



Written Statement of the Alliance for a Stronger FDA
Regarding FY2011 Appropriations
for the US Food and Drug Administration

Submitted to the House Committee on Appropriations, March 18, 2010

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The Alliance for a Stronger FDA requests at least \$2.857 billion for the US Food and Drug Administration for FY11. This request is exclusive of user fees.

We thank the House Appropriations Committee for the opportunity to present our views on the FY 2011 appropriations for the US Food and Drug Administration. The Alliance has 180 members from every stakeholder group interested in FDA. Our members include consumer and patient groups, associations, non-profits, health professions organizations, individuals and industry. Three former DHHS Secretaries and 6 former FDA commissioners are also part of our cause. We are united in the belief that:

**A strong FDA benefits all Americans:
Patients, consumers, health professionals, industry
....and the whole world benefits, too.**

We would like to express our appreciation to the House Appropriations Committee and its Subcommittee Chair, Representative Rosa DeLauro and Ranking Member, Representative Jack Kingston. The FDA's appropriation has gone up significantly over the last three years and their support and leadership has been essential.

Those increases have been critical to strengthening the agency. Nonetheless, there remains an extraordinarily large gap between FDA's responsibilities and FDA's resources. Every year, the agency's job becomes more complex scientifically and more difficult to implement. New laws affecting FDA are enacted with some regularity, further straining the FDA's ability to meet the expectations of the Congress and the American people.

There are a number of legislative initiatives this year that would further expand the responsibilities of the FDA. As a very broad-based coalition, we take no position on the merits of any of these.

We are concerned, however, that FDA's appropriation reflect any further increases in responsibilities. As will be described, we are recommending a \$495 million increase or more for the agency. This is the amount we believe is needed to make further progress against existing responsibilities. Any new legislation needs to come with the assurance that there will be larger "budget authority" appropriations to cover the cost of the additional work.

We remind the committee that FDA's appropriation is quite small, especially when matched against its jurisdiction over one-quarter of consumer spending, 80% of the food supply and all of the drugs, biologics, medical devices, animal drugs, cosmetics and dietary supplements used anywhere in the United States. FDA must also deal with the food and medical products that are sourced from overseas. Despite three years with appropriations above the break-even point, the FDA still gets only \$2 billion per year. There cannot be many agencies in the US government that have such a vast scope of responsibilities and so few dollars to get the job done.

As a way to sum up many points about the agency, we have 10 things that we hope policymakers will know and remember about FDA:

- FDA is a comparatively small agency with an appropriation: just \$2.35B in 2010 to regulate products that represent a quarter of all consumer spending.
- Twenty-five years ago, FDA and CDC were the same size; today the CDC budget is nearly 2 1/2 times as large.
- A strong FDA is good for the US economy and for our balance of trade.
- FDA is an integral part of our response to public health emergencies, including defense against bioterrorism.
- FDA's appropriation is almost entirely staff costs, requiring nearly 6% increase each year to sustain program levels.
- After three years of good increases (thank you, Congress), FDA staffing levels from the 2010 appropriation have only just been restored to the previous high-level achieved in 1994.
- User fees serve valuable functions, but they are targeted and support only specific activities. They don't strengthen the FDA in carrying out its overall public health mission.
- All FDA stakeholders support a stronger FDA (consumers, patients, health professionals, and industry).
- FDA's responsibilities increase each year---through new mandates, globalization, scientific complexity.

- **FDA touches every American multiple times each day. Today's investment (2 cents per day per American) is a pittance compared to the benefit of a strong FDA and the risk of an underfunded FDA.**

The Alliance often compares the FDA's budget to that of the Montgomery County school system's budget. The Superintendent of Schools and the FDA Commissioner had offices less than three miles apart before the Commissioner moved to White Oak. When the Superintendent looks out his window, he reflects on the educational needs between Takoma Park and Germantown. When the Commissioner looks out his window, he reflects on the food and medical product needs of the entire world. Yet, until last year, the Superintendent had a significantly larger budget to spend than the Commissioner.

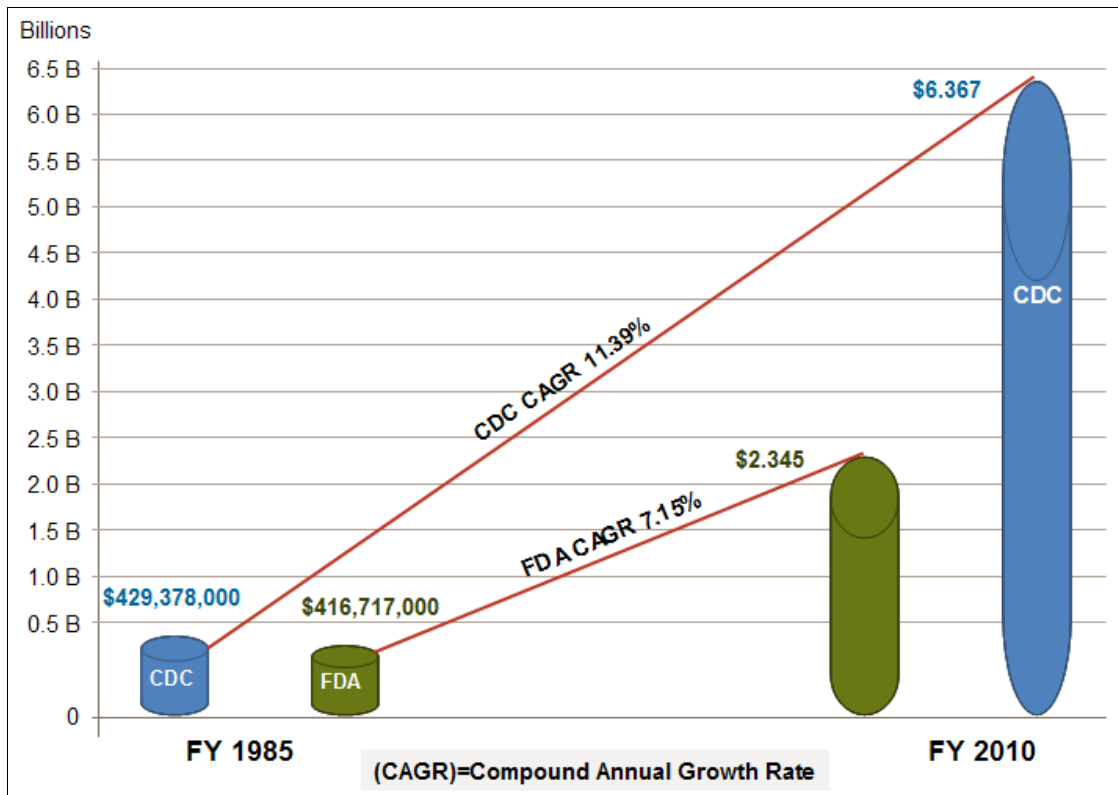
More than 80% of the FDA's budget is people-related. This includes salary, benefits, rent, telecom, training, office equipment, travel, etc. There are no grants to pull back if the money comes up short. Instead, over much of the last 20 years, when FDA's funding has been inadequate, the result has been layoffs, hiring freezes and buy-outs. Now that the agency's funding situation has improved, there are still many FDA managers concerned that this year's hires may need to be dismissed if next year's appropriation doesn't continue to grow.

