Coburn Amendment #____ - To Require an Independent Assessment of the FDA's Drug Application Review Process.

What The Amendment Does

This amendment requires FDA to contract with an independent management company to conduct an assessment of all of the drug review and approval processes.

The *medical device* user fee agreement includes the requirement for an independent assessment of FDA's management. This is a common-sense requirement that will help inform FDA's leadership and Congress – however, this review *does not apply to the drug review process*.

Congress, consumers, and patients deserve an independent and objective look at FDA's management of its mission and resources.

Key GAO Findings

According to a March 2012 GAO report,[1] FDA did not meet all of its user fee performance goals for priority and standard New Drug Applications (NDAs) and Biologic License Applications (BLAs) received from FY 2000 through FY 2010. FDA review time for NDAs and BLAs—the time elapsed between FDA's receipt of an application and issuance of an action letter—increased slightly from FY 2000 through FY 2010.

The same GAO report said industry identified challenges with working with FDA, such as FDA actions or requirements that increase review times (such as taking more than one cycle to approve applications) and insufficient communication between FDA and stakeholders throughout the review process. Stakeholders also noted a perceived lack of predictability and consistency in reviews. Advocacy group stakeholders noted issues related to inadequate assurance of the safety and effectiveness of approved drugs. FDA is taking steps that may address many of these issues, including issuing new guidance, establishing new communication-related performance goals, training staff, and enhancing scientific decision making.

Arguments For Why This Amendment Is Needed

Charge: This will require additional resources.
Response:

- Wrong. FDA can use existing resources for fulfilling this amendment.
- FDA can afford to pay consultants for independent management review: Since 2008, FDA expenditures on consulting projects with the private company McKinsey are more than $26 million – that's for contracts *with just one company*.
- Industry agreed to pay a total of approximately $3.5-4 billion over 5 years: $693,099,000 in year one, then that same amount each year afterwards, adjusted for workload and inflation. FDA can afford one management review to ensure they are managing correctly.

Charge: This is duplicative and is already required.
Response:

- No, actually, the *medical device* user fee agreement includes the requirement for an independent assessment of FDA's management, but this review does not apply to the drug review process.
- Congress, consumers, and patients deserve an independent and objective look at FDA's management of its mission and resources.

[1] http://www.gao.gov/assets/590/589762.pdf

Charge: GAO should do a review instead of FDA contracting with a company.

Response:

- GAO does a great job, but they already have several studies mandated under this bill.
- Moreover, the FDA could benefit from the expertise of professional management consultants.

Charge: The FDA could spend a lot of money on an independent management review and then it might just sit on a shelf. How do we know this improves anything?

Response:

After the management review is completed, the FDA is required to:

1) analyze the recommendations for improvement opportunities identified in the assessment, develop and implement a corrective action plan, and ensure it effectiveness;
2) incorporate the findings and recommendations of the contractors, as appropriate, into the management of the premarket review program of the Food and Drug Administration; and
3) incorporate the results of the assessment in a Good Review Management Practices guidance document, which shall include initial and ongoing training of FDA staff, and periodic audits of compliance with the guidance.