Introduction

The Alliance for a Stronger FDA is a not-for-profit corporation that is dedicated to a single goal: increasing the level of appropriated funding for the Food and Drug Administration (FDA). Formed three years ago with the merger of the FDA Alliance and the Coalition for a Stronger FDA, the Alliance is unique because its members represent all of FDA’s stakeholders, including consumer and patient groups, health profession’s societies, associations and industry. The Alliance’s 180-plus members are committed to assuring that FDA has the funding needed to protect and advance the Nation’s health.

The Alliance is pleased to report that FDA has received significant funding increases in every year that the Alliance has advocated on its behalf. In FY 2007, FDA received an appropriation of $1.569 billion. By FY 10, this had grown to $2.345 billion, roughly a 50% increase in agency funding in 3 fiscal years. During this period, the FDA was also given a $150 million one-time supplemental appropriation. These increases have begun to give FDA the resources, personnel and tools it requires to fulfill its ever expanding list of public health responsibilities.

While the recent funding increases represent a marked change from two decade’s of chronic underfunding, the FDA’s appropriation remains significantly below the levels required to accomplish the agency’s mission. The Alliance and its members remain committed to sustained and substantial multi-year increases in resources for FDA. We believe it is necessary to restore the agency’s regulatory and scientific capacities, master the increasing complexity of science, and deal with the globalization of medical products and food.

A reinvigorated and redoubled effort by the Alliance and its stakeholder members will be needed in 2011--and the years ahead-- to ensure that FDA continues to receive the funding that it needs to maintain and enhance its status as the world’s gold standard for promoting and protecting the public health.

Funding Success

FDA’s appropriated budget for FY 2010 was $2.345 billion, a $776 million increase over FY 2007 (3 years). In contrast, FDA received an increase of only $180 million over the four prior fiscal years. (See chart below).
Thanks in part to the Alliance’s efforts, the President’s FY 11 Budget Request proposed an appropriation of $2.508 billion for the FDA, an increase of $163 million over the previous year. While the proposed 6 ½% gain over the prior year was significantly smaller than the gains made in the previous two years, the FDA fared better under the President’s budget request than almost all other federal agencies.

In 2010, there were four instances when Congress proposed FY 11 funding based on its priorities, rather than using a general standard (flat funding). The bill approved in the House Appropriations subcommittee mark-up on July 1 provided FDA with about $55 million more than the President’s request. The bill approved in the Senate Appropriations Committee on July 15 would have given FDA its funding at the President’s Request level. Finally, in December the House approved and the Senate considered bills that would have given FDA funding at the President’s Request level or above.

The FY 11 funding battle eventually devolved in a series of Continuing Resolutions through March 4, 2011 that limit virtually all government agencies at the level of their FY 10 appropriation. FDA’s funding situation is a reflection of across-the-board flat-funding, rather than the strength of FDA’s case for increased resources.

The Alliance has been preparing for a difficult environment in 2011, while hoping for better. In the new year, the Alliance will be simultaneously fighting for more money for FY 11 (the current year), while giving equal energies to the FY 12 process. We will keep reminding Congress that FDA needs to be an exception to budget cutting. The chart below provides the FDA’s appropriated funding over the last seven years and the President’s proposed FDA funding for FY 2011:
The FY 10 federal budget deficit is generally recognized to be unsustainable in future years. As a result, efforts to reduce government spending have become front and center in the policy debate. Estimates recently released by the Congressional Budget Office underscore the urgency of the Nation’s fiscal challenges:

- The Federal deficit for 2010 will be $1.3 trillion or 9.2% of gross domestic product
- The amount of federal debt held by the public has jumped from 40% GDP in 2008 to 62% by the end of 2010; even with substantial annual reductions in the budget deficit this will grow to almost 67% by 2020 –almost $15 trillion
- Federal spending will rise to approximately 23% of GDP by 2020

Both Democrats and Republicans campaigned on a promise of deficit reduction in the 2010 mid-term elections. President Obama has singled out deficit reduction as a major priority of his Administration and has proposed flat-funding for most domestic federal agencies.

