



2011 Annual Report to the Members of the Alliance for a Stronger FDA

January 5, 2012

Introduction

As we head into a new year, it is important to look back to evaluate what our group accomplished and to identify new opportunities for the future. This is the Alliance for a Stronger FDA's report to its members on its advocacy activities and accomplishments during Calendar Year 2011.

Despite the challenging appropriations environment in 2011, the Alliance:

- **Succeeded in its core mission** to advance the FDA's funding for FY 11 and FY 12 by \$157 million,
- **Strengthened the political foundation supporting FDA appropriations** by engaging new advocacy tools and honing timely messages to strengthen relationships with Members of Congress, the Administration, FDA and other advocates, and
- **Increasing membership value** through improved communications and opportunities to understand FDA issues.

The Alliance is a not-for-profit advocacy coalition focused on increasing the level of appropriated funding for the Food and Drug Administration (FDA). The Alliance is made up of nearly 200 members, including consumer, patient, and industry organizations. We advocate for resources for the regulation of products in all areas of FDA statutory responsibility, including food, drugs, biologics, medical devices, cosmetics, dietary supplements and veterinary products.

Continued Increases in FDA Funding in 2011 Despite Severe Federal Budgetary Constraints

This year brought significant challenges. Administration and Congressional efforts to reduce the federal budget deficit reduction dominated every government agenda. The year was particularly noteworthy for the inability of the House and the Senate to forge agreements prior to critical deadlines—threatening to close the government at several points for lack of a spending bill and nearly creating a technical default on the national debt.

Not surprisingly, the Alliance's advocacy was impacted by the larger debate about government spending and deficit reduction.

However, the Alliance adapted to these challenges and was able to effectively mobilize the energy and resources of its broad and diverse coalition. Not only were we able to stave off FDA budget cuts, but we were successful in increasing FDA funding.

During 2011, Congress finished work on the FDA's FY 11 budget and adopted a new FY 12 budget. The Alliance strongly appreciates the decision of Congress to provide increases for the FDA in both fiscal years.

In the Final FY 2011 Continuing Resolution, which was passed in April of 2011, FDA received a \$107 million increase over the prior year. For FY 2012, FDA received a \$50 million increase over FY 2011. While this last increase was not as large as in prior years, FDA did quite well in the face of a possible \$285 million cut that was passed by the House of Representatives. **The agency was one of the few federal programs to receive more dollars in both FY 11 and FY 12.**

FDA has received funding increases in every year since the Alliance began its advocacy on behalf of the agency. In FY 2007, FDA received an appropriation of \$1.569 billion. By FY 2012, this had grown to \$2.5 billion, nearly a 60% increase in agency funding in five fiscal years. These increases have been based on need and merit, and we hope they continue in the future.

Activities Employed to Strengthen Support for FDA Appropriations

The Alliance carried out a multipronged advocacy campaign in 2011 that included year-long outreach activities directed towards Members of Congress and Administration officials. The Alliance engaged in new and effective tactics to support its mission. For example, we published a FDA economic impact study in March, met with key Committee and Subcommittee Chairs in their districts in August and ran political advertisements in Capitol Hill publications in September.

Congressional Outreach Activities

- **Capitol Hill Meetings.** The Alliance's advocacy on Capitol Hill was concentrated on members of the Senate and House Appropriations Committees' Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies. We also met with the leadership offices in the Senate and House, as well as authorizers and new Members of Congress.

Throughout the year, the Alliance was in contact with the staff of various members to provide updates on FDA funding related issues. In March, the Alliance held its annual "Stronger FDA Hill Day," which consisted of over 50 meetings with appropriators and other Members of Congress.

- **Economic Impact Study.** In March, the Alliance issued a white paper entitled, "The U.S. Food and Drug Administration: A Cornerstone of America's Economic Future." (http://fdaalliance.files.wordpress.com/2011/03/fda_cornerstone_of_american_economy)

[finalforprint2.pdf](#)). The document details the far-reaching and positive economic impact of a strong FDA and the industries it oversees. The report proved a valuable tool in explaining why cutting FDA was counter-productive to the goal of reducing deficits and creating new jobs. Moreover, the white paper pointed out that FDA is a different kind of regulatory agency, as reflected in the support of all stakeholders for a stronger, better funded FDA, seeing it as in their own interests, as well as that of the nation.

