ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN



February 14, 2008

The Honorable Jim Nussle
Director
Office of Management and Budget
Executive Office of the President
725 17th Street, N.W.
Washington, D.C. 20503–0009

Dear Director Nussle:

On January 29, 2008, the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce held a hearing examining the Food and Drug Administration's (FDA) current capacity to protect the Nation from unsafe food, drugs, medical devices, and other consumer concerns. Several of the witnesses at that hearing were members or expert advisors to FDA's Science Board—an advisory group to the Food and Drug Commissioner.

In December 2006, FDA Commissioner Andrew von Eschenbach requested that the Science Board form a special subcommittee to assess whether "science and technology" at the agency are capable of supporting existing and future regulatory operations. The subcommittee had extensive input from 30 external advisors, leaders representing industry, academia, and other Government agencies. These experts were chosen based on their extensive knowledge of cutting-edge research, budget, science, and management operations. Their assessments were compiled in a report, which was released in early December 2007, entitled, "FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology."

The FDA Science Board's review was unique in many respects. First, it was only the second time in FDA history that the entire agency had been reviewed by an external committee. Second, the expertise and level of accomplishments of the members were almost unprecedented in a single committee, especially considering their scope of knowledge in regulatory science and understanding of the agency's regulatory mission. The committee membership was a veritable "who's who" in the field of food and drugs and included a Nobel laureate in pharmacology, 14

members of the National Academy of Sciences, a renowned economist and specialist in workforce issues, a leader in healthcare policy and technology assessment, a former CEO of a large pharmaceutical company, a former Assistant Secretary for Health and Human Services, a former FDA Chief Counsel, and a former Under Secretary for Food Safety at the U.S. Department of Agriculture.

The findings of the Science Board report are sobering and were reflected in hearing testimony. Collectively, the findings underscore the concern that FDA's overall mission—to protect the public health—is at considerable risk because the agency is woefully underfunded. While the review's findings were extensive, key findings were identified as follows:

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

2. The agency does not have the capacity to ensure the safety of the Nation's food supply;

3. The agency's ability to provide basic inspections, conduct key rulemakings, and carry out enforcement actions is severely eroded, as is its ability to respond in a timely manner to outbreaks related to unsafe food sources;

4. The decrease in FDA funding over the past 35 years has forced the agency to impose a 78 percent reduction in food inspections;

5. The agency faces substantial employee recruitment and retention challenges; and

6. The agency cannot fulfill many of its core regulatory functions because its information technology (IT) infrastructure is obsolete, unstable, and inefficient.

Unfortunately, the findings presented in the Science Board report and at the hearing came as little surprise to some Members of this Subcommittee. In 2007, the Subcommittee held four hearings on FDA's efforts to protect Americans from substandard foods. Investigations associated with those hearings uncovered ample evidence that FDA is increasingly struggling to perform its most rudimentary regulatory missions—including the finding that the agency inspects less than 1 percent of the Nation's food supply.

Last year, in addition to investigating food safety, the Subcommittee examined FDA's foreign drug inspection program revealing that FDA's IT system for managing drug imports and related inspections is broken, and lacks the capacity to provide necessary information to the agency. Similarly, the Science Board found that FDA's IT infrastructure was woefully inadequate.

Even more alarming was the Subcommittee's discovery, through a concurrent audit conducted by the Government Accountability Office (GAO), that resource constraints on field inspectors and related travel has resulted in FDA inspecting only 7 percent of foreign drug establishments in any given year. Although experts recommend that foreign drug manufacturing firms should be inspected at least once every few years, FDA's resources allow inspection of each foreign firm once every 13 years. In a similar vein, GAO testified at the recent hearing that while FDA is required by law to inspect domestic medical device manufacturers once every 2 years, the agency's resource limitations only allow inspections of medium-risk firms once every 27 years.

Reports from this Subcommittee, the Science Board, GAO, and others share a common theme: FDA's regulatory responsibilities are ever-increasing, its financial and human resources are steadily dwindling, and the agency is stretched to the breaking point. It compelled the Science Board to conclude that "American lives are now at risk."

In order to better understand how the Administration's budget will address the FDA's considerable resource constraints, we request you provide information. Specifically, please address the following:

1. Have the Department of Health and Human Services (HHS) and the Office of Management and Budget (OMB) been briefed by the core members of FDA's Science Board regarding the findings of their report? If not, do HHS and OMB intend to be briefed by Science Board members in the future?

2. Did HHS and OMB consider the Science Board's report when preparing FDA's fiscal year (FY) 2009 budget?

3. Will the President's FY2009 budget close the gaps illustrated by these reports, particularly those related to food safety, foreign imports (drugs, medical devices, and food), and the agency's IT system? If the President's FY2009 budget does not close these gaps, why not?

4. The Administration has repeatedly stated that American consumers have one of the safest food supplies in the world. The Science Board, however, found that "the FDA does not have the capacity to ensure the safety of food for the nation." Please explain the discrepancy between the statements of the Administration and those of the Science Board.

5. Please explain what plans the Administration has to implement the recommendations of the FDA Science Board.

The statements and testimony of the Science Board, GAO, and other witnesses who appeared before this Committee on January 29, 2008, can be found on the Committee's Web site at http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.012908.FDASelfAssessment.shtml.

We thank you in advance for your attention to this public health matter and would appreciate a response by Friday, February 22, 2008. If you have any questions, please contact us or have your staff contact Christopher Knauer 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