As a result of the 2010 mid-term election, Republicans took control of the House of Representatives, effective with the start of the 112th Congress in January. The Senate remained in Democratic hands, but with a much slimmer majority. As a consequence, there will be some changes in the committees that authorize, appropriate and oversee FDA. The turnover is especially notable in the case of the Senate and House Agriculture Appropriations Subcommittees. In the Senate, the Agriculture Appropriations Subcommittee will lose five current members, including the ranking member. In the House, the Agriculture Appropriations Subcommittee will lose three current members and a new Republican Chairman will take the reins in January.

The new budgetary scenario provides the Alliance with an opportunity to highlight how a well-resourced FDA is uniquely important to America, including playing an important role in helping to reduce the deficit. The new political dynamics on Capitol Hill present an opportunity for us to amplify our advocacy efforts for increased FDA funding with current and new members of Congress.

FDA “Exceptionalism”

Recognizing that that future increases would be harder to get for FDA, the Alliance used 2010 to build on the theme that FDA needs to be an exception to budget cutting. The Alliance developed and used a number of arguments to promote FDA’s exceptionalism:

- **The Public Health Benefits of a Stronger FDA Merit Additional Investment.** FDA has been and remains significantly underfunded relative to its public health mission and responsibilities. For the better part of a decade, FDA 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.

- **A Strong FDA is a Driver of Economic Growth.** FDA plays a central and critical role in the U.S. economy because of the diverse and widely-used products that it regulates. The food, pharmaceutical, cosmetics and medical device industries in the United States lead the world in innovation. They provide millions of high-paying jobs and are among the few industries with a positive trade balance with other countries.

- **An Adequately Funded FDA is Key to Fostering Innovation and Advancing American Competitiveness.** To succeed in innovation, the industries regulated by the FDA need an agency with strong scientific and regulatory capacity that can provide clear, timely, predictable, consistent and reliable science-based guidance and decisions. A vibrant, effective regulatory system at the FDA is a key to our nation’s economic success in the face of these challenges.

- **FDA Plays a Vital Role in Advancing America’s National Security Interests.** The agency is responsible for safeguarding our food supply, combating bioterrorism through the approval of medical countermeasures, protecting against an influenza pandemic and other emerging infectious diseases, and strengthening the nation’s public health infrastructure to prepare for and respond to large scale emergencies and disasters.

- **A Stronger, Better Funded FDA Will Help Reduce Entitlement Spending and the Deficit.** Medicare, Medicaid and Social Security are major drivers of federal spending, representing approximately 40% of total government expenditures. In 2008 chronic disease cost the U.S. $1.65 trillion dollars – roughly equivalent to FY 10’s entire federal deficit. A properly-funded and modern FDA can help ensure that promising research is translated into new treatments to slow or reverse the onset and progression of chronic diseases, or ultimately prevent the diseases from developing. By playing a vital role in reducing the costs of chronic disease and sickness, a strong FDA can play a key role in helping to reduce America’s deficit.

The central focus of the Alliance’s advocacy efforts will continue to be the extraordinary public health benefits brought about by a well-resourced FDA. In addition, we have built arguments around current policy issues dominating the nation’s agenda, including rebuilding the economy, creating new jobs, and enhancing American competitiveness. To this end, the Alliance has developed white papers highlighting the important roles FDA plays in helping to stimulate economic growth, providing high-paying jobs, fostering innovation and advancing America’s national security interests.

**Where Might Increased Funding Go?**

Below is a summary of FDA’s public health initiatives and agency programs identified as priorities in Commissioner Hamburg’s message accompanying the President’s FY 2011 budget.
request. The initiatives have been singled out as critical parts of FDA’s overall public health mission and will be advanced by FDA’s budget initiatives.

