



I am pleased to transmit the attached Annual Report of the Alliance for a Stronger FDA.

The Alliance was formed three years ago to advocate for increased appropriated funding for the Food and Drug Administration, an agency that has been chronically underfunded for many years. Our membership is 180-plus, consisting of significant representation from every constituency affected by FDA.

During the past three years, as you can see in the Annual Report, the FDA has gained in appropriated funding. I firmly believe that our advocacy has played a central, essential role in this success.

We have been able to deliver very effectively, to both the Congress and the Bush and Obama Administrations, the messages that FDA is worthy of higher funding levels, and that failure to fund the FDA adequately has public health, individual health and economic consequences.

As we look to 2010, we know we will be face new challenges in our advocacy for the FDA. I am enthused about a new project we have undertaken, the "Metrics Project," which will help us and the Congress understand better how the increased funding has been used, and how it has advanced the public health.

I have been honored to serve as President of the Alliance since its inception. During this next year we need to continue to refine our messages and meet the challenges posed by a tough budget environment.

With your support, I am confident that we will again be successful in our advocacy for a stronger FDA.

Wayne L. Pines

President

Alliance for a Stronger FDA



## **2009 Annual Report**

**To**

### **The Membership of the Alliance for a Stronger FDA**

#### **Introduction**

The Alliance for a Stronger FDA is a not-for-profit corporation that is dedicated to advocating for increased appropriated funding for the Food and Drug Administration (FDA). Each year, the Alliance provides a summary of its activities in support of FDA appropriations to its over 180 members. This is the Annual Report for Alliance activities during calendar year 2009.

During this past year, President Obama and Congress enhanced appropriated funding for the agency. This represents the third consecutive year of significant increased funding for the agency and is an undeniable step forward in strengthening the FDA. However, consistent funding increases over a sustained period of time are necessary to fully restore the agency's capacities. If the increased funding is not sustained, inflation and new responsibilities will erode the agency's funding base and compromise FDA's abilities to protect the public health.

Serious barriers still stand in the way of FDA receiving the consistent year-over-year increases that are required if the agency's resources are to ever match its expanding workload. Most notably the President has announced an extremely tight budget environment for Fiscal Year 2011, which will make further funding gains difficult, even as more responsibilities are being placed on FDA.

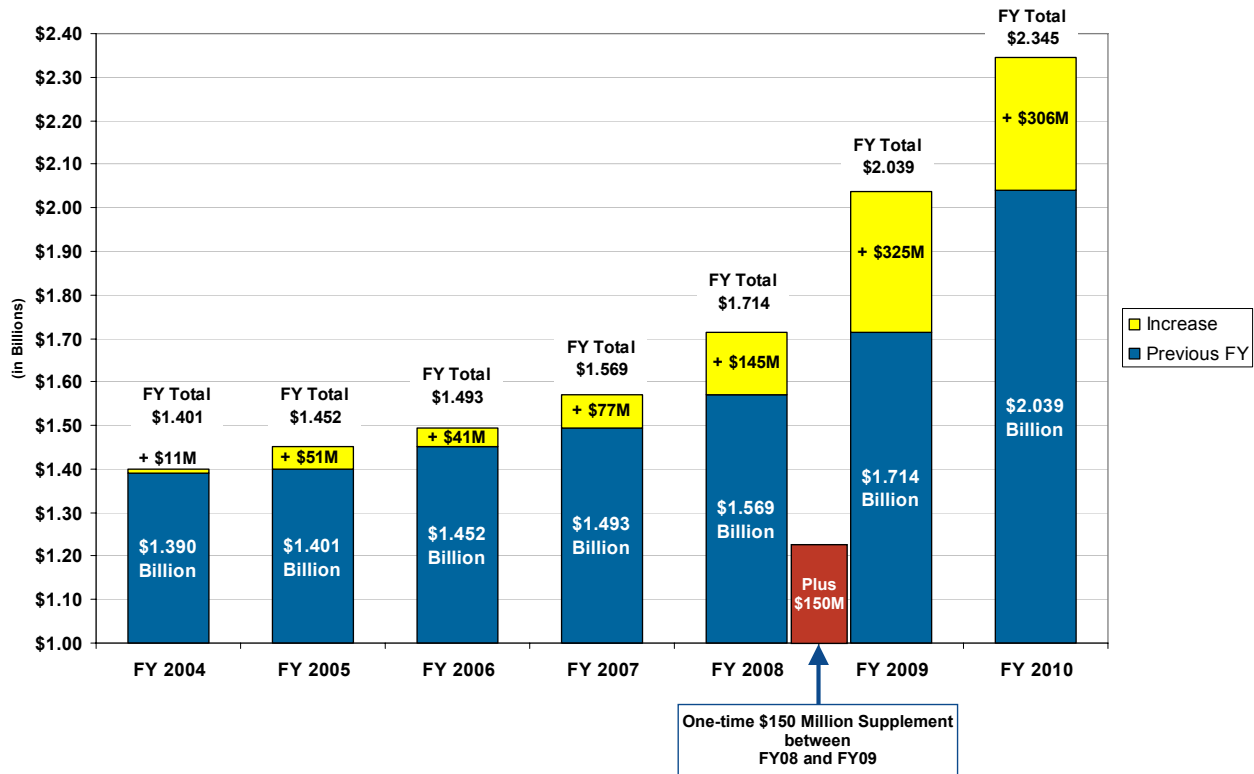
Therefore, if the recent progress made in strengthening FDA is to be sustained, our Alliance and our 180-plus stakeholder members will need to redouble our advocacy and outreach efforts in support of more funding for Fiscal Year 2011.