At this point, FDA needs more than \$100 million more each year just to sustain the prior year's FTEs and program initiatives. Substantial dollars are needed above that level to help close the gap between responsibilities and resources.

The solution, which is also our goal, is to strengthen FDA's ability to operate a modern, scientifically-based regulatory program. To do so, the FDA needs to be provided with resources to rebuild the infrastructure and assure the safety of foods and cosmetics and the safety and efficacy of drugs and medical devices.

In the mid-1980's, FDA and CDC had similar budgets (about \$400 million each in FY 1985). In FY 10, CDC has a budget authority appropriation of \$6.37 billion dollars, a compound annual growth rate greater than 11%. In comparison, FDA has a budget of \$2.35 billion, a compound annual growth rate of about 7%.

The impact is particularly pronounced when the differences are graphed and the upward slopes compared (below). The chart is in nominal dollars. If we were to look at constant dollars, CDC is a substantially bigger agency than 25 years ago. In FDA's case, the net grown over the same period has been insubstantial and much of the growth is in the last three years.



We are not suggesting that FDA should have a \$6 billion budget. Rather, the degree to which FDA has fallen behind is often hard to see, because the agency is being compared to itself. In this comparison, it is dramatic and can lead to only one conclusion: FDA is not funded to meet its responsibilities as a public health and regulatory agency.

We do not know what the right number for FDA is....only that it is significantly more than the current budget. Large increases for a number of years are going to be needed.

For the immediate timeframe, the Alliance for a Stronger FDA requests a \$495 million increase or more for the FDA in FY 2011. We believe that the President's budget request of \$154 million is a step in the right direction, but substantially below what is needed. Below, our request is broken down by centers and major functions. We show FY 2008, 2009 and 2010 for comparison. This recognizes that growth over the last three has changed the direction of the agency. More will be needed....this year, next year and thereafter.

Function Note: budget authority only, by center	FY 08 Actual (December 2007)	FY 09 Final (March 2009)	FY 10 Final (October 2009)	FY 11 Recommendation of the Alliance for a Stronger FDA
Food	\$ 510 million	\$ 649 million	\$ 784 million	\$ 955 million
Human Drugs	\$ 353 million	\$ 413 million	\$465 million	\$580 million
Biologics	\$ 155 million	\$ 183 million	\$206 million	\$255 million
Animal Drugs/Feed	\$ 97 million	\$ 116 million	\$135 million	\$165 million
Devices & Radiological Health	\$ 238 million	\$ 280 million	\$315 million	\$385 million
Natl. Ctr. For Toxicol. Res.	\$ 44 million	\$ 52 million	\$59 million	\$72 million
HQ, Off. of Comm./ Other	\$ 97 million	\$ 121 million	\$144 million	\$183 million
Rent & Facilities	\$ 220 million	\$ 223 million	\$237 million	\$250 million
<u>TOTAL, Salaries and Expenses</u>	<u>\$1.714 billion</u>	<u>\$2.039 billion</u>	<u>\$2.346 billion</u>	<u>\$ 2.857 billion</u>

We have allocated new money to building and facility rental, which is more than 20% of the FDA's budget. We are told that the FDA will reach a point where White Oak (even with the new building being constructed) and College Park will barely fit the FTE's that have been authorized and/or will be transferring from Parklawn and other facilities that are closing. A more substantial increase in rental costs may be needed in FY 2011. We hope the Committee will follow this closely and assure that rental costs are fully funded. Increases in rental costs should not be covered by tapping into new program monies or by disproportionate allocations from user fees.

New monies from this year and last year are now flowing into the FDA and are being translated into recruitment, hiring, training and deployment. Because of the nature of FDA jobs, many of the new hires may not reduce division workloads for upwards of a year. This is a slow process, but necessary to grow and strengthen FDA.

Going forward, The Alliance is committed to working with the Congress and FDA to ensure:

- Transparency in how new appropriated monies are spent, and
- Clear communications from FDA about the public health benefits that have been achieved with the new funding.

In closing, the Alliance for a Stronger FDA reiterates its appreciation for the efforts of Committee members and their staffs to change the course of the FDA. They are strengthening the agency and guiding it toward success.

We remain available to the Committee to provide information and analysis at any time.