Introduction

The Alliance for a Stronger FDA is dedicated exclusively to increasing the level of appropriated funding for the U.S. Food and Drug Administration (FDA). The Alliance is unique because its members represent all of FDA’s stakeholders, including consumer and patient groups, health professions’ societies, associations, industry and individuals who are all united in advocating for increased appropriated resources for the FDA. The Alliance’s 180-plus members are committed to assuring that FDA has the funding needed to protect and advance the nation’s health and fulfill the agency’s growing responsibilities.

We made some progress in strengthening the FDA’s appropriated funding base in 2012. However, serious challenges remain, as the agency had been chronically underfunded for decades, and its workload is growing exponentially; globalization, scientific complexity, growing industries and new laws and mandates are all putting significant new pressures on an already overburdened and under-resourced agency. Unprecedented fiscal pressures on the federal government are expected for the foreseeable future, and intense competition for government revenues is certain.

Continued FDA Funding Success Despite Serious Challenges

The Alliance is making significant strides in ensuring that the FDA receives the resources it needs to fulfill its rapidly growing list of complex public health responsibilities.

- Currently, FDA’s FY 2013 appropriated funding (part of the continuing resolution that funds the government through the end of March 2013) stands at $2.51 billion, a slight increase of $7.5 million above last year’s level.

- In the six-year period since the Alliance started its advocacy efforts, FDA’s appropriations have increased by more than $1 billion, a more than 60% increase (from a base budget of $1.493 billion in fiscal year 2006 to a base budget of $2.51 billion in fiscal year 2013.)
• Over the past six years, FDA’s appropriated budget has increased every year.

While FDA’s appropriated funding increases were modest this past year compared to the sizeable increases the agency received in prior years, the Alliance is encouraged that the agency’s budget was not reduced as many other government agencies have been in this period. Furthermore, it is possible that FDA could fare better if Congress passes an omnibus in March 2013 when the continuing resolution expires.

FDA had been underfunded for decades. Thanks to the Alliance’s dedicated stakeholders in 2012, we gained the attention of Members of Congress and promoted understanding that FDA needs increases in order to continue its vital mission. Even through some very tough years for discretionary programs, FDA garnered out-sized increases that were badly needed and long overdue. The progress we made in the last year is all the more impressive when one considers the complicated set of challenges we faced in 2012.

**2012: A Budget Crisis, Fiscal Cliff, Sequestration and a Complex Appropriations Cycle**

FDA’s appropriated funding was maintained and slightly increased thus far in Fiscal Year 2013 despite severe challenges, including a prolonged federal budget crisis and a highly complex and unpredictable appropriations process. Fiscal Year 2013 was the fourth straight year where the federal budget exceeded revenue by more than $1 trillion. In addition, Congress did not pass a budget for Fiscal Year 2013, and instead adopted a continuing resolution that funded government agencies at FY 2012 levels plus a very small increment (+.022%).

Federal agencies faced a “fiscal cliff” on Jan. 2, 2013, when about $110 billion in immediate (FY 13) spending cuts were slated to take effect across-the-board. The spending cuts, also known as the “sequester,” posed a dangerous threat to funding for every government agency, as it mandated an 8% to 10% across-the-board cut in discretionary and a lesser percentage in some mandatory spending. Sequester would be particularly devastating to the FDA because the agency’s funding would be reduced to FY 10 levels at the very same time that its public health responsibilities are expanding and intensifying.

The Alliance conducted several advocacy initiatives aimed at averting the devastating impacts sequester would have on FDA, including increasing our presence on Capitol Hill and coordinating with other public health funding stakeholder organizations. At the start of 2013, the sequestration process was avoided when Congress and the administration struck a deal to temporarily delay the across-the-board spending cuts. Sequestration still, however, looms as a threat to the mission of the FDA. If it occurs—as presently scheduled, on March 1—we estimate the agency will have to cut about $200 to $240 million in current year spending in just seven months.

**A Review of 2012 Key Legislative Activities Impacting FDA’s Appropriated Funding**

The Budget Control Act of 2011 significantly impacted the appropriations process, as the law mandated ceilings for FY 2012 through FY 2021 and superseded the normal process by which the ceilings are set each year. Below is a summary of the key legislative events that directly impacted FDA’s funding levels in 2012:
• **President’s FY 2013 Budget Proposal.** In February 2012, President Obama proposed a FY 2013 budget for FDA totaling $4.49 billion. Of that, only $2.51 billion was from appropriated funds, a slight increase in budget authority appropriations of $11.5 million above FY 2012 levels.

