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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
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Washington, DC 20515-6115

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January 16, 2008

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The Honorable David M. Walker
Comptroller General
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Comptroller General Walker:

The U.S. Food and Drug Administration (FDA) is considering the creation of a new class of "Behind-the-Counter" drugs. This new class could allow certain medications that previously required a prescription to be made available behind a pharmacy counter, requiring a pharmacist's intervention with education or brief patient assessment before dispensing.

FDA has considered such a class in the past, and the Government Accountability Office (GAO) produced a report in August 1995 (B-252141) entitled, "Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated." This excellent report detailed the experiences of other countries that have created such a class of "Behind-the-Counter" drugs. Given FDA's proposal and its recent public meeting on the issue, it is imperative that more data be provided to assess accurately the true benefits, if any, of a "Behind-the-Counter" class of drugs.

Therefore, we ask that GAO update their 1995 study by examining any new data available since the original study. We do not expect on-the-ground investigations in countries that have established a "Behind-the-Counter" class as in the previous study, but rather a rigorous examination of any additional data since the original study that may allow us to evaluate the effects of a third class of drugs.

The Honorable David M. Walker
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Thank you for your prompt attention to this matter. If you have any questions related to this request, please contact us or have your staff contact 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