Committee shows that Inmar confirmed to McNeil that no product would be purchased during this assessment.

Importantly, the issue that prompted the discussion and eventual recall in September 2009 presented only a remote risk to patient safety. The September 2009 voluntary recall was undertaken out of an abundance of caution because objectionable bacteria had been found in raw material that was rejected and not used in production. McNeil tested the raw materials, and 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. Subsequently, McNeil tested retained samples, which also tested negative for 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.

Finally, your letter asks whether this contractor document is related to the April 2010 recall. As best we are able to determine, it is not. The recall conducted in April 2010 was undertaken by McNeil because of issues identified regarding particles in April 2010, as described in Ms. Goggins' testimony last May. The contractor document appears to be related to the recall conducted in September 2009.

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I would like to close my testimony by noting my appreciation for Ms. Goggins' leadership of Johnson & Johnson's consumer group. As you know, she has announced that she will retire from Johnson & Johnson next year. During this busy and important time at Johnson & Johnson, she has demonstrated strong leadership as we work to address the quality issues that led to the recent recalls. I am grateful for her long service to the company.

Mr. Chairman, our efforts to assess and improve the quality issues we found at McNeil began many months ago. We have made considerable progress, and we are working quickly to resolve any outstanding issues and resume production of our children's liquid products. As you know from our several personal meetings, I am committed to working cooperatively with the Committee and the FDA to get the McNeil products back on the shelves for the people who rely on them. We look forward to earning back the trust of all those who have depended upon Johnson & Johnson to take care of themselves and their families for decades.

I would be happy to answer your questions.