Q. Does the Alliance have an FY14 request for FDA?

A. The Alliance for a Stronger FDA urges the U.S. Congress to recognize the critical role and expanding public health mission of the U.S. Food and Drug Administration (FDA). FDA's pre-sequestration budget authority (BA) appropriation of $2.53 billion is significantly less than the amount the agency needs to meet its growing public health and safety responsibilities. The sequestration puts Americans at even greater risk.

The Alliance requests appropriated FDA funding in FY 14 that fully restores the agency's base lost in the FY 13 sequester and adds modest additional funding above that level. Specifically, we are requesting budget authority appropriations of $2.60 billion. This is a 4% increase for the agency over FY 12 and restores $30 million in “base adjustments” that would be cut under the President's budget request.

FDA's vital, complex world-wide public health responsibilities cannot be accomplished with its existing budget, particularly post-sequestration.

Q. How do I respond when Congressional staff (or reporters) point out that FDA received a net increase in total revenue for FY 13, a feat matched by very few federal programs?

A. We are pleased that FDA will have more resources in FY 13 than FY 12. However, this masks two important points that we need to keep making to policymakers and media:

- The agency’s mission and responsibilities are not static. In FY 13, the agency will be implement three new laws (food safety, biosimilars and FDASIA, including a dramatically increased generic drug program) and
must continue to deal with globalization, scientific complexity and industry growth. So, the question is not whether FDA can do more with less, but whether it is even possible to deal with such a substantial increase in responsibilities without substantial additional monies.

- All sources of FDA revenue are not equally useful to meeting the agency’s broad responsibilities. Much of the new money is available for very specific functions, while most of the cutbacks are to dollars that can be applied to a broad range of activities. Bottom-line appearances to the contrary, the addition of $300 million in generic user fee revenue does not offset the BA losses (available for any priority) or, even within CDER/CBER, the PDUFA user fee losses (available for a wide variety of drug safety and efficacy programming).

**SEQUESTRATION**

**Q.** What impacts will there be from the sequester and when are we likely to start seeing them? In particular, given that FDA’s budget is almost entirely staff costs, how can FDA absorb the 5% sequester without furloughs or lay-offs?

**A.** We have described the impact of the sequester as “death by a thousand cuts.” Despite the Administration’s dire warning of specific horrendous consequences at many agencies, it will generally be the case that there will be a real cut in responsiveness and delays in a broad range of responsibilities rather than dramatic changes that will affect and be visible to the general population. It has been predicted the sequester will result in 750,000 jobs lost in the economy….and those, too, will be spread out over time and, to an extent, over geography.

At FDA, regulations, guidances, meetings and product reviews will not be timely because there will not be the necessary manpower to keep up with the work. In addition, inspections will be postponed, cancelled or fall further behind in the queue. The decision that there will be no lay-offs or furloughs is NOT an indication that the impact will be minimal. Rather, the agency has not been filling all its vacancies for a while (because of the uncertainty of the FY 13 budget) and will continue along this path for the rest of the year.

“No furloughs” was really just a statement that the FDA’s headcount on March 2, 2013 was less than the headcount that they will be allowed post-sequester. But for internal FDA planning, it is important to understand that all of the existing headcount are not in the right place: every BA-funded offices and many user fee-funded offices will wind up short-handed. Thus, to avoid lay-offs or furloughs at FDA, some people will need to be transferred to offices/activities that have funding or have too few people to function.
Q. **FDA seems to be weathering the sequestration better than they or the Administration first forecast. Why is that and what are the long-term consequences?**

A. In general, it now appears that the Administration overstated the immediate consequences of sequestration, with FDA being merely a specific example of how this has created a credibility gap with Congress. This isn’t a surprise because we have written a number of times that sequestration would be mostly “death by a thousand cuts,” rather than dramatic, attention grabbing program failures.

Assuring a diffused impact was why the sequester law specified that the cuts were to be taken evenly from all programs. This was to make it harder for an agency to concentrate cuts in a specific area to force public attention. There is even a widely-held suspicion that the two sequester exceptions thus far—meat inspectors and air traffic controllers—were achieved by the Agriculture and Transportation departments allocating larger cuts to those workforces.

FDA has said that it has been able to marginalize the impact of the FY 13 sequester through cuts to travel and contracts, as if such cuts do not have real programmatic impact. Further, some portion of the “savings” is being achieved by not filling all vacancies, which started earlier in the fiscal year. Nonetheless, the agency has fed an impression on Capitol Hill that FDA had 5% worth of waste ($209 million) that it could trim without consequences.

We do not believe there are extra dollars in the agency budget and wonder how that could be true in the face of massive expansion of agency responsibilities over the last five years, plus the costs of dealing with globalization and increased scientific complexity. For example, we certainly hope that there are no major food safety incidents, but think it is obvious that the risk of such incidents is higher post-sequester than pre-sequester. For another example, we have written that the number of new drug and device approvals this year will likely stay high—that the impact of sequester is more likely to be felt in pipeline developments where meetings, response letters and other feedback will be slowed by a lack of manpower.

