



December 2008

Annual report to the Membership of the Alliance for a Stronger FDA:

Thank you for participating in our effort to strengthen the Food and Drug Administration (FDA) through education and advocacy for increased appropriated resources for the Agency. We appreciate your commitment to this effort.

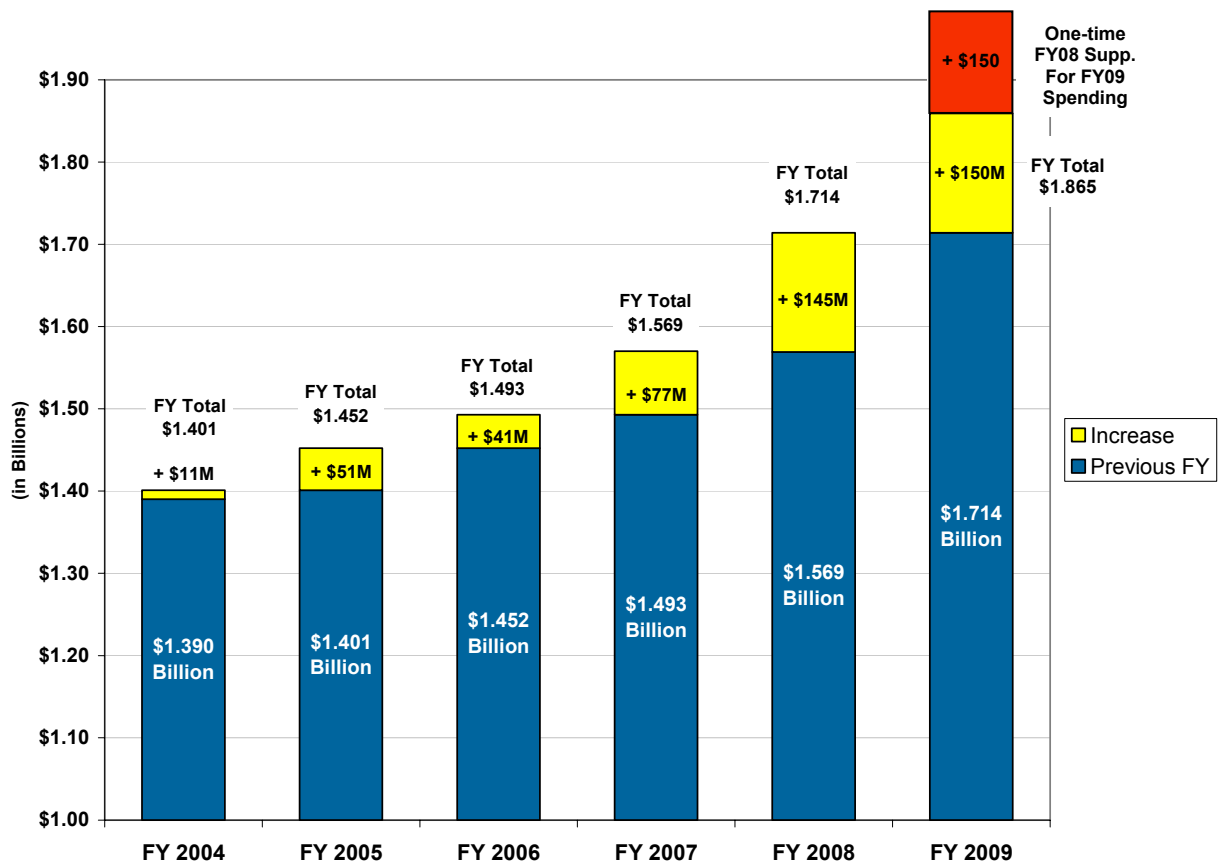
This report to our members provides highlights and a summary of Alliance activities during 2008. This marked the first-year of the Alliance for a Stronger FDA, which was created by the merger of the FDA Alliance and the Coalition for a Stronger FDA. The combined organizations provided a more focused and powerful effort and have produced a series of successes on behalf of our cause.

Funding Success

2008 will go down as a milestone year in the effort to properly fund the Food and Drug Administration (FDA). \$150 million was added to the FDA's budget through the 2008 Supplemental Budget, and \$150 million was added into the agency's base through the FY 2009 Continuing Resolution. These increases were on top of a \$145 million increase to the FDA base that Congress provided in December of 2008. In the last 12 months, Congress had three opportunities to treat FDA like other agencies and give it flat or inflation-only funding. All three times the agency has been given special consideration and enhanced funding.

In addition to measurable funding increases, we believe we have succeeded in creating and fortifying a strong perception among opinion leaders, decision makers and the media that FDA does not have adequate capacity to carry out its mission and that a meaningful infusion of new resources is absolutely necessary.

The below chart provides the top line agency appropriated funding over the last seven years:



Where Will the Increased Funding Go?

