2013 Annual Report To
The Members of the Alliance for a Stronger FDA

Introduction

The Alliance for a Stronger FDA is a 180-member coalition comprised of a diverse and unique group of all of the Food and Drug Administration’s (FDA) stakeholders—consumers, patients, health professionals, trade groups and industry. Our sole purpose is to advocate for increased appropriated resources for the FDA. The Alliance is in its seventh year of existence and through this annual report is proud to share with our membership the progress made over the past year toward achieving our goal of providing the FDA with adequate appropriated resources to fulfill its rapidly growing critical public health mission. FDA’s responsibilities are proliferating exponentially in both scale and scope, driven by increased statutory mandates, globalization, advances in innovation and scientific complexity and an unprecedented rise in new complex public health challenges. The Alliance works to ensure that key policy makers remain apprised of FDA’s need for consistent and predictable appropriated funding increases in order to keep pace with its constantly expanding workload.

FDA is Exceptional and Should be Funded as a National Priority

As discussed more in-depth throughout this report, the past year was characterized by significant fiscal threats presented by the sequester, the government shutdown and the series of short-term continuing resolutions for Fiscal Year 2013 and Fiscal Year 2014, all of which made the Alliance’s advocacy efforts more important than ever. Our advocacy centered around underscoring the concept of “FDA exceptionalism,” why FDA needs increased appropriated resources regardless of the overall or specific budget situation and that a strong, effective and adequately –resourced FDA should be national priority. We pointed out that American consumers expect government to ensure their food is safe and that patients have timely access to medical products that are safe and effective and these vital responsibilities are entrusted to one relatively small agency -- the FDA-- which oversees foods, drugs, medical devices, dietary supplements, animal foods and drugs, radiological products, tobacco, bioterrorism countermeasures, and more.
FDA Funding Increases Despite Significant Budgetary Challenges

Since the time we issued our last annual report in February of 2013 Congress has considered and passed two appropriations bills: Fiscal Year 2013 and Fiscal Year 2014 and the Alliance is pleased to report that FDA stood virtually alone among government agencies in receiving funding increases under both bills despite severe budgetary and fiscal challenges. Below is information regarding FDA’s appropriated funding status under both FY 2013 and FY 2014:

- **Fiscal Year 2014.** Currently, FDA’s FY 2014 appropriated funding stands at $2.561 billion, an increase of $100 million above the FY 2013 enacted level and more than $200 million above FY 2013 actual (post-sequester).

- **Fiscal Year 2013.** In FY 2013, FDA was provided an approximate $74 million in new budget authority (BA, taxpayer) monies. However, the agency’s appropriated funding was subjected to the the 2.513% rescission and the $126 million sequester of BA funds, resulting in a net, BA appropriations decrease by about $117 million (4.7%), also reflecting that Congress gave FDA extra funds sufficient to offset the rescission and slightly lessen the impact of the sequester.

- In the seven-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 $2.552 billion in fiscal year 2014).
Alliance’s Core Messaging

The Alliance’s success in helping to increase FDA’s appropriated funding is in part a result of our ability to ensure that key policy makers receive and appreciate compelling and persuasive messaging that underscores the importance of an adequately funded FDA. Below is a summary of some of the major messaging points from our advocacy campaign in the past year:

- **FDA Fulfills Vital Public Health Responsibilities.** The centerpiece of the Alliance’s advocacy campaign is to articulate and emphasize the critical public health mission of the FDA. To be funded as an exception — essentially outside the deficit reduction paradigm — FDA must be seen in its appropriate light: American consumers expect government to ensure their food is safe and that patients have timely access to medical products that are safe and effective. This vital responsibility is entrusted to one relatively small agency — the FDA -- which oversees foods, drugs, medical devices, dietary supplements, animal foods and drugs, radiological products, tobacco, bioterrorism countermeasures, and more.
Our nation is less safe and less healthy if FDA cannot excel at its mission.