#### **Funding Success**

Since the Alliance's founding three years ago, FDA's appropriated budget has grown nearly 50 percent, from \$1.57 billion to \$2.343 billion, an increase of almost \$800 million. Over the past two appropriations cycles alone (FY 08 and 09), the agency received more than \$600 million in new funds. These remarkable funding increases represent a stark divergence from past years when the agency's annual increases averaged \$50 million, an amount far less than what was needed simply to keep up with inflation. Thanks to our members' efforts, FDA is beginning to receive more resources, personnel and tools to carry out its mission of protecting and promoting

the public health. We owe gratitude to Congressional Appropriators and the past and current Administrations for their dedication to this effort.

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



### Where Will the Increased Funding Go?

The Alliance was privileged to hear first-hand from FDA Commissioner Margaret Hamburg how resources significantly affect FDA’s ability to protect and promote the public health when she addressed the full Alliance membership in July of 2009. Below is a summary of some of the priorities Dr. Hamburg mentioned, all of which share a common “resource-related” theme:

- **Improving the Public Health.** FDA intends to become a more public health focused agency by keeping track of how the agency’s actions impact measurable outcomes, such as reductions in diseases and illnesses. Because of the agency’s unique mission and historic underfunding, this new approach will explicitly link the agency’s budget needs to public health goals.
- **Strengthening FDA’s Regulatory Science Capacity.** Extraordinary advances in new science and technology represent both a challenge and an opportunity for the FDA. Investment must be made to enhance the agency’s regulatory science to keep pace with new emerging fields such as stem cell therapy, nanotechnology and genomics. More money will allow the agency to recruit and retain more experts in regulatory sciences and for a larger and renewed collaboration with the broader scientific community.

- **Meeting the Demands Of Globalization.** The proliferation of international trade and the unprecedented increase in volume of FDA regulated products has expanded the scope and scale of FDA's mission. FDA will allocate more personnel and resources to help address this challenge.
- **Increasing Transparency.** The agency is committed to providing the public with more information regarding FDA regulatory activities and how decisions are made. More open access to FDA's operations will allow a better understanding of how the agency's resources are being utilized.
- **Implementing the New Tobacco Regulation.** FDA is currently planning a tobacco center and in the process of hiring 600 staff. The agency is currently exploring its capacity to assess user fees so that charges are appropriate and complete. No other FDA components will be forced to make cuts as a result of the added tobacco responsibilities.
- **Creating Readiness Against a Global Pandemic.** FDA is working on the lab tests, drugs and vaccines that may be needed in the event of a global influenza pandemic. In this area alone, FDA will need significant resources to be successful because the job is both complex and unpredictable.
- **Broader and Deeper Collaboration with Other Public Health Organizations.** FDA will forge closer ties with other government and non-government organizations to improve the public health. Examples include working with the Centers for Disease Control, National Institutes of Health, Centers for Medicare and Medicaid, state public health agencies and industry, patient and consumer groups.
- **Restoring Public Confidence.** FDA is striving to make its enforcement mechanisms more effective to improve the safety and quality of FDA regulated products, increasing both consumer and industry trust in the agency's ability to protect the public health. FDA plans to utilize the recent funding increases to help strengthen its regulatory enforcement mechanisms.

### Advocacy Activities

#### Administration

2009 brought about significant changes to Washington including new senior leadership at the FDA, its parent Department, HHS, and at the White House. The Alliance focused its advocacy activities on the new key decision makers that arrived at their posts in the executive branch.

