ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

May 20, 2008

The Honorable W.J. "Billy" Tauzin
President and Chief Executive Officer
Pharmaceutical Research and Manufacturers of America
950 F Street, N.W.
Washington, D.C. 20004

Dear Mr. Tauzin:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating misleading and deceptive practices in direct-to-consumer (DTC) advertising of prescription pharmaceutical products.

In our hearing on May 8, 2008, we asked several pharmaceutical companies about their future business practices related to DTC advertising, but we did not obtain adequate assurances that they would reduce misleading and deceptive DTC advertisements (ads). The witnesses invoked the Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines on DTC advertising for their policy. We are concerned, however, that these guidelines as currently written may not prevent some of the misleading and deceptive practices discussed in our hearing.

Therefore, we ask that you answer the following questions:

1. Will PhRMA update its guidelines to incorporate the American Medical Association's guidelines regarding the use of actors and health professionals in DTC advertisements?

2. Will PhRMA update its guidelines to specify that member firms should not market a product in DTC advertisements until a valid outcomes study of the product is completed and results are released?

3. Will PhRMA update its guidelines to specify that member firms should not engage in DTC advertisement for two years on new prescription drug products, as recommended by the Institute of Medicine?

4. Will PhRMA update its guidelines to specify that member firms should not engage in the marketing of off-label uses for prescription products in DTC advertisements?

5. Will PhRMA update its guidelines to specify the addition of the Food and Drug Administration's (FDA) toll-free MedWatch phone number in all DTC advertisements?

We also ask that you answer one additional question that was not asked at the hearing:

6. Will PhRMA update its guidelines to specify that all "black box" warnings required by FDA in the labeling of a product be included in DTC ads for that product?

Finally, we ask that you provide to the Committee all records of communications between PhRMA and the American Medical Association or any other organization of physicians or surgeons related to DTC advertising since 1999.

Please deliver copies of your response to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Room 316, Ford House Office Building. We ask for your immediate response as the Subcommittee is considering a second hearing on DTC advertising, and your answers will determine the nature as well as PhRMA's role in the hearing. Please note that for the purpose of responding to this request, the terms "record" and "relating" should be interpreted in accordance with the attachment to this letter. After review of the records, we may require additional records and/or staff interviews with PhRMA officials.

Thank you for your prompt attention to this matter. If you have any questions about this request, please contact us or have your staff contact John F. Sopko or Paul Jung with the Committee staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

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

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

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.