- **FDA’s Resources are Not Keeping Pace with Its Growing Responsibilities.** Another key narrative the Alliance strives to convey is that the FDA’s resource capacities have not kept pace with the exponential growth of the agency’s critical public health responsibilities, primarily because congress continues to shoulder FDA with more statutory mandates and because of an acceleration of globalization and increase in scientific complexity.

  - **New Responsibilities Mandated By Congress.** There is a massive disconnect for FDA between what congressional authorizers are doing and what appropriators are doing. Congress has passed five new laws affecting FDA in 4 years (2009-2012), including tobacco regulation, biosimilars, food safety, and FDASIA initiatives (which include drug and device changes plus a large new generics program). This year, Congress passed new laws in the areas of animal drug user fees, track and trace/counterfeiting, and compounding, and there are a number of topics under consideration for possible action sometime this year or early next year. This continual expansion of the FDA’s mandate has created financial challenges for the agency in the absence of corresponding funding.

  - **FDA Responsibilities Grow Each Year Because of Globalization and Scientific Complexity.** Even were Congress not active in legislating new mandates for FDA, the agency’s mission and responsibilities would grow enormously each year for reasons unrelated to new laws. While there is no one way to fully convey the enormity of this shift and the resources required, the following bullet points illustrate the scale of the FDA’s growing challenges:

    - **Food Imports are growing 10% annually.** Altogether, 10-15% of all food consumed in the U.S. is imported. This includes nearly 2/3 of fruits and vegetables and 80% of seafood.

    - **Device Imports are also growing about 10% annually.** Currently, about 50% of all medical devices used in the US are imported.

    - **Drug Imports are growing even more quickly, about 13% annually.** Approximately 80% of active pharmaceutical ingredients (API) are manufactured abroad, as are 40% of finished drugs.
A Strong, Fully Funded FDA Is Essential to Meet New and Emerging Public Health Challenges. During the past year alone FDA was on the front lines of numerous important public health initiatives including combating antibiotic resistant bacteria, alleviating shortages of life-saving medicine, implementing a new system to reduce foodborne illness and continuing to drive advances in the field of personalized medicine to unlock the promise of emerging technologies such as genomics and nanotechnology to cure and conquer deadly diseases. Without increases in funding FDA will lack the human, scientific and technological resources to tackle these critical public health challenges.

Advocacy Efforts Become More Important In An Unforgiving Budget and Appropriations Landscape

Between the sequester, the government shutdown and the short-term continuing resolutions, the budget and appropriations landscape in FY 2013 and FY 2014 was complex and unpredictable and posed serious challenges to an adequately funded FDA. Over the past year the Alliance conducted a series of advocacy initiatives directed at policy makers to underscore the critical importance of strong, adequately funded and reliable science-based FDA. As mentioned previously, a significant element of our advocacy campaign over the past year was to highlight “FDA exceptionalism,” why FDA needs increased resources regardless of the overall or specific budget situation. We also worked to ensure that policymakers understood the significant consequences of sequestration and the government shutdown on FDA’s funding levels and risks to the public health.

Sequester and Shutdown

In March, the sequester, the automatic across-the-board spending cuts mandated by the Budget Control Act of 2011 went into effect and FDA was faced with a 5% reduction from sequester on top of a 2.15% rescission. In response to the threats presented by the sequester the Alliance conducted significant analysis of impacts of the budget cuts on FDA and developed advocacy materials explaining and highlighting the risks to the public health. In October, the federal government shutdown began and lasted for six-teen days after lawmakers were unable to reach an agreement for funding government agencies. During this time the Alliance worked to understand the effects of the shutdown on FDA and provided our membership with updates on the shutdown’s impacts on the FDA’s operations and implications for its public health mission. Over the course of both the sequester and the shutdown, we provided in-depth analyses of the budgetary impacts on FDA on a center-by-center basis in order for all of our membership organizations FDA stakeholders to better understand the consequences of each development on their respective constituents and sectors. Below is a summary of some of the other advocacy initiatives the Alliance conducted over the past year.