- A. **Meeting with Presidential Transition Team.** In late 2008 the Alliance sent then-President-elect Obama a letter congratulating him on his election victory and urging him to make strengthening the FDA a priority for his administration. The letter highlighted the importance of (1) the timely nomination of an FDA Commissioner and (2) increased funding for the agency. The letter was sent to key members of the Obama transition team

and signed by the Alliance's Executive Committee. As a follow-up to the letter member the Alliance met with members of the Obama transition team.

- B. Meetings with FDA Commissioner Margaret Hamburg.** The Alliance was fortunate to meet with Commissioner Hamburg on two occasions. As discussed above, Commissioner Hamburg addressed the full membership of the Alliance in July and then met with the Alliance Board in August.
- C. Meetings with FDA Principal Deputy Commissioner Joshua Sharfstein.** Principal Deputy Commissioner Sharfstein addressed the Alliance full membership and the Alliance Board in October.
- D. Meeting with Department of Health and Human Services Secretary Kathleen Sebelius.** In October the Alliance met with Secretary Sebelius to discuss the Department's funding priorities for FY 2011.
- E. Meetings with FDA Center Directors and Senior Leadership.** Throughout 2009 the Alliance was pleased to be able to hold a series of meetings with other members of FDA's leadership team, including Center Directors. These meetings allowed the Alliance to gain a better understanding of how recent funding increases are being put to use and how additional monies would help the agency to better fulfill its mission. The Alliance met with the following senior FDA officials:
  - Janet Woodcock, Director, Center for Drug Evaluation and Research
  - Stephen Sundlof, Director, Center for Food Safety and Applied Nutrition
  - Rachel Behrman, Director, FDA Critical Path Initiative
  - Mike Chappell, Director, FDA Office of Regulatory Affairs
  - William Slikker, Director, FDA National Center for Toxicological Research
  - Bernadette Dunham, Director, FDA Center for Veterinarian Medicine

## **Congress**

In 2009 the Alliance continued to maintain a visible presence on capitol hill, bringing the message of the need for more FDA funding to both republicans and democrats in the House and Senate. As expected, our congressional advocacy efforts remained focused primarily on the House and Senate Agriculture Appropriations Subcommittees.

- A. Meetings with Agriculture Appropriators.** In February of 2009 the Alliance met with the staffs of all twenty-eight members of the House and Senate Agriculture Appropriations Subcommittees regarding the need to increase FDA funding in the FY 2010 appropriations cycle. These meetings normally consisted of six to seven Alliance members in attendance with consumer, patient and industry all represented.

- B. Written Statement to House Appropriations Agriculture Subcommittee on FY 2010 Budget.** In May of 2009 the Alliance submitted a written statement to the House Committee on Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies outlining the organization's funding request for FY 2010 of \$2.45 Billion.
- C. Chairs of the House and Senate Agriculture Appropriations Committees.** The Alliance remained heavily engaged with the two chairs of the agriculture appropriations subcommittee, Senate Agriculture Appropriation Subcommittee Chairman, Senator Herb Kohl (D-WI), and House Agriculture Appropriations Subcommittee Chairwoman, Representative Rosa DeLauro (D-CT). We continued to enjoy excellent working relationships with the staff of both Chairs, meeting and communicating with them regularly throughout the year. Chairman Kohl and Chairwoman both played pivotal roles in helping to secure FDA recent funding increases and the Alliance looks forward to continuing to work with them on this critical issue.
- D. Leadership.** The Alliance also held briefings with the staff of House and Senate leadership.
- E. Authorizers.** The Alliance also conducted significant outreach efforts towards the staff of key members of the authorizing committees in each chamber.
- F. Congressional Testimony.** In February, Alliance spokesman Bill Hubbard testified at a Senate Committee on Agriculture, Nutrition and Forestry hearing, "Examination of Federal Food Safety Oversight in the Wake of Peanut Products Recall." The focus of Hubbard's testimony was increased funding and resources for the FDA. Also testifying at the hearing was Caroline Smith DeWaal of the Center for Science and the Public Interest, an Alliance Board member.
- G. Stronger FDA Hill Day.** In March of 2009 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.

### **Messaging and Media**

The Alliance was successful in continuing to generate significant media attention throughout 2009 on FDA's funding crisis. Headlines along the lines of "Advocates Hope Obama boosts FDA Funds," "FDA Requests Largest-Ever Budget Increase," and "Alliance Begins Looking for Ways to Show FDA Uses Money Well" appeared on a regular basis in newspapers, television and radio news programming and helped to remind the public and policymakers of FDA's severe resource deficiencies.

