

How Much Will it Cost to Adequately Fund FDA's Core Programs? Energy & Commerce Leaders Release Recommendations of Former Members and Advisors to FDA's Science Advisory Board

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NEWS RELEASE
Committee on Energy and Commerce

Rep. John D. Dingell, Chairman

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How Much Will it Cost to Adequately Fund FDA's Core Programs? Energy & Commerce Leaders Release Recommendations of Former Members and Advisors to FDA's Science Advisory Board

Leaders of the Committee on Energy and Commerce today released expert estimates of the cost of adequately funding the Food and Drug Administration's core programs. The funding recommendations were provided to the Committee by former members and advisors to the Science Board, an advisory board to the FDA Commissioner, in response to a request by Reps. John D. Dingell, Henry A. Waxman, Bart Stupak, and Frank Pallone.

“These estimates show that the President’s budget has completely missed the mark in terms of what is truly needed to protect Americans,” said Dingell (D-MI), Chairman of the Committee on Energy and Commerce. “These experts have recommended a funding increase for the FDA that is seven times what the President has proposed. We’d be wise to not only heed the warnings raised in their original report, but also use this new information to begin rebuilding this Agency’s ability to conduct its critical public health mission.”

“This is the best evidence we’ve seen that the FDA needs a serious infusion of resources if we want to avert catastrophe,” said Waxman, Chairman of the Oversight and Government Reform Committee and a senior member of the Committee on Energy and Commerce. “Yet in the face of this dire situation, the President has betrayed the FDA and the American people by proposing a budget that essentially flat-funds the Agency. So we simply cannot look to this Administration for guidance on what FDA needs to do its job.”

In December 2006, FDA Commissioner Andrew von Eschenbach requested that the Science Board form a subcommittee to examine whether the state of science and technology at the Agency is capable of supporting current and future public health responsibilities. The subcommittee was directed not to assess available resources. However, it became readily apparent to the Subcommittee that “the gaps [in scientific expertise and technology] were so intertwined with two decades of inadequate funding that it was impossible to assess one without the other.”

The Subcommittee produced a report, entitled, “FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology,” which was released in December 2007. This report found that “FDA’s resource shortfalls have resulted in a plethora of inadequacies that threaten our society – including, but not limited to, inadequate inspections of manufacturers, a dearth of scientists who understand emerging new science and technologies, inability to speed the development of new therapies, an import system that is badly broken, a food supply that grows riskier each year, and an information infrastructure that was identified as a source of risk in every FDA Center and function.” The Subcommittee was composed of respected leaders from industry, academia, and other government agencies. The level of expertise and accomplishment of the members is almost unprecedented in a single committee, considering their scope of knowledge in regulatory science and understanding of the FDA’s regulatory mission.

On February 25th, 2008, Reps. Dingell, Waxman, Stupak and Pallone wrote to Dr. Gail Cassell, the former Chair of the Science Board’s Subcommittee on Science and Technology, requesting an estimate of what it would cost to adequately fund FDA’s core programs and implement the recommendations outlined in the report. In response, the Committee was provided the attached estimate signed by nearly every member of the original group that authored the Science Board report. Of importance, the Subcommittee recommended that the FDA’s appropriated, non-user fee budget be increased by \$375 million in FY 2009. In contrast, the President has proposed an increase of only \$51 million in non-user fee resources. In addition, the Subcommittee states, “It is anticipated that FDA will need a substantial increase in the number of FTEs (personnel) to significantly expand the field force to do food, drug, device and other inspections.”

“The years of neglect cannot be wiped away instantly, so we have provided 5-year estimates for the amounts required,” said Dr. Cassell. “The Subcommittee did not do a program by program analysis, with specific needs down to the lowest operational levels. However, the Subcommittee did conduct a thorough review of the Agency’s major programs and capabilities, and has concluded that most of the programs are massively underfunded if they are to carry out the public and Congressional expectations presented to them. Thus, whether the Subcommittee has reached a proposed number that is accurate to the dollar is not the issue; it is that FDA needs a very substantial increase in resources if it is to protect us as the public expects and Congress demands.”

“This report further confirms what we already knew to be true --- FDA is in need of a serious infusion of cash and talent in order to fulfill its scientific and regulatory mission,” said Pallone (D-NJ), Chairman of the Energy and Commerce Committee’s Subcommittee on Health. “Unfortunately, the Bush administration shortchanges this critical agency, which imperils the public health. How many more lives will have to be lost to tainted imports, deadly drugs, or adulterated foods before the administration realizes that FDA is in crisis?”

“For more than a year, the Committee on Energy and Commerce has held hearing after hearing underscoring the breakdowns in FDA’s efforts to protect Americans against tainted food, drugs, and other dangerous imports,” said Stupak (D-MI), Chairman of the Energy and Commerce Committee’s Subcommittee on Oversight and Investigations. “A central theme in all of these investigations is that the agency lacks the resources to do its job. It is truly broken. I hope that this new information will serve to send a message that if we wish to protect the nation from unsafe commodities it can’t be done on a shoestring budget. I look forward to hearing from Secretary Leavitt and Commissioner von Eschenbach as to whether they agree with this critical assessment of FDA’s financial needs.”

Letter to Chairmen Dingell, Stupak, Waxman, and Pallone

FDA Science Board Report

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Prepared by the Committee on Energy and Commerce

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