

S.L.C. Hassan

Hassan S. 4348 Amendment # 3

AMENDMENT NO. _____ Calendar No. _____

Purpose: To require contractors to make ongoing reports
of any conflicts of interest.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 4348

To amend the Federal Food, Drug, and Cosmetic Act to
revise and extend the user-fee programs for prescription
drugs, medical devices, generic drugs, and biosimilar
biological products, 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 Ms. HASSAN

Viz:

1 At the appropriate place in title IX, insert the fol-
2 lowing:

3 **SEC. 9__.** **REQUIREMENTS REGