

For Immediate Release

John Hart (Coburn) 202-228-5357

John_hart@coburn.senate.gov

May 18, 2012

David Ward (Burr) 202-228-1616

David_ward@burr.senate.gov

GAO Finds Not All FDA Employees Are Held Accountable for Meeting User Fee Agreement Goals

(WASHINGTON, D.C.) – U.S. Senators Tom Coburn, M.D. (R-OK) and Richard Burr (R-NC) today highlighted the findings of a Government Accountability Office (GAO) report – “[Food and Drug Administration: Employee Performance Standards for the Timely Review of Medical Product Applications](http://www.gao.gov/products/GAO-12-650R).” (<http://www.gao.gov/products/GAO-12-650R>) Given FDA’s statutory commitment to meeting specific performance goals, Sens. Coburn and Burr asked GAO to examine whether or not FDA reviewers are professionally accountable to help FDA meet its performance goals under user fee agreements. GAO examined whether or not employee personnel templates 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.

“Earlier this year, GAO empirically demonstrated the FDA’s inconsistency in meeting key performance goals. This report takes it a step further and confirms what many feared: FDA has not adequately institutionalized accountability for meeting user fee goals,” said **Senator Coburn**. “Despite agreeing to review goals and timelines negotiated with the device and drug industries, FDA could not tell GAO the number of total reviewers involved in the review process, nor were all personnel involved individually held accountable in their annual performance review. The result of higher employee performance standards has the potential to save the lives of so many patients who rely on FDA to make timely decisions that will allow them access to life-saving medical products that are waiting to hit the market.”

“America’s patients depend on the FDA for timely review of safe and effective life-saving medical products, and the Agency should be held accountable for meeting its performance goals. A GAO report released today on FDA employee performance underscores an opportunity to improve accountability at the employee level when it comes to timely review of user fee agreements for prescription drugs and medical devices,” said **Senator Burr**. “Congressional oversight is critical

for helping FDA to identify steps to strengthen their work on behalf of patients. The Senate FDA user fee reauthorization bill includes important transparency and accountability provisions from the Burr-Coburn PATIENTS' FDA Act, which will help FDA better achieve its important public health mission on behalf of patients.”

Key Findings

- At the time of GAO’s review, 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 directly 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.
- FDA could not tell GAO how many of the roughly 250 Commission Corp staff participating in the review process were expected to meet timeliness goals or the more explicit UFA goals, because the Corp staff are not required to use FDA’s performance templates.
- FDA’s tracking of management performance is not centralized and electronic; it is dispersed and paper-based.

Additional 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.
- 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.

###