- **Advancing Regulatory Science for Public Health**: During the past two decades, extraordinary investments have led to revolutionary advances in the life and biomedical sciences. Many key discoveries, however, have yet to translate into real therapies for patients. Additional resources will help FDA to begin to strengthen its core scientific capacities. This will help FDA to identify pathways to product development and approval for new and emerging medical technologies that offer promising new opportunities to diagnose, treat, cure, and prevent disease.

- **Protecting Patients**: The Protecting Patients Initiative advances safe, quality health care for all Americans. The resources in this initiative will support the safety of drugs, devices, and vaccines, as well as the blood supply. Additional resources will also strengthen FDA’s ability to act as a strong and smart regulator.

- **Transforming Food Safety**: FDA is leading efforts to establish a new food safety system to protect the American public. The agency will use additional monies to set standards for safety, expand laboratory capacity, pilot track and trace technology, strengthen the import safety program, improve data collection and risk analysis and begin to establish an integrated national food safety system with strengthened inspection and response capacity.

- **Economic Recovery and American Competitiveness**: FDA’s budget increases will also help to maintain America’s leadership in food and medical products regulated by FDA. To succeed in innovation, the industries regulated by the FDA need an agency with strong scientific and regulatory capacity that can provide clear, timely, consistent and reliable science-based guidance and decisions. A vibrant, effective regulatory system at the FDA is a key to our nation’s global competitiveness.

**Advocacy Activities**

**Administration**

The Alliance’ advocacy activities aimed at the administration included meetings and communications with officials from the White House, FDA, its parent Department, HHS, and the Office of Management and Budget.

- **The White House, Domestic Policy Council**: The Alliance met with members of the Domestic Policy Council (DPC) about the need to continue funding increases for FDA. DPC is the lead office at the White House for coordinating domestic policy.

- **FDA Commissioner Hamburg**: The Alliance was fortunate to continue its interaction with FDA Commissioner Hamburg in 2010. Commissioner Hamburg’s vocal support of the need for increased appropriated funding on Capitol Hill and within the Administration has been vital in ensuring that FDA’s funding shortfalls do not go unnoticed. In August, the Alliance was honored to have been invited by the Commissioner’s Office to attend a
special ceremony celebrating the launch of FDA-TRACK, an agency performance measurement initiative.

C. **FDA Principal Deputy Commissioner Joshua Sharfstein.** The Alliance met with Deputy Commissioner Sharfstein on a number of occasions, primarily to discuss FDA-TRACK, a new performance management program launched in 2010, and the agency’s broader efforts to link concrete public health improvements to the recent funding increases it has received. Dr. Sharfstein addressed the full Alliance membership at a member meeting and also met with a smaller group of Alliances representatives.

D. **Department of Health & Human Services (HHS).** Alliance advocacy efforts also included significant interaction with FDA’s parent Department, HHS. The Alliance met on two separate occasions with William Corr, Deputy Secretary, and Ellen Murray, Assistant Secretary for Financial Resources.

E. **Alliance Membership Letters Regarding FY 2012 to Kathleen Sebelius, Secretary, Health and Human Services.** The Alliance organized a letter writing campaign to urge Secretary Sebelius to make FDA a priority in the FY 2012 budget process. Many of the Alliance’s members participated in this initiative and the significant number of letters were generated. This provided a good start to the Alliance’s FY 2012 efforts.

F. **Meetings with FDA Center Directors and Senior Leadership.** Over the past two years the Alliance has met with most FDA Center Directors. The meetings provide an opportunity for the Alliance to gain a better understanding how specific FDA programs are putting additional resources to work. The Alliance has met with the following center directors and senior officials:

- Janet Woodcock, Director, Center for Drug Evaluation and Research
- Karen Midthun, Director, Center for Biologics Evaluation and Research
- Stephen Sundlof, Director, Center for Food Safety and Applied Nutrition
- Rachel Behrman, Director, FDA Critical Path Initiative
- Luciana Borio, Director of FDA Medical Countermeasures Initiative
- William Slikker, Director, FDA National Center for Toxicological Research
- Bernadette Dunham, Director, FDA Center for Veterinary Medicine
- Patrick McGarey, Director, Office of the Budget
- Mike Chappell, Acting Director, FDA Office of Regulatory Affairs

The Alliance looks forward to continuing its meetings with Center Directors and other FDA senior officials in 2011.

G. **Meeting with Office of Management and Budget (OMB).** The Alliance met with officials from the public health division at OMB for the third consecutive year. As the lead agency in determining the federal budget, OMB remains a key component to our overall campaign.
Congress

The Alliance remained highly engaged with Members of Congress and their staffs throughout 2010. As expected, Congressional advocacy efforts remained focused primarily on the House and Senate Agriculture Appropriations Committee, with special emphasis on meeting with Agriculture/FDA subcommittee members. Extended outreach included authorizing committees and other interested Members of Congress.

A. **Meetings with Agriculture Appropriators.** In early 2010, the Alliance met with the staffs of all 28 members of the House and Senate Agriculture Appropriations Committees regarding the need to increase FDA funding in the FY 2011 appropriations cycle. These meetings normally consisted of a cross section of Alliance stakeholders with consumer, patient and industry groups represented.

B. **Written Statement to House and Senate Appropriations Agriculture Subcommittee on FY 2011 Budget.** In March of 2010, the Alliance submitted a written statement to the House and Senate Committees on Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies outlining the Alliance’s funding request for FY 2011 of $2.857 million.

C. **Chairs of the House and Senate Agriculture Appropriations Subcommittees.** The Alliance continued its close working relationships 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 were also in regular contact with the staffs of both Chairs. Chairman Kohl and Chairwoman DeLauro are strong supporters of FDA and provided leadership in to ensure the agency has adequate funding.

D. **Letter to Congressional Leadership Regarding FY 2011 Omnibus Budget.** In November, the Alliance sent a letter to Congressional leadership advocating the Senate to recede to the House’s higher number for FDA appropriated funding.

E. **Authorizers.** The Alliance was benefitted by a Congressional letter sent to HHS Secretary Sebelius advocating for increased funds in the FY 2012 budget by House Energy and Commerce Committee Chair Henry Waxman, Senate Health, Education, Labor and Pensions Chair Tom Harkin and Representatives John Dingell (D-MI), Frank Pallone (D-NJ) and Bart Stupak (D-MI)

F. **Stronger FDA Hill Day.** In March of 2010 the Alliance held its third annual “Stronger FDA Hill Day” and met with more than 50 Congressional offices, including those of Members serving on the House and Senate Agriculture Committees, House E&C, and Senate HELP.
Messaging and Media

While topics such as the health care reform battle, the oil spill in the Gulf of Mexico and financial meltdown seemed to dominate the news coverage in Washington and across the nation, FDA’s resource shortfalls remained a recurring news theme throughout 2010. Headlines such as “FDA budget draws cries of 'not enough’,” “Congressmen Urge Greater FDA Funding Next Year” and “FDA stresses need to modernize its science” appeared on a regular basis in newspapers, television and radio news programming and helped to reinforce that that FDA has severe resource deficiencies.

As part of its advocacy campaign the Alliance issued the following media releases in 2010:

- Alliance for a Stronger FDA applauds FDA’s new accountability initiative, FDA Track Seen as a Positive Step Towards More Accountability and Greater Transparency at FDA
- Alliance for a Stronger FDA appreciates but has concerns about the Senate Appropriations Committee’s FY 11 mark for FDA
- Alliance for a Stronger FDA hails Waxman-Harkin letter supporting higher funding for FDA
- Alliance Praises Dr. Hamburg’s Leadership and FDA’S Role In Egg Recall, Calls for Additional FDA Funding to Reduce/Prevent Further Outbreaks
- DHHS Secretary Sebelius Declares Investment in FDA Regulatory Science to be a Critical Component of National Security, New HHS Report Highlights FDA’s Role in Countermeasures to Be Used During a Bioterror Attack
- Alliance Commits to More FDA Funding in Continuing Resolution, Alliance to Focus on Funding Bill that Congress Will Consider After Election Day