**DEBT CEILING**

Q. **There are reports that with tax revenues up and federal spending down, the debt ceiling might not be breached until the Fall. How will that effect FY 14 appropriations?**

A. Currently, the House and Senate Budget Resolutions are about $90 billion apart for discretionary spending (about 9%). Not only dollars separate the two bodies, but also deficit reduction strategies and political philosophies.
Currently, the Senate is pressing for a conference to try to resolve the differences, while the House has not wanted to engage, considering the exercise futile. It was widely believed the House would come to the table in the summer, believing that the need to raise the debt ceiling would provide them with leverage.

If the debt ceiling doesn’t need to be raised until the Fall, that makes a budget deal even less likely before the new fiscal year begins on October 1. As a result, the House will likely allocate and mark-up appropriations bills that fit within its own lower ceiling and the Senate will do likewise with its higher level.

While a couple of appropriations bills may become law because both houses will agree on a bottom-line for them (e.g. military construction), the bulk of bills will be too far apart, mirroring the gap between the budget bills. While any number of additional factors could come into play, that suggests that FY 14 is almost certain to start with most of the government being funded under a continuing resolution.

**CONTINUING RESOLUTION**

**Q.** What would happen if there was a continuing resolution at the beginning of the fiscal year instead?

**A.** As noted above, CR funding on October 1 is an increasing likelihood. The fate of FDA can be defined, but not specified. For example, a CR could be set at either the FY 13 pre-sequestration OR post-sequestration levels. The gap between the two (including user fees if there is no provision to the contrary in the CR) is $209 million or slightly more than $17 million per month.

Even if FDA were to have the higher level to spend, it would most likely do what it did during the initial FY 13 CR: hold back on hiring and contracts to blunt the impact of potential cuts later in the fiscal year, which might come from either appropriations cuts or a new sequester. This would not be an issue if the CR were set at the lower FY 13 post-sequester level, because that approximates (on a proportional basis) the likely FDA funding level if the House budget levels prevail.

**Q.** The House has just released is 302(b) allocations for FY 14 appropriations. What are the implications for FDA funding?

**A.** Relative to the BCA/2011 and the FY 14 House budget resolution, we have previously written that FDA’s proportional share for FY 14 is about the same as its post-sequester funding level. By dint of the agriculture/FDA subcommittee getting approximately the post-sequester funding level to spend, the probability of either a major increase (e.g. the President’s request level) or a further substantial decrease for FDA funding in FY 14 have been reduced. We might have benefited if the House 302(b) allocation for agriculture/FDA were larger, but we also
avoided a situation (faced by several other House subcommittees) of being given less to spend than the FY 13 post-sequester amount.

The Senate numbers are likely to be much better, but this foreshadows the eventual difficulties in reconciling FY 14 appropriations bills from the House and Senate that will have dramatically different bottom-line totals. FDA's best hope is still that the Congress and the President agree on a major deficit reduction package that reduces the pressures for further cuts in domestic discretionary spending.

**USER FEES**

**Q.** Is FDA still prohibited from spending user fee income?

**A.** The March 2, 2013 sequester of $209 million included approximately $83 million in user fees. Those are not available to the agency to spend, i.e. less a prohibition and more a "you can't spend money that isn't in your account." The total is approximately $36M from PDUFA, $15M from GDUFA, $3M from MDUFMA, $25M from tobacco, and a few dribs and drabs from other user fees, such as the animal drug ones. This doesn't quite add up to the total, but gives roughly the proportional shares and sources.

The FY 13 sequestered user fees (which is about 5% of the total) never become available to FDA unless Congress re-appropriates them, which would almost certainly require offsetting cuts elsewhere. So, the absence of the money is permanent (without new legislation or new interpretation by OMB) but the impact is defined as March, 2 to September 30, 2013. At that point, the topic becomes FY 14 user fees, which are also "at risk."

**Q.** Will there be a sequester in FY 14 and how would that affect appropriations and user fees?

**A.** Under the Budget Control Act, if Congress spends more than the budget cap in any particular year, another series of across-the-board cuts will go into place to get the spending levels underneath the overall discretionary spending caps.

For FY 14: if the appropriations committees can keep their spending within the cap, no across-the-board cuts will be required. If not, there will be new across-the-board cuts for FY 14 that might be larger or smaller than in FY 13. The percentage cut will be dictated by the amount of money needed to bring the total spending under the cap.

Under current law and OMB interpretation, user fees would be included within a sequester, the same as in FY13. However, the possibility remains (because the
process is just getting started) that FDA could be excluded from any new sequestration, either in whole or just the user fee portion.

As we have noted in previous Updates, Congress has three choices for FY 14:

- cut a major budget deal to allow enough discretionary spending to reach pre-sequester (base) levels and appropriations committees can pick winners and losers;
- only pass appropriations bills that in the aggregate do not exceed the BCA level; or
- don’t cut a deal, pass bills that exceed the allowable total and allow across-the-board cuts to bring the total back to the BCA level.