William C. Weldon
Chairman and CEO

One Johnson & Johnson Plaza
New Brunswick, NJ 08933

May 30, 2008

By Hand Delivery

The Honorable John Dingell
Committee on Energy & Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Bart Stupak
Subcommittee on Oversight and Investigations
Committee on Energy & Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Dingell and Chairman Stupak:

I appreciate the opportunity to answer the questions posed in your May 20, 2008, letter and to address Johnson & Johnson's policies with respect to broadcast television advertisements for prescription drugs. You asked whether Johnson & Johnson would commit to the following guidelines:

1. Follow the American Medical Association's guidelines regarding the use of actors and health professionals in DTC advertisements (ads).

Johnson & Johnson will not use actors to portray doctors in its broadcast direct-to-consumer prescription drug advertisements and will not use doctors to discuss the benefits of a medicine in these advertisements. The use of a doctor to discuss risks and other issues relating to prescription medicines, particularly with regard to contraindications and warning information, however, can be a very effective means of conveying this important information to patients. To the extent that a doctor appears in a broadcast television advertisement for a prescription medicine, Johnson & Johnson will indicate if the doctor has been compensated.

2. To not market products in DTC advertisements until a valid outcomes study of the product is completed and results are released.

As you know, studies concerning the efficacy and safety of a medicine are part of the registration file submitted to the FDA for the approval of a prescription medicine. These studies always measure clinically meaningful endpoints, even if they do not measure long-term outcomes like heart disease, stroke, or survival. They frequently demonstrate important therapeutic benefits that should be communicated to the public. Johnson & Johnson, therefore, would have concerns about categorically prohibiting direct-to-consumer broadcast advertisements before the completion of long-term studies of an undetermined time and nature.

3. Place a two-year DTC advertisement moratorium on new prescription drug products, as recommended by the Institute of Medicine.

We have adopted internal guiding principles on direct-to-consumer advertising for prescription drugs. For the pharmaceuticals group of operating companies, Johnson & Johnson requires that our operating companies spend at least six months after approval of a new medicine educating health professionals before commencing a direct-to-consumer advertising campaign. The principles also specify criteria for our operating companies to use in determining whether more time is needed for physician education before an advertising campaign. These criteria include the importance of informing patients of the availability of a new medicine, the complexity of the risk-benefit profile of the new medicine, and health care professionals' knowledge of the condition being treated. Finally, the principles state that our operating companies should continue to educate health care professionals as additional valid information about a new medicine is obtained from all reliable sources. Thus, Johnson & Johnson does not believe a particular fixed period of time for an advertising moratorium is appropriate in all circumstances.

Johnson & Johnson has implemented the guidance adopted by the Pharmaceutical Research and Manufacturers of America (PhRMA) concerning direct-to-consumer broadcast advertisements. That guidance likewise recommends that a manufacturer refrain from direct-to-consumer advertising until physicians are adequately educated about a new drug.

4. To not market off-label uses for prescription products in DTC advertisements.

Johnson & Johnson does not market prescription medicines for off-label uses in its direct-to-consumer advertising.

5. Add the Food and Drug Administration's (FDA) toll-free MedWatch phone number in all of your DTC advertisements.

Johnson & Johnson will add the FDA's MedWatch telephone number (1-800-FDA-1088) to its direct-to-consumer broadcast advertisements for prescription medicines.

You also asked that Johnson & Johnson answer one additional question:

6. If a product of Johnson & Johnson is required by FDA to include a "black box" warning in its labeling, will Johnson & Johnson commit to add these "black box" warnings in DTC ads for such product?

Johnson & Johnson is committed to ensuring that its direct-to-consumer broadcast advertisements contain relevant and appropriate information, including information related to boxed warnings, consistent with the FDA's regulatory requirements and guidance about the content of direct-to-consumer broadcast advertisements. Johnson & Johnson will seek advice from the FDA about how to incorporate relevant and appropriate boxed warning information into the "major statement" of any broadcast advertising it runs for its prescription drugs.

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Please let me know if you have any questions concerning this information.

Sincerely,

William C. Weldon

William C. Weldon

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy & Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight & Investigations