ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

November 21, 2007

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

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the ability of Institutional Review Boards (IRBs) to protect human subjects in biomedical research.

In particular, we are interested in the Food and Drug Administration's (FDA) inspections of IRBs through its Bioresearch Monitoring program. Please provide the following within two weeks of receipt of this letter:

1. All Inspectional Observations Reports (FDA–483), Establishment Inspection Reports (EIRs), from both surveillance and directed inspections, for Western Institutional Review Board and Chesapeake Research Review, Inc.;

2. All communications between FDA and Western Institutional Review Board, and between FDA and Chesapeake Research Review, Inc.;

3. Final Center determinations made for each EIR noted above (i.e., No Action Indicated, Voluntary Action Indicated, or Official Action Indicated); and

4. All warning letters that resulted from the above mentioned inspection reports.

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 of the Committee staff at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

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

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations