Coburn Amendment #____ - To Require FDA Employee Performance Standards Hold Reviewers Held Accountable for Their Contribution Toward Meeting User Fee Agreement Goals

Amendment Needed Because of GAO Findings

On Friday, May 18, 2012, GAO released a report in response to a request by Dr. Coburn and Sen. Burr. Given FDA's statutory commitment to meeting specific performance goals, Dr. Coburn and Sen. Burr asked GAO to examine whether or not FDA reviewers are professionally accountable to help FDA hit the performance goals.

The GAO product examines whether or not employee personnel standards used to assess employee performance include any mention of PDUFA-or MDUFA-related goals (Prescription Drug or Medical Device User Fee Agreements). **A review of the evidence shows that, during the period of GAO's evaluation, not all FDA employees involved in the review process of medical products were required to be explicitly evaluated with regard to their role in helping the FDA meet the user fee agreement goals.**

Key GAO Findings

- Not all performance management plans for Center Directors explicitly included timeliness goals related to PDUFA or MDUFA.
- FDA could not tell GAO how many employees were involved in the work of meeting the UFA goals.
- While GAO said FDA does know how many FTEs are *associated* with UFA-related work, GAO said this does not equate to people; FDA also could not tell GAO the percentage of time their work was focused on the UFA goals.
- Of key accountable officials in CDER, only 2 in 18 had specific goals related to the UFAs.
- Of roughly 250 Commission Corp staff participating in the review process, none had required timelines goals in their template that explicitly mentioned the UFA goals.
- FDA's tracking of management performance is not centralized and electronic; it is dispersed and paper-based.

Why This Amendment Is Needed

FDA told GAO that the timeliness of application reviews is just *one* aspect of employee performance.

- That is true, but the fact is that FDA already recognized it is an important metric of employee performance standards—because FDA already included it in some of the cases GAO examined.
- This amendment would require it to be a metric in all employee performance standards if that employee is part of the review process.

FDA told GAO that the Center Directors in CDER, CBER, and CDRH are ultimately accountable for meeting the timelines related to the PDUFA and MDUFA performance goals—including the percentages of reviews conducted within designated time frames.

- However, at the time of GAO's review, not all Center Directors had the timeliness of UFA goals included as a metric in their employee performance standards.

FDA told GAO it is also important to balance timeliness with the agency's standards for medical product safety and effectiveness, and said multiple employees are responsible for the review of a single application.

- While this is true, FDA already recognized it is an important metric of employee performance standards—because FDA already included it in some of the cases GAO examined.
- Moreover, this amendment gives FDA *significant discretion* with regard to how to implement the provision, so the FDA can continue to balance timeliness with the agency's standards for medical product safety and effectiveness.

About GAO's Methodology

GAO reviewed documentation of standards for employee performance for three centers at FDA:
(1) Center for Drug Evaluation and Research (CDER);
(2) Center for Biologics Evaluation and Research (CBER);
(3) Center for Devices and Radiological Health (CDRH).

These centers identified the employee positions involved with new medical product application reviews. GAO then reviewed standards for employee performance which are contained in employee performance plan *templates*. These templates are standardized by employee position and maintained separately by each center. The centers may customize these templates to create individual performance plans for each employee. FDA conducts performance assessments of its employees on an annual cycle. Most staff involved in the review of medical product applications (drugs and devices) develop performance plans with their managers at the beginning of a performance cycle, and are assessed at the end of a cycle based on the standards in the performance plan.

Specific Findings By Center

- **Center for Drug Evaluation and Research**—For non-executive employees, timeliness was mentioned as one part of the performance plan templates that CDER provided for all 18 nonexecutive employee positions involved in the review of applications. *However, none of the templates explicitly stated that the employees are expected to meet timeliness goals associated with PDUFA.* Two templates referred to FDA guidance that explicitly mentions these timeliness goals.

- **Center for Biologics Evaluation and Research**—Employee timeliness is mentioned in the performance plan templates CBER provided for all five nonexecutive employee positions involved in the review of applications, *but only two of these templates explicitly stated that the employees are expected to meet timeliness goals associated with PDUFA or MDUFA.*

- **Center for Devices and Radiological Health**—Employee timeliness is mentioned in the performance plan templates CDRH provided for all six nonexecutive employee positions involved in the review of applications, *but only four of these templates explicitly stated that the employees are expected to meet timeliness goals associated with MDUFA. At the time GAO conducted this work, the Center Director's performance plan template did not cite the MDUFA goals.*