• **Senate Appropriations Committee Mark-Up.** In April, the Senate Appropriations Committee considered and adopted the FY 2013 Ag-FDA appropriations bill, which contained a $24 million increase for FDA above the FY 2012 level. Essentially, this was the same as the President’s request for an $11.5 million increase, with the Senate adding another $12.5 million specifically for implementation of the Food Safety Modernization Act.

• **House Appropriations Committee Mark-Up.** In June, the House Appropriations Committee adopted a bill that set FDA’s appropriated funding at $2.497 billion, a decrease of about $16 million below its FY 12 funding level.

**The Year Ahead: Bigger Budget Battles Loom**

While FDA avoided the potentially devastating consequences of sequestration at the beginning of 2013, the next year is certain to present even greater challenges to our mission of ensuring that the agency receives increases in funding to match its rapidly growing public health responsibilities. The agreement reached by the administration and Congress on Jan. 1 to avoid the “fiscal cliff” spared the automatic across-the-board spending cuts at federal agencies for a few months. But it set up potentially bruising budgetary and appropriations showdowns over the next two months that will be centered around three events that the Washington Post calls a “triple threat:” the Appropriations Process (concluding FY13 and starting FY14), sequestration, and the debt ceiling debate. Bottom line: all of these factors could impact FDA significantly.

**Advocacy Activities Highlights**

Throughout the past year, the Alliance conducted a series of advocacy initiatives that were directed toward members of Congress and administration officials.

**Congressional Outreach Activities**

• **Capitol Hill Meetings Regarding FY 2013 Appropriations.** The Alliance’s advocacy on Capitol Hill regarding the FY 2013 appropriations cycle was directed primarily at members of the Senate and House Appropriations Subcommittees on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies. We also met with the leadership offices in both the Senate and House. Throughout the year, the Alliance was in contact with the staff of various Members of Congress to provide updates on FDA funding-related issues. In March, the Alliance held its annual “Stronger FDA Hill Day,” which consisted of more than 50 meetings with appropriators, authorizers, and freshman members.

• **Sequestration-Related Advocacy Activities/ Increased Hill Presence.** While we typically have a particularly strong Hill presence each spring, we kept a consistent
presence throughout the year in 2012. We were frequently on the Hill October through December, holding a series of meetings with both appropriators and authorizer staff regarding the negative impacts sequestration would have on the FDA. In connection with these meetings, the Alliance produced a “sequestration fact sheet” that detailed the adverse effects the across-the-board cuts would have on the FDA.

- **Capitol Hill Globalization Briefing.** In September, the Alliance organized and held a briefing on Capitol Hill regarding the growing public health role FDA is playing in globalization. The event, “Challenges of FDA in a Globalized World,” was sponsored by the Alliance, with Chairman Jack Kingston (R-GA) and Ranking Member Sam Farr (D-CA) of the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies.

- **Increased Coordination with Other Public Health Funding Stakeholder Organizations.** We have coordinated more closely with other public health funding stakeholder groups, including the Coalition for Health Funding, the NDD Summit and NIH advocates. While we didn’t divert from our FDA priority, this has allowed us to better understand the overall challenging situation and educate a broader coalition about FDA’s needs.

**Administration Activities**

- **Meetings with FDA Officials.** Throughout the year, the Alliance held meetings with FDA officials, primarily center directors and other senior agency officials. The purpose of the meetings is to help the Alliance and its member organizations gain a better understanding of how resources issues are impacting FDA’s mission. In the past 12 months, the Alliance increased coordination with FDA Commissioner Margaret Hamburg, the most respected voice on FDA matters. We have increased discussions with her office, and she has elevated her voice in raising concerns for the agency.

- **Office of Management and Budget (OMB).** The Alliance leadership staff was in regular contact with officials at the Public Health Division at OMB throughout the year to advocate on behalf of the agency for the FY 2013 appropriation cycle, as well as to keep abreast of how sequestration-related developments impacted FDA.

**Other Advocacy Initiatives**

- **Quarterly Membership Meetings.** The Alliance held four quarterly meetings for its membership in 2012. At these meetings, members heard updates regarding legislative developments impacting FDA funding as well as presentations on the Alliance’s advocacy initiatives. At the November meeting, a special panel comprised of former Congressional and administration officials held a discussion regarding the election results and their potential impacts on FDA funding.

- **Friday Updates and Analysis.** Another important element of the Alliance’s advocacy efforts are the weekly updates and analysis the Alliance staff prepares and provides to Alliance membership. Members receive weekly updates on Congressional and Executive
Branch activities that affect FDA’s funding and resources. We also provide in-depth analysis every week on the President’s budget request and activities, reports and studies that impact FDA’s resource needs.

Core Messages

Our ability to continue FDA’s upward funding trajectory in a challenging and complex budgetary and legislative landscape this past year was in part a result of the Alliance’s effective messaging campaign. Below is a brief outline of the primary messages that were a part of our advocacy campaign:

- **FDA’s Vital Role as Protector and Promoter of Public Health.** FDA is a protector of food and drug safety and a gateway to medical innovation and science. American consumers expect the government to ensure their foods is safe and that patients have timely access to medical products that are safe and effective. These vital responsibilities are entrusted to one relatively small agency—the FDA. There is no other organization or agency that does this work.

- **FDA’s Workload is Increasing Exponentially.** FDA has a rapidly growing list of complex public health responsibilities and new demands placed on the agency by Congress.
  - **New Complex Public Health Challenges.** Last year, some of FDA’s challenges included drug shortages, new food pathogens, the need for bio-defense products, new sources of imports and the advance of new science and medical technologies. Science is growing more complex; thus, requiring more time, manpower and knowledge than in the past to perform a comparable activity (review an application for approval, evaluate a clinical trial, perform a field inspection, etc.). For example, FDA is deeply involved in the emerging field of nanotechnology, which is used in some foods and cosmetics and is proposed for use in other FDA-regulated products, including medicines.
  - **Globalization.** Chief among the growing demands on FDA are the resources needed to handle globalization. For example:
    - Nearly 40% of the drugs and 50% of the devices Americans use are made overseas.
    - About 70% of seafood and 35% of fresh produce in the U.S. come from foreign countries.
    - Food imports have increased nine-fold since 1993, and FDA-regulated imported food products come from more than 300,000 foreign facilities located in more than 150 countries.

- **New Mandates.** An already overworked and understaffed FDA is being asked to do more without a corresponding increase in appropriated funding. In the past two decades,
Congress has added more than 125 new statutory obligations to FDA’s portfolio. In FY 2013, FDA will be implementing the Food Safety Modernization Act (FSMA), the Biologics Price Competition and Innovation Act (BPCIA), and the FDA Safety and Innovation Act (FDASIA).

- **Economic Growth/National Competitiveness/Innovation.** FDA is vital in helping to stimulate economic growth, enhance national competitiveness and drive innovation. FDA plays a key role in the innovation eco-system, working closely with companies during product development to bring safe and effective new products to market. A strong, science-based, and well-funded agency is essential to promote predictability in the regulatory environment so that firms can invest in new innovations and drive economic growth.

- **Sequester Messaging.** Across-the-board cuts would have devastating impacts on FDA and the public health, including less safe food, slower drug and device approvals, more problems with globalization and imports and significant compromises to the FDA’s regulatory science capacities. Congress needs to return federal budget-making to a process under which national priorities such as FDA are adequately funded.

**Conclusion**

Over the last six years, FDA has been one of few discretionary programs to receive substantial funding increases. This reflected both Legislative and Executive Branch recognition that the agency was dramatically underfunded for its growing responsibilities in an increasingly complex world. The FDA requires continued sustained funding increases to create a 21st century regulatory agency; implement a growing list of mandates, including the Food Safety Modernization Act; assure science-based, predictable decision making on medical products; and deal with the burgeoning demands of globalization.

The cost of meeting FDA’s obligations are still rising more quickly than funding, especially when the agency is asked, each year, to implement a larger set of activities. While FDA is not as far behind as it once was, the agency is still underfunded.

Thank you for your membership in the Alliance for a Stronger FDA. The breadth and commitment of our membership is our greatest strength. We look forward to working with you in 2013 to increase the budget authority appropriations received by the FDA.

Margaret Anderson  
Alliance for a Stronger FDA President (2012)