

Congress of the United States
House of Representatives
Washington, D.C. 20515

February 4, 2008

Gail H. Cassell, Ph.D., D.Sc.
Vice President, Scientific Affairs
Distinguished Lilly Research Scholar for
Infectious Diseases
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Indianapolis, IN 46285

Dear Dr. Cassell:

Today, President Bush released his Fiscal Year (FY) 2009 Budget for the Food and Drug Administration (FDA). We are deeply concerned that the budget submitted by the President is grossly inadequate to meet the many challenges at FDA as identified by the Science Board. It barely covers the cost of inflation and continues the trend of the inadequate budgets of previous years that have led to the current crisis at the agency. We want to ensure that funding for FDA is sufficient to permit the agency to fulfill its many regulatory responsibilities. We are therefore writing to seek your assessment of the budget and your guidance as a member of FDA's Science Board and as the former head of the Science Board's Subcommittee on Science and Technology.

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 is capable of supporting existing and future regulatory operations. The subcommittee had extensive input from 30 external advisors 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 entitled, "FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology."¹ The report was released in early December of last year and was posted on FDA's Web site.

¹ *FDA Science and Mission at Risk, Report of the Subcommittee on Science and Technology*, Nov. 2007 (online at: http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007_4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf).

The subcommittee review was unique in many respects. First, it is only the second time in more than a century that the agency has been reviewed as a whole by an external committee. Second, the committee was composed of leaders from a number of sectors with knowledge of FDA that include industry, academia, and other Government agencies. Third, the expertise and level of accomplishments of the members are almost unprecedented in a single committee, especially considering their scope of knowledge in regulatory science and understanding of the agency's regulatory mission. In fact, the subcommittee included members with extensive credentials ranging from 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 Chief Counsel for FDA, and a former Under Secretary for Food Safety at the U.S. Department of Agriculture.

While the team's findings were extensive, among the key concerns raised include:

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 to food-related outbreaks in a timely manner;
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 IT infrastructure is obsolete, unstable, and inefficient.

As the Science Board points out, American lives are now at risk as a result of years of starving FDA of the resources necessary to maintain its scientific and regulatory strength. The subcommittee found that FDA's scientific capacity has been so eroded that it can no longer fulfill a frightening number of critical regulatory and public health responsibilities and many of these are, according to the report, related to a lack of resources. The Subcommittee recognized that the severe loss of scientific capacity at FDA threatens not only the health of our citizens, but the viability of the industries FDA regulates, the pace of medical innovation, and the security of our Nation.

Given these troublesome findings, we want to ensure that the FY2009 FDA Appropriations are based on the best available advice about the resources needed to allow the agency to avert the kind of catastrophe described in the Science Board's report. Consequently, we request that the Subcommittee on Science and Technology assist us by assessing whether the President's FDA budget will provide the increased resources needed to correct the serious deficiencies noted in the Science Board's report. We further request that the subcommittee provide the specific funding levels necessary to address the findings of your Science Board and enable the agency to fulfill its vitally important public health mission.

We recognize that the Subcommittee on Science and Technology of the Science Board was recently disbanded and no longer exists as a formal entity. We therefore request that you convene any available members from the Subcommittee to consider this request on an informal basis.

We appreciate the invaluable work that you and the Subcommittee have done thus far, and look forward to receiving this additional information as soon as possible.

Sincerely,



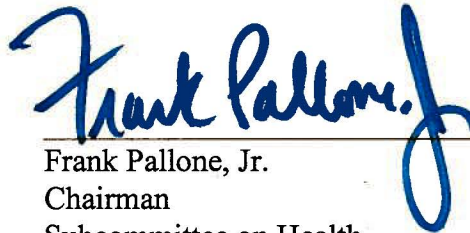
John D. Dingell
Chairman
Committee on Energy and Commerce



Henry A. Waxman
Chairman
Committee on Oversight and
Government Reform



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce



Frank Pallone, Jr.
Chairman
Subcommittee on Health
Committee on Energy and Commerce

Gail H. Cassell, Ph.D., D.Sc.

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

The Honorable Tom Davis, Ranking Member
The Committee on Oversight and Government Reform

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health
Committee on Energy and Commerce