The Alliance played an active role in ensuring that FDA's budget shortfalls received prominent attention 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, Fox News and Bloomberg.

Some highlights of the Alliance's media campaign include:

- Alliance Honorary Co-Chairman Tommy Thompson and Executive Director Ladd Wiley appearing on CNN's Lou Dobbs Tonight to discuss the agency's resource shortfalls.
- Alliance President Wayne Pines and Alliance Board Member Ellen Sigal quoted in a Reuters Story regarding the President's Proposal to boost FDA funding.
- Alliance spokesman Bill Hubbard and Alliance Board Member Don Kennedy featured in National Public Radio's piece regarding current and future challenges at FDA.
- Alliance spokesman Bill Hubbard and Alliance Board Member Caroline Smith DeWaal appeared on CNBC's program "On The Money" to discuss salmonella outbreaks and the need for more funding at FDA.
- Alliance Honorary Co-Chairman Tommy Thompson appearing on FOX News regarding food safety and FDA's resource constraints.

### **Metrics Project**

In 2009 the Alliance embarked upon a special project to augment its existing advocacy activities. Called the "Metrics Project," the goal is to elucidate the benefits derived from the increase in appropriated funding.

The concept of the Metrics Project was borne out by the recent successes of the Alliance in advocating funding increases for FDA and the 1) need to understand and explain whether and how the increases are actually achieving public health purposes, and 2) need to demonstrate to the Administration and Congress that FDA needs further funding increases.

The Alliance staff developed a three-tiered approach for each of three regulated product categories (foods, drugs/biologics and medical devices). The first tier is the resources that are needed to fund those activities. The second tier describes the activities that the agency needs to take to produce the public health outcomes. The final tier for each of the product categories describes the public health outcomes that we believe the agency should seek to achieve. The Alliance requested and received stakeholder input on the draft documents through several working group telephonic conference sessions. We envision several more working group sessions will take place before a final document is developed by the summer of 2010.

### **FDA Remains Severely Underfunded**

Despite the recent funding increases FDA continues to face severe resource constraints caused by a prolonged period of financial neglect and a rapidly growing list of complex public health challenges.

For the better part of the last decade FDA has received annual budget increases less than the amount needed to keep up with inflation. Moreover, the agency's workload has soared to include

major public health initiatives such as H1N1 influenza, bioterrorism, and the inspection of an unprecedented amount of food and medical products from around the globe.

The imbalance between FDA's funding and its expanding portfolio of public health responsibilities has left the agency ill equipped to effectively carry out its mission as the world's premier protector of public health.

For instance, even with these recent funding increases, FY 10, FDA's appropriation will support about 9100 full-time employees, the same personnel level as 1994, a time in which FDA faced challenges lesser in sheer numbers and in complexity.

### **Challenges Ahead**

We face significant challenges in ensuring that FDA receives adequate funding in 2010.

- A. Tight Budget Environment in FY 2011.** The Administration has signaled that cutting the federal deficit this year will be a major priority. In this environment it is very unlikely that cabinet agencies will see increases to their budgets and may in fact face funding decreases. This is particularly true for FDA given that Congress singled out the agency over the past three years as one of the only federal agency's to receive significant funding improvements. As a result, appropriators may view their work at FDA as done, at least for now.
- B. Unfunded Mandates.** We are concerned about the prospect of an already overworked and understaffed FDA being shouldered with even more demands without a corresponding increase in appropriated funding. Recent funding increases could be wiped out if Congress gives FDA more responsibilities without providing the agency with the extra funding needed to implement these new initiatives.
- C. Need for Sustained Funding Increases.** FDA requires consistent year-over-year funding increases to allow the agency to develop a coordinated comprehensive plan to respond to and *prevent* public health emergencies. On-again, off-again budget cycles prevent the agency from addressing existing and potential threats in a systematic manner and render FDA a reactor instead of a proactive problem solver. For instance, shortly after September 11, 2001, Congress provided FDA with a one-time infusion of money to boost FDA capacity's to conduct inspections but subsequently gave FDA very small increases that negated the impact of the post-9/11 funding.

### **Conclusion**

During 2009, the Alliance for a Stronger FDA made a significant effort to impact the appropriations for the FDA. Our advocacy was met by welcome ears both in the White House and in Congress. For the third year in a row, significant increased appropriated funds were provided to the FDA.

We face a challenging budgetary environment in 2010, and look forward to working with our membership to meet that challenge and strengthen the FDA.