Johnson-Johnson

Testimony of

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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, I am Colleen Goggins, the Worldwide Chairman of the Consumer Group of Johnson & Johnson. I appreciate the opportunity to appear before you today, as I did in May 2010, to discuss our efforts to address the quality and process issues at McNeil Consumer Healthcare. Because my May 2010 testimony contains considerable detail concerning McNeil and the recent recalls, I will be brief in my testimony today.

Since my prior appearance before this Committee, we have continued to work very hard to address the problems at McNeil. In July, McNeil submitted to the FDA a "Comprehensive Action Plan" (CAP). The CAP applies to all the manufacturing facilities McNeil operates to supply the U.S. market – not just the Fort Washington facility that remains closed. The CAP is part of our ongoing dialogue with the FDA to improve product quality, improve quality systems, and enhance training. Under the CAP, we have engaged leading experts on manufacturing processes, and we have also dedicated Johnson & Johnson's own experts to our efforts at McNeil.

We are committed to dealing aggressively with the quality and process issues at McNeil, and I believe we are living up to that commitment, although we recognize we still have work to do. As you heard from Mr. Weldon, our employees have dedicated themselves to addressing the quality concerns at McNeil. Johnson & Johnson has directed new personnel and additional resources to the efforts at McNeil. And as Mr. Weldon said, we are working very hard to bring the pediatric products back to the market.

Mr. Chairman, let me address a question you raised in your letter inviting me to appear today. When I testified in May, the Committee asked about McNeil's use of a contractor in 2009 in connection with the two lots of 8-caplet Motrin vials determined to have a dissolution issue. I learned that the Committee was interested in this issue for the first time during the morning session of the hearing in May. Based on the information available at the time, I informed the Committee that the FDA was told of McNeil's plans for Motrin, and I committed to provide the Committee with further information relating to this issue.

Since the May hearing, the company has provided documents to the Committee that reflect discussions with the FDA, including an April 21, 2009, field alert submitted to the FDA's

San Juan office. That field alert notified the FDA that McNeil had hired a contractor to visit retail outlets and remove any product still found in stores by July 15, 2009. Based upon this and other documents, I continue to believe that the FDA was informed of McNeil's plans.

At the hearing, I also stated that I had no personal knowledge of statements reflected in excerpts from a subcontractor's document shown to me during the hearing, which I had never before seen. As I understand it, neither McNeil nor Johnson & Johnson had seen these instructions prior to the hearing. Since the hearing, the company located and provided to the Committee a copy of instructions issued by McNeil to its contractor on the Motrin matter. At the time of the hearing in May, I had no personal knowledge of and had not seen the contractor or McNeil instructions. Since then, however, I have reviewed the McNeil instructions to the contractor that instructed the contractor to purchase the product without engaging in discussions with the store personnel. Based on what I have learned since May, I believe that McNeil should have handled things differently. We, as a company, have learned from this process.

Finally, Mr. Chairman, I recently announced that I will retire from Johnson & Johnson early next year. I have been thinking about retiring for some time, as I have spent nearly 30 years with the company and almost 10 years in my current position. With the McNeil remediation plan in place, I announced my retirement now in order to ensure an orderly transition at this critical time for the company. Even after I retire, I have committed to the company that I will be available for anything they need, and I extend the same commitment to the Committee.

Mr. Chairman, I would be happy to answer any questions that you or the other Committee Members may have for me.