ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

February 7, 2008

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
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 its Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the Nation from unsafe food, drugs, and medical devices.

On January 29, 2008, the Subcommittee on Oversight and Investigations held a hearing to receive testimony from witnesses with knowledge of FDA's current capacity to protect the Nation's food, drug, and medical device supply. Testimony from key members or advisors to FDA's Science Board, the Government Accountability Office, and the Congressional Research Service painted a bleak picture of FDA's capacity and capability to protect the Nation—a picture that you testified you did not share. The Science Board's findings along with the hearing testimony suggest that much of FDA's core regulatory mission—to protect the public health—is at considerable risk. Thus, as stated in the Science Board report, "American lives are now at risk."

At the hearing, we informed you that we would be sending a letter asking you to specifically address each major finding of the Science Board. Thus, for each of the major findings listed below, please state whether you agree with the finding. If you agree with the finding, please describe how you are going to fix the problem, how long it will take, and how much it will cost.

1. FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak.

2. FDA cannot fulfill its mission because its scientific workforce does not have sufficient capacity and capability.

3. FDA cannot fulfill its mission because its information technology (IT) infrastructure is inadequate.

4. FDA does not have the capacity to ensure food safety for the Nation.

5. The development of medical products based on "new science" cannot be adequately regulated by FDA.

6. There is insufficient capacity for modeling, risk assessment, and analysis.

7. FDA's science agenda lacks a coherent structure and vision, as well as effective coordination and prioritization.

8. FDA has substantial recruitment and retention challenges.

9. FDA has an inadequate and ineffective program for evaluating scientist performance.

10. FDA has inadequate funding for professional development.

11. FDA has not taken sufficient advantage of external and internal collaborations.

12. There is evidence of important, but slow, progress to improve information sciences and technology at the FDA over the past few years, however, significant gaps remain.

13. FDA lacks the information science capability and information infrastructure to fulfill its regulatory mandate.

14. FDA cannot provide the information infrastructure support to regulate products based on new science.

15. FDA IT infrastructure is obsolete, unstable, and lacks sufficient controls to ensure continuity of operations or to provide effective disaster recovery services.

16. FDA's IT workforce is insufficient and suboptimally organized.

17. FDA's regulatory mission has broadened substantially, while its resources have dwindled.

18. Recommendations of excellent FDA reviews are seldom followed.

We request that you respond to this letter no later than two weeks from the date of this letter as we are now reviewing the proposed Fiscal Year 2009 budget. If you have any questions about this request, please contact us or have your staff contact Christopher Knauer or Kevin Barstow 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