- **Stronger FDA Advertisement Campaign.** In September, the Alliance ran timely and strategic political advertisements for the first time, appearing in several Capitol Hill publications for three days. The advertisement listed approximately 90 Alliance member organizations as signatories and coincided with the timing of the Senate Agriculture Appropriations Subcommittee FY 2012 Mark-Up.
- **In-State/District Meetings.** As part of its congressional advocacy, the Alliance scheduled, coordinated and held two in-state/district meetings in August.
 - **Chairman Kohl/Wisconsin Meetings.** The Alliance held three events in Wisconsin with Senator Herb Kohl (D-WI) to honor and thank the Senator for his work to strengthen FDA as Chair of the Senate Agriculture Appropriations Subcommittee. The meetings occurred at the following Wisconsin-based FDA-regulated stakeholders: American Pasteurization Company (Milwaukee); Exact Sciences, Inc. (Madison); Ocean Spray, Inc. (Wisconsin Rapids). Participants and speakers included Wisconsin-based patient, consumer, and industry stakeholders, as well as representatives of Alliance member organizations from Washington, DC.
 - **In-District Meeting with Congressman Tom Latham (R-Iowa, 4th District).** The Alliance also met with Representative Tom Latham in Ankeny, Iowa at Umbria Health Sciences. Several Alliance members from Congressman Latham's district and Iowa based organizations participated in the event.
- **Conference Letter Writing Campaign.** In November, the Alliance organized a letter writing campaign to support FDA funding in the FY 2012 Appropriations cycle. Specifically, we assisted Alliance member organizations in drafting and sending letters encouraging House appropriators to accept the higher Senate level for FDA's budget.
- **Food & Drug Law Institute Article.** In July, Alliance Executive Director Ladd Wiley and Deputy Executive Director Steven Grossman co-authored an article that ran in the Food and Drug Law Institute's Policy Forum, "Does FDA Have Enough Funding to Fulfill Its Critical Public Health Responsibilities?" The article highlighted the continuing expansion of the agency's public health responsibilities and the urgent need to increase FDA funding.

Administration Activities

- **Meetings with FDA Officials.** Throughout the year, the Alliance held meetings with FDA officials to gain a better understanding of how resource issues are impacting FDA's mission. In 2011, the Alliance increased its number of meetings, requests for information and communications with the Center and Agency leaders.

- **Meetings with the White House, Office of Domestic Policy Officials.** With the Administration’s focus on innovation, the Alliance was asked for its insights into FDA’s role into advancing innovation and job creation.
- **Office of Management and Budget.** Throughout the year, and especially in the Fall, the Alliance communicated and met with officials from the White House and the Public Health Division at the Office of Management and Budget regarding the Fiscal Year 2013 budget cycle.

Increasing Membership Value

As a membership organization, we are keenly aware that we need to prove value to our members. The Alliance Board took steps this year to strengthen the organization internally and improve member support. These steps included:

- Enhancing our external speaker’s program and creating opportunities for members to meet with FDA experts as a coalition.
- Focusing on membership recruitment in order to put the Alliance on solid financial footing. The Alliance is now functioning in the black for the first time.
- Engaging in leadership “listening sessions” with members to improve our communications and our offerings.
- Redesigning the Alliance website to better serve both the public and our membership by making information more accessible and timely.
- Initiated an effort to start web-casting appropriate membership meetings to enhance membership accessibility.
- Enhancing Friday Updates and analysis. Our weekly updates provide Alliance membership with the information and insights to be effective advocates. This is supplemented by additional analysis provided before, during and after key milestones in the budget process.
- Engaging the Board in new levels of strategic long-term planning.

These efforts resulted in improved service offerings to our membership, increased our ability to communicate with our growing membership and function effectively, and helped us to achieve our mission and goals as an organization.

The Road Ahead: Significant Budgetary and Political Challenges

In 2012, we expect policy-makers in Washington will be even more intensely focused on reducing government spending than they were in 2011.

The President's FY 13 request will be released in early February 2012. We are hopeful that he recommends an increase for FDA funding that protects the agency from the deep spending cuts and recognizes the agency's increased responsibilities.

Deep Cuts in Spending. FY 13 Appropriations will require deep cuts in federal spending. This is likely to be a two-stage process.

First, aggregate FY 13 appropriations must meet aggregate spending targets for domestic discretionary programs that are set by the Budget Control Act of 2011. The target is only marginally higher than the aggregate for FY 12.

Second, additional deficit reduction cuts are mandated in the amount of \$1.2 trillion in 10-year program savings. These will be accomplished by across-the-board cuts ("sequestration") on January 2, 2013, and will mostly hit discretionary domestic and defense spending. Unless Congress passes substantial deficit reduction legislation next year in lieu of sequestration, FDA must prepare for a possible cut in the range of \$150 million to \$250 million that will be taken from whatever amount the agency received during the regular appropriations process.

New Responsibilities. Traditionally, FDA's growing responsibilities have been attributed to additional statutory mandates adopted by Congress (most recently in 2010 with passage of the Food Safety Modernization Act and enactment of a new approval pathway for biosimilar products). We anticipate that the legislation reauthorizing various user fees in 2012 will become a vehicle for Congress to add new, unfunded responsibilities to FDA's portfolio. We will work hard to draw attention to this and call for additional appropriated funding to support these new activities.