Throughout the year many of our member organizations played an important role in generating attention to FDA’s resource shortfalls in their capacities as individual organizations. Examples of stakeholders carrying the Alliance’s message as part of their own initiatives includes: the head of a consumer organization testifying before Congress and highlighting their membership in the Alliance; the CEO of a leading pharmaceutical company appearing in a series of major news stories calling attention to FDA’s funding deficiencies; and trade associations issuing press releases articulating why a stronger FDA is important to their respective industries. The Alliance urges its member organizations to carry forward the message of increasing FDA’s resources as integral parts of their own policy agendas.
Unfunded Mandates and New Responsibilities

The Alliance continues to be concerned about the prospect of an already overworked and understaffed FDA being asked to do more with 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. Major near-term unfunded mandates and responsibilities include the passage of food safety legislation, follow-on biologics and the exponential growth in both volume and complexity of new innovative products and fields.

- **Food Safety Legislation.** Food safety reform legislation, passed in late December, 2010 will dramatically increase FDA’s workload. The Congressional Budget Office’s analysis of the Senate food safety bill projects an additional $600 million in appropriated funds will be required for food safety programs at FDA by the fifth year after enactment. CBO estimated that the total cost will be about $1.4 billion over the 2011-2015 period.

- **Follow-On Biologics.** As part of health reform, FDA has been directed to create an approval pathway for follow-on biologics. This will require substantial manpower and resources to implement the complex new law to generate the knowledge within FDA sufficient to regulate an expanded range of biological products.

- **New Scientific Complexity.** Biology (drug development, food safety), chemistry (manufacturing, diagnostics, cosmetics), and physics (medical devices, radiation-emitting products) are dynamic fields. New knowledge (and usually more complex knowledge) is an every-day event for FDA in carrying out its regulatory responsibilities. It might take FDA a number of years to build the culture of science it needs and have all the tools in place. Even then, the knowledge and the tools will change every day and require increased effort.

Alliance Administrative Activities

The Alliance is grateful to its 180+ stakeholder members for their support and dedication to our important mission. An active and engaged membership has been vital to our success. The progress made in improving FDA’s resources would be impossible without the hard work, effort and participation of our stakeholders.

The Alliance leadership and staff support the overall mission of building a stronger FDA by working hard to ensure that our message resonates with policymakers here in Washington and across the country. In addition to directing the Alliance’s advocacy activities, the Alliance’s staff is also responsible for carrying out certain administrative functions including:

- **Scheduling and Conducting Meetings.** Alliance members meet regularly with Members of Congress—House and Senate, appropriations and authorizing committees. We also interact with FDA through meetings with center directors and senior agency personnel. In addition, our four membership meetings each year often feature speakers from the Hill
and FDA. We also run an annual “Strengthen FDA Hill Day,” during which we meet with 50 or more offices in a single day.

- **Providing Up to Date News and Analysis of FDA Related Developments.** 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.

- **Maintaining and Updating the Alliance Website.** The Stronger FDA website includes wide ranging information on the Alliance, including its membership, recent and upcoming advocacy initiatives, copies of our weekly updates, links to relevant news and media and advocacy documents.

- **Operating a Non-Profit Entity.** As a non-profit corporation the Alliance is required to file certain documents with the Internal Revenue Service and comply with state corporate reporting requirements. The Alliance’s staff is responsible for fulfilling these accounting and reporting responsibilities as well as ensuring that the organization complies with its bylaws and other relevant non-profit governance rules and practices. Other administrative duties such as sending annual membership invoices and maintaining the organization’s financial records are also performed by the Alliance’s staff.

**Conclusion**

The key to future success in securing appropriated funding increases for FDA is harnessing the collective resources, know-how and commitment of the Alliance’s 180 members. Working together, the Alliance’s members have a great opportunity to increase FDA’s appropriated funding through its advocacy. The FDA needs the tools, resources and personnel to succeed in the 21st Century. The Alliance’s investment in the FDA must be at a level commensurate with the critical importance the agency plays in the lives of every American.