The FDA has provided to Congress the following strategic objectives for use of the added funding:

Prevention	Intervention
<ul style="list-style-type: none"> • Ensure the safety of imports by increasing FDA's presence beyond our borders and building capacity with foreign partners. • Conduct risk-based prevention to better protect America's food supply. FDA will better understand food safety and food defense risks and use this understanding to define the optimum preventive controls to establish. • Develop and validate rapid detection tools to quickly detect and mitigate a potential problem. 	<ul style="list-style-type: none"> • Apply risk analysis to set priorities for food inspections and interventions. • Design and build risk-based algorithms to conduct inspections and detect food risks. Understanding the risks defines the number and types of inspections and tests needed to ensure that preventive controls are working. • Deploy rapid detection technologies and assays and build laboratory infrastructure for faster testing. FDA will deploy state-of-the-art technology to improve the integration of incoming signals and achieve faster mitigation and response.

Response

- Enable real-time communication of lab results, develop protocols to facilitate tracebacks of foodborne illnesses and rapidly detect and respond to foodborne outbreaks.
- Enhance risk communication through aggressive, targeted food safety campaigns that disseminate clear and effective messages with regular updates through a variety of media to all target audiences.

Safer Drugs, Devices, and Biologics

- Use new science and analysis to improve the safety of medical products. Leverage advances from one product area to promote safety in a different area.
- Develop and implement quantitative decision-making tools to assess the safety and effectiveness of drugs, biologics, and devices throughout their lifecycle.
- Strengthen field operations to better protect public health. The sheer volume of products, manufacturing plants, distributors, and importers demands a more robust inspection force with better capacity to reach the community that FDA regulates.

Modernizing FDA Science and Workforce

- Enhance science programs across the agency, especially in emerging areas such as nanotechnology and tissue engineering. FDA will establish mechanisms to access the best scientific knowledge and expertise to modernize its regulatory science. FDA will strengthen its capacity to support emerging areas of science and manufacturing that are essential to regulating FDA products.
- Upgrade its science capacity by providing more training and professional development support for FDA science staff. Create an Agency-wide two-year Science Fellows Program intended to include up to two thousand trainees to develop a new cadre of emerging leaders in regulatory science. Upgrade facilities that do not adequately support FDA's current or future mission.

Messaging and Media

Apart from increased appropriations, the most significant accomplishment in 2008 was the widespread acceptance of the Alliance's message as fact. Congress, the Executive Branch and the media all echoed our message that FDA desperately needs more appropriated resources. At times, the media was saturated with stories, with many repeated instances of our message being presented independent of Alliance initiated activities. Some important examples include frequent references on CNN's Lou Dobbs Show and high-profile editorials by the New York Times.

The relationship of a strong message in the media to our congressional strategy was confirmed in an early meeting with appropriations staff. In that meeting, we asked what further activities would convince appropriators of FDA's funding needs. The answer: keep FDA resource needs in the Washington Post and the New York Times.

The Alliance was extremely proactive in issuing press releases and insuring the press was focused on important developments. Important to our efforts was the ability to push media towards our resource message as part of their examination of highly-visible product contaminations, such as heparin and jalapeño peppers. The Alliance's core team, our officers and our board of directors were quoted in a number of media outlets throughout the year, including the New York Times, Wall Street Journal, Washington Post, LA Times, Business Week, the AP, Reuters, CNN, NPR, and Bloomberg.

Two particularly important media events involving Alliance efforts were the FDA Science Board Report and Commissioner von Eschenbach's Professional Judgment Budget.

- A. **FDA Science Board Report.** In late 2007, the FDA Science Board, an independent advisory committee to the FDA Commissioner, issued a four hundred page report that concluded the state of science at FDA was highly problematic – mainly due to lack of resources. The Science Board report provided an important independent determination that FDA needs additional funds and was the catalyst for significant attention.

The Alliance worked throughout 2008 with members of the FDA Science Board to ensure the report received appropriate attention from the media and members of Congress. The Alliance issued a press release on the report, sponsored a media briefing featuring members of the Science Board, and helped coordinate several Congressional hearings on the report.

- B. **Commissioners Professional Judgment Budget.** In late Spring of 2008, FDA Commissioner Andrew von Eshenbach issued a highly-unusual, and extremely helpful, professional judgment budget, in which he provided his personal view, uninhibited by OMB restrictions, of FDA budget needs. The Commissioner's professional judgment budget requested \$275 million on top of the \$50 million already requested by the Administration. The Alliance played an important role in raising the media's awareness of the Commissioner's request. In fact, a major national media outlet broke the story after the Alliance called attention to the letter. The letter was critical in pushing the Administration to significantly increase its budget request and was an important catalyst for House and Senate appropriators to add significant funding for FDA in their July 2008 mark-ups.

Congressional Activities

Over the past year, the Alliance conducted more than one hundred meetings with Members of Congress and their staffs regarding the need to increase funding for FDA. Our congressional advocacy efforts focused primarily on the House and Senate Agriculture Appropriations Subcommittees and the House and Senate leadership. The Alliance also devoted significant efforts to ensuring that members and staff of each chamber's authorizing committees were apprised of the need for increased FDA funding.

