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ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051
FACSIMILE (202) 225-4784
MINORITY (202) 225-5074

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September 20, 2010

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Hamburg:

I am writing in regard to the Oversight Committee's ongoing investigation of Johnson & Johnson's recall of over 135 million bottles of pediatric medicine and a "phantom recall" of an adult Motrin product that came to light as a result of the Committee's hearing on May 27, 2010.

Representatives of Johnson & Johnson and its McNeil Consumer Healthcare (McNeil) subsidiary have stated that Johnson & Johnson/McNeil employees informed the FDA of the phantom recall before it was conducted and continued to update the FDA while it was being conducted. Moreover, it has been alleged that FDA approved the Johnson & Johnson/McNeil phantom recall. As you know, the FDA denies the Johnson & Johnson/McNeil version of events.

To assist us in our investigation, please provide the Committee with copies of all records in the care, custody, or control of the FDA that relate in any way to Johnson & Johnson's phantom recall of Motrin, including all communications between Johnson & Johnson/McNeil employees and employees of the FDA from January 2009 to June 2009.

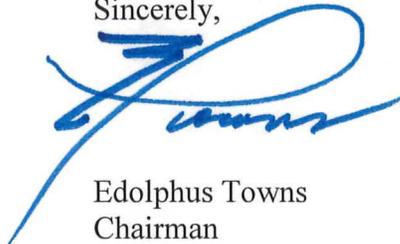
Please deliver the requested records to the Committee on Oversight and Government Reform, room 2157 Rayburn House Office Building, no later than 4:00 p.m. on Friday, September 24, 2010. To facilitate delivery and review, we prefer that the records be delivered in digital form. Please note that the terms "records" and "relating to" are defined in the attachment to this letter.

The Honorable Margaret A. Hamburg, M.D.

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Should you have any questions with regard to this request, please contact either John Arlington or Chris Staszak of the Majority Staff at 202-225-5051.

Sincerely,

A handwritten signature in blue ink, appearing to read "Edolphus Towns", with a large, stylized flourish above the name.

Edolphus Towns
Chairman

Attachment

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

WITNESS INFORMATION SHEET

The following is a summary of some of the pertinent rules and procedures applicable to witnesses testifying before the Committee on Oversight and Government Reform:

- Witnesses should provide 100 copies of their written testimony to Carla Hultberg, Chief Clerk, 2157 Rayburn House Office Building, no later than 10:00 a.m. two business days prior to the hearing. Witnesses should also provide their statement by this date in electronic format, either as a CD or via e-mail to carla.hultberg@mail.house.gov.
- At the hearing, each witness will be asked to summarize his or her written testimony in five minutes in order to maximize the time available for discussion and questions.
- House Rule XI clause 2(g)(4) requires that witnesses appearing in a nongovernmental capacity submit to the Committee in advance of the hearing “a curriculum vitae and a disclosure of the amount and source (by agency and program) of each Federal grant (or subgrant thereof) received during the current fiscal year or either of the two previous fiscal years by the witness or by an entity represented by the witness.” (See the attached form.)
- The Committee does not provide financial reimbursement for witness travel or accommodations. Witnesses with extenuating circumstances; however, may submit a written request for such reimbursements to Robin Butler, Financial Administrator, 2157 Rayburn House Office Building, at least one week prior to the hearing. Reimbursements will not be made without prior approval.
- Witnesses with disabilities should contact Committee staff to arrange any necessary accommodations.
- Committee Rules governing this hearing are online at www.oversight.house.gov.
- The Committee on Oversight and Government Reform is the principal oversight committee in the U.S. House of Representatives. The jurisdiction of the Committee is set forth in the House Rules X, clauses 1(m), 2, 3, and 4.

For inquiries regarding these rules and procedures, please contact the Committee on Oversight and Government Reform at (202) 225-5051.

DIRECTIONS TO THE CVC HEARING ROOM (HVC-210)

Enter the Capitol Visitor Center through the First Street, SE, entrance. After clearing security and are inside the Visitor Center, you will turn left and then right at the two statues. Take the stairs or elevator down to the next level. At the bottom of the stairs, you will take a left. Walk past the astronaut statue to the three metal doors labeled "U.S. House of Representatives Meeting Rooms." Please stop at the appointments desk to the left of these doors to show ID and obtain a pass before entering. Proceed down this hallway to the hearing room, HVC-210, which is the 2nd door on the right. Please check in with the clerk of the Committee when you arrive.

If you need assistance with finding the room, please go to the appointments desk in the CVC or back to security and they will be able to help you or you can also phone the Committee office at 202-225-5051.