Congress of the United States

House of Representatives

Washington, D.C. 20515

May 4, 2007

The Honorable Andrew von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

CONFIDENTIAL

Dear Dr. von Eschenbach:

In the course of oversight work relating to drug safety, Committee on Energy and Commerce staff has become aware of data and scientific analyses supporting the conclusion that the drug rosiglitazone (Avandia), a diabetes drug taken by millions of patients, substantially increases the risk of heart attacks. We understand that the FDA is in possession of at least some of this information and is reviewing this safety issue.

Some of us joined Senator Grassley in an earlier communication on this topic. We write to you today in the spirit of protecting the public heath to express the broad nature of the concern here. Based on our understanding of what staff has learned, we are concerned about the severity and likelihood of harm to some patients currently taking this drug while the FDA determines the appropriate action under customary procedures.

We would be most appreciative if the FDA could meet with Committee staff by May 15, 2007, to explain the process for determining the action to be taken, and whether FDA can either expedite this process as a public health emergency and/or take any appropriate, interim steps to protect public health before it makes a final decision.

Thank you in advance for your attention and consideration to this request.

Sincerely,

John D. Dingell
Chairman
Committee on Energy and Commerce

Joe Barton
Ranking Member
Committee on Energy and Commerce

Bart Stupak
Chairman
Subcommittee on Oversight
and Investigations

Ed Whitfield
Ranking Member
Subcommittee on Oversight
and Investigations

Henry Waxman
Chairman
Committee on Oversight and
Government Reform

Tom Davis
Ranking Member
Committee on Oversight and
Government Reform