Congress. The Alliance held meetings with congressional offices throughout the year, meeting with all of the staff of House and Senate Agriculture Appropriations Subcommittee members. We held our annual “Stronger FDA Hill Day,” in March which consisted of more than 50 meetings with appropriators and authorizers. In addition, the Alliance held a series of meetings in May with the staff of freshman and sophomore
members of Congress focused on providing staffers with consumer, patient and industry perspectives on the critical importance of FDA.

Our congressional advocacy also included submitting written testimony to House and Senate Appropriations Committees regarding FY 14 and FY 15 appropriations levels. At the end of the year the Alliance organized a sign-on letter to the Chairs of the House and Senate Appropriations Committee’s urging the Congress fund the FDA as a national priority in FY 2014 and FY 2015.

In our interactions with Congress we also emphasized the importance of lawmakers returning to “regular order” and full appropriations cycles as FDA funding increases are much more likely to occur when the appropriations committees write and pass twelve individual spending bills and are able to prioritize spending on important national priorities.

- FDA. The Alliance’s advocacy activities also included meeting with key FDA officials to gain a better understanding of how resource issues are impacting the agency’s ability to address challenges and meet its regulatory priorities. Throughout the past year we held meetings with the FDA Commissioner, FDA’s Chief Operating Officer, FDA’s Chief Financial Officer, FDA’s Associate Commissioner for International Programs and Director of Office of International Programs, FDA’s Director of FDA’s India Office, FDA’s Director of FDA’s China Office, Director of the Center for Drug Evaluation and Research, Director of the Center for Biologics Evaluation and Research and Center and the Deputy Commissioner for Foods and Veterinary Medicine.

- Analysis and Strategic Planning. The life-blood of the Alliance and its advocacy campaign is the close engagement of our membership organizations. To facilitate an active Alliance membership we provided weekly email updates containing analysis of the budget and appropriations climate and developments as they relate to FDA’s appropriated funding levels. Our efforts on this front include developing fact sheets, conducting analysis of administration and congressional budget proposals and congressional mark-up activities, monitoring hearings, formulating budget level requests, and holding membership meetings and conference calls to keep our membership apprised of the key policies and legislative developments impacting FDA’s funding levels.

**Continued Congressional Leadership Is Vital**

Over the past year members of the appropriations committees have been very supportive about funding FDA. It is one of few non-defense programs that received more money under both the House and the Senate agriculture FY 2013 and FY 2014 appropriations bills than it would under the continuing resolutions. The Alliance is grateful for their support and appreciative the opportunity to continue working to further strengthen FDA. Authorizers have also been supportive of FDA's resource needs. They have recognized that the multiple pieces of FDA legislation enacted over the last three years cannot be implemented without FDA receiving additional resources. Although they do not have jurisdiction over FDA funding, they are credible voices acknowledging the funding needs. Continued leadership in congress from our champions
is essential to ensure that the agency has adequate resources to fulfill its rapidly growing list of complex public health responsibilities.

**Conclusion**

The Alliance’s success in impacting FDA’s appropriated funding is a result of a strong coalition of membership organization stakeholders holding the shared goal of an adequately resourced Food and Drug Administration. Without our members support the Alliance would not exist. It is through the strength of our shared objective that we impact in FDA’s favor make a stronger FDA a national priority. Over the last seven years, FDA has been one of few discretionary programs to receive substantial funding increases congress and the administration recognized FDA as a priority for funding increases despite a time of continuing deficit reductions and an austere fiscal environment. This reflected both Congressional and Executive Branch recognition that the agency was dramatically underfunded for its growing responsibilities in an increasingly complex world. FDA still needs more resources, even though the downward budgetary pressures have become significantly greater.

While the Alliance is fully supportive of recent FDA funding increases, the level of appropriated funding for FDA needs to be increased further—well above the FY 14 level--to reflect the agency’s vast public health responsibilities, its continually increasing workload and to offset decades of chronic underfunding. The Alliance is designed to be a multi-year effort to ensure the FDA receives the consistent and sustained funding increases it needs to fulfill its dramatically increasing workload. Both existing and new responsibilities will go unmet without the needed dollars to support staff and programming. Consumers, patients and a highly-productive industry are all losers without an adequately-funded FDA.