- A. **Chairs of the House and Senate Agriculture Appropriations Committees.** The focus of our legislative advocacy strategy was extensive engagement with Senate Agriculture Appropriation Subcommittee Chairman, Senator Herb Kohl (D-WI), and House Agriculture Appropriations Subcommittee Chairwoman, Representative Rosa DeLauro (D-CT). Our engagement included direct contact with the members and their staffs. The Alliance could imagine no better champions for our cause than the two chairs of the agriculture appropriations subcommittees.
- B. **Agriculture Appropriators.** In addition to working with Chairs DeLauro and Kohl, the Alliance met with the staffs of all twenty-eight members of the House and Senate Agriculture Appropriations Subcommittees and with a number of key appropriators themselves. The Alliance engaged in a number of member meetings and developed

additional champions in the committees, including Senator Bennett (R-UT), Senator Brownback (R-KS), Representative Farr (D-CA) and Representative Emerson) (R-MO).

- C. Leadership.** The Alliance also held briefings with the staff of House and Senate leadership. In the House, we met with staff from Speaker Nancy Pelosi's office, House Majority Leader Steny Hoyer, and Appropriations Committee Chairman David Obey. On the Senate side, we met with Majority Leader Reid's (D-NV) office, Assistant Majority Leader Senator Richard Durbin's (D-IL) office and Senator Murray's (D-WA) Office. We were particularly pleased with Senator Durbin's leadership on a letter supporting increased FDA resources that was signed by a bipartisan group of 19 Senators which included 13 Democrats and 6 Republicans.
- D. Authorizers.** The Alliance also conducted significant outreach efforts towards the staff of key members of the authorizing committees in each chamber. We met with staff from the following House Energy & Commerce Committee (E&C) Members: Chairman John Dingell; Chairman of the Oversight and Investigation Subcommittee Bart Stupak; Edward Markey; Frank Pallone; Albert Wynn; Diana DeGette; Mike Doyle; Charles Gonzalez; Ranking Member Joe Barton; Cliff Stearns; Nathan Deal; Ed Whitfield; John Shimkus; Heather Wilson; John Shadegg; Marsha Blackburn; Lee Terry; Mike Rogers and Sue Myrick.

Of particular note, the Alliance met with the staff of Representative Henry Waxman (D-CA), who chaired the House Committee on Oversight and Government Reform, regarding FDA oversight issues. Waxman, who is due to become the Chairman of the full Energy & Commerce Committee, wrote a letter on the Alliance's behalf. We view Congressman Waxman as a key ally as we move forward in our efforts to fully fund the FDA.

In the Senate, the Alliance met with staff from the following members of the Health Education, Labor and Pensions Committee (HELP): Chairman Ted Kennedy, Barbara Mikulski; Hillary Clinton; Lamar Alexander; Richard Burr; and Tom Coburn.

- E. Stronger FDA Hill Day.** In April 2008 the Alliance held "Stronger FDA Hill Day" and met with over 50 congressional member offices, including those serving on the House and Senate Agriculture Committees, House E&C, and Senate HELP.
- F. Other Notable Meetings.** In February the Alliance met with the Government Accountability Office (GAO) to discuss methods and data relating to GAO's review of FDA's fiscal needs.
- G. Congressional Hearings.** Congress held at least 10 hearings involving FDA-related issues this past year. When/where appropriate to raise funding issues, the Alliance testified and/or was "represented" by other organizations (many of them Alliance members) to highlight the need to increase FDA's resources.

Challenges Ahead

One good year (even a very good year) is not enough to ensure that FDA receives adequate funding. Alliance had a successful year, but our work is not done. We face significant challenges in ensuring that FDA receives adequate funding on a year-over-year basis.

Resources added over the last 12 months will make an enormous difference, but there is still a substantial mismatch between FDA's growing responsibilities and the resources it is provided.

2009 will be an especially challenging year because of the extraordinarily tight budget environment that the Congress will face.

Unquestionably, the greatest strength of the Alliance is its broad-based bipartisan group of stakeholders. As the year ends, the Alliance is comprised of more than 180 members, including patient and consumer groups; health professional organizations; trade associations; food, drug, medical device and biotechnology companies and individuals dedicated to working together to increase appropriated funding for the FDA. The continued success of the Alliance is heavily dependent on its ability to maintain and expand its current membership. In 2008 the Alliance was active in membership recruitment and in 2009 we will continue to focus on recruiting additional members committed to ensuring that FDA receives adequate funding to carry out the agency's growing responsibilities.

Our success as advocates brings us to a new phase. The Congress and media have recognized the resource-driven nature of FDA's problems. The Alliance has been successful in helping to deliver first installments of needed funds. We must sustain our momentum-gaining recognition for the advances made possible by new monies, while being clear that much higher levels of funding will be needed in FY 2010 and beyond.