ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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September 21, 2010

Mr. William C. Weldon
Chairman and Chief Executive Officer
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Dear Mr. Weldon:

I am writing in connection with the Committee's ongoing investigation of the circumstances surrounding your recall of over 135 million bottles of infant and children's medicines and the phantom recall of a certain adult Motrin product.

In the course of reviewing documents you provided to us in response to our earlier request, we found an internal McNeil Consumer Healthcare email sent by Bob Miller to other McNeil executives, including the president of McNeil, Peter Luther (see copy attached). The Miller email reads in part, 'As you know we have negotiated an agreement with FDA not to formally conduct a recall for Motrin 8's but rather conduct a "soft market withdrawal."'

Unfortunately, we have been unable to find a copy of the "agreement with FDA" among the documents you provided to us. To clarify this issue, please respond to the following:

1. Was there a written agreement between Johnson & Johnson and the FDA to not conduct a formal recall of Motrin 8's? If so, please provide a copy of the agreement.

2. Was there an oral agreement between Johnson & Johnson (including J&J employees and contractors) and the FDA to not conduct a formal recall of Motrin 8's? If so, describe the provisions of the agreement in detail; how this agreement was negotiated; and when it was negotiated. In addition, please identify and provide complete contact information for all employees or contractors who were involved in negotiating such agreement.

Please deliver to the Committee the requested information no later than 12:00 noon, Wednesday, September 22, 2010.

Should you have any questions about this request please contact John Arlington or Chris Staszak of the Committee staff at 202-225-5051.

Sincerely,

Edolphus Towns
Chairman

Enclosure

cc: The Honorable Darrell Issa
Ranking Minority Member
Committee on Oversight and Government Reform

From: Benedict, Gary [MCCUS] [GBened1@its.jnj.com]
Sent: Wednesday, May 27, 2009 10:10 PM
To: Figus, Daniel [MCCUS]
Subject: FW: Market withdrawal of Motrin 8's

I'm totally in the dark on this? I thought we did not have to take any action. If you're on email, please respond back to me tonight or call me on my cell.

From: Luther, Peter [MCCUS]
Sent: Wednesday, May 27, 2009 10:03 PM
To: Miller, Bob [MCCUS]; Benedict, Gary [MCCUS]; Mahony, John [MCCUS]; Widmer, Kathy [MCCUS]
Cc: Parziale, Carolyn [MCCUS]; DiPaolo, Paul [MCCUS]
Subject: RE: Market withdrawal of Motrin 8's

Group,

Where is the miss here? Given our current financial situation, I hope we're not going to really double our cost to do this. Let's make this happen ASAP.

Thanks,

Peter

From: Miller, Bob [MCCUS]
Sent: Wednesday, May 27, 2009 9:51 PM
To: Benedict, Gary [MCCUS]; Luther, Peter [MCCUS]; Mahony, John [MCCUS]
Cc: Parziale, Carolyn [MCCUS]; DiPaolo, Paul [MCCUS]
Subject: Market withdrawal of Motrin 8's

Gary

As you know we have negotiated an agreement with FDA not to formally conduct a recall for Motrin 8's but rather conduct a "soft market withdrawal". This was a major win for us as it limits the press that will be seen. We had committed to FDA to complete this withdrawal by July 15th. There has been continuing issues trying to get a PO from the marketing group which is now putting our ability to meet the July 15th timeframe in jeopardy. At the same time as we delay this work the cost to complete the work continues to increase because of the fact that the outside resource will now need more resources to expedite the work. We can NOT extend our commitment date to FDA. It is now estimated that this will cost approx. $400K which is approximately 2x that which was originally quoted. We need to start this work ASAP. If I we are unable to get a PO by Friday, we will issue the PO from QA and then back charge to marketing. Please let me know how you want to proceed or how we can get the PO. Carolyn Parziale is leading this effort and should be your POC for any questions you have. Please let me know if you have any questions.

Bob