FDA responsibilities continue to grow even without imminent legislative changes, due to globalization, increased scientific and regulatory complexity, and growth in the industries that FDA oversees. This is reflected in the statistics we have included in our communications with Capitol Hill, such as:

- Over the last 15 years, a massive shift in FDA's focus has occurred because of the globalization of the industries that the agency regulates. FDA-regulated products are imported from roughly 200 countries, using 825,000 importers, through over 300 U.S. ports-of-entry. Today, \$184 billion worth of FDA-regulated products are imported into the United States. FDA has recently clearly stated that it "does not – nor will it – have the resources to adequately keep pace with the pressures of globalization."
- America increasingly depends on other nations to produce the food, drugs, cosmetics, and devices we use in our daily lives. Between 10% and 15% of all food consumed by American households is imported from abroad. According to the U.S. Government Accountability Office (GAO) nearly two-thirds of the fruits and vegetables—and 80% of seafood—eaten domestically come from outside the U.S. Half of all medical devices used in this country are imported, while 80% of the active pharmaceutical ingredients in medications sold here are manufactured elsewhere.

The Alliance's Greatest Strength

In order to overcome the serious challenges that stand in the way of a better funded FDA in 2012, the Alliance will have to build upon its successful advocacy efforts and continue to leverage the organization's greatest strength: the breadth and commitment of its membership. The Alliance's success is a result of each of the individual member organizations. By working closely together to draw attention to and explain the critical relevance of FDA funding to specific interests and districts, we can show why the FDA needs Congressional support and funding. Our continued progress will undoubtedly be dictated by the degree to which our alliance remains strong and focused.

Conclusion

Over the last five years, FDA has been one of few discretionary federal programs to receive substantial funding increases. 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. 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 handle the burgeoning demands of globalization.

Attached below for your use is a summary of messaging the Alliance used last year.

Thank you for your membership in the Alliance for a Stronger FDA. We look forward to working with you in 2012 to improve the appropriations of the FDA.

Nancy Bradish Myers
President, Alliance for a Stronger FDA

Core Messages: Why Does FDA Need More Funding?

The Alliance for a Stronger FDA's ability to successfully navigate a challenging and complex legislative environment and secure increased funding for FDA over the past year was in part a result of the Alliance's effective messaging campaign. In 2011, our advocacy efforts continued to be centered on emphasizing the vital importance of FDA as a protector and promoter of public health.

We stressed FDA's role as a pre-eminent public health agency that assures that our food supply is safe and that drugs, vaccines and medical devices are safe and effective. Its mandate includes a number of other important public health purposes from over-the-counter drugs to pet food, from bottled water to dietary supplements and from cosmetics to standards for radiation-emitting devices, such as cell phones. Multiple times every day, Americans use products for which FDA has oversight responsibilities. There is no back up if the agency isn't there.

In addition to pointing to the agency's critical public health role, we included several other key messages in our outreach and communications initiatives, including emphasis on the agency as a driver of national productivity, competitiveness, innovation and job creation.

Exceptionalism. Despite the challenging budget environment, FDA needs to be an exception to deficit reduction. The Alliance is aware of the economic and budgetary imperative to control federal spending. Because of decades of funding neglect and rapidly growing responsibilities, the FDA needs to be an exception to the budget cutting that is likely to occur this year and next.

- FDA needs to be a priority because of the essential services it provides in assuring safe foods and safe and effective medical products. If the scope of the federal government is significantly diminished, an intact FDA needs to be part of what survives.
- These are services that the American people cannot do without. If FDA cannot perform these services, nobody else will.
- An adequately funded FDA is in everybody's interests, including consumers, patients and industry. Everybody benefits when the agency has the resources to provide clear, timely, consistent and reliable science-based guidance.

Global Competitiveness. FDA oversees nearly 25% of all consumer spending — assuring safe foods, safe and effective medical products, etc. The economic impact of the industries and products the agency oversees is enormous — and has the potential to lead growth in our economy and job development (see our white paper). Unlike other regulatory agencies, a strong FDA is welcomed by the industries it oversees.

FDA has been severely underfunded for decades. Funding is needed to catch up with globalization and the increasing complexity of science. Nanotechnology is just one example of new science that is developing into job growth and a plus for our economy. It is equally important to appreciate how much the FDA-regulated industries are growing, which requires more FDA resources to keep up.

Development of new products and more efficient means of manufacturing and delivery hold the potential for the FDA-regulated portion of the economy to continue to grow in size, employment and exports. For example, the FDA-regulated food industry, contributes \$1.165 trillion (about 8%) to the U.S. GDP. As a nation, we feed our own people and also much of the world. Without FDA, exports would be greatly reduced because many international buyers would not have the same comfort level in buying from the U.S.

Conclusion. FDA's job is much like national defense — essential to our nation's well-being and providing protection that is apt to be taken for granted until a crisis occurs. Even with economic pressures to decrease the deficit, now is not the time to cut the FDA.