

AMENDMENT NO. _____ Calendar No. _____

Purpose: To provide that a portion of the performance awards of each employee of the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research be connected to an evaluation of the employee's contribution to goals under the user fee agreements.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

S. 3187

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. COBURN

Viz:

1 At the end of title XI, add the following:

2 **SEC. 11 ____. PERFORMANCE AWARDS.**

3 (a) IN GENERAL.—Not later than 1 year after the
4 date of enactment of this Act, the Secretary of Health and
5 Human Services (referred to in this section as the “Sec-
6 retary”) shall establish a system by which a portion of
7 the performance awards of each employee described in

1 subsection (b) shall be connected to the evaluation of the
2 employee's contribution, in the discretion of the Secretary,
3 to the goals under the user fee agreements described in
4 section 101(b), 201(b), 301(b), or 401(b), as appropriate.

5 (b) EMPLOYEES DESCRIBED.—

6 (1) IN GENERAL.—Subsection (a) shall apply
7 only to employees who—

8 (A) are employed by the Center for Drug
9 Evaluation and Research, the Center for De-
10 vices and Radiological Health, or the Center for
11 Biologics Evaluation and Research; and

12 (B) are involved in the review of drugs, de-
13 vices, or biological products.

14 (2) COMMISSIONED CORPS.—For purposes of
15 this section, the term “employee” includes members
16 of the Public Health Service Commissioned Corps.

17 (c) EFFECT ON AWARD.—The degree to which the
18 performance award of an employee is affected by the eval-
19 uation of the employee's contribution to the goals under
20 the user fee agreements, as described in subsection (a),
21 shall be proportional to the extent to which the employee
22 is involved in the review of drugs, devices, or biological
23 products.

24 (d) REPORT.—The Secretary shall issue an annual
25 report detailing how many employees were involved in

1 meeting the goals under the user fee agreements described
2 in section 101(b), 201(b), 301(b), and 401(b), and the
3 manner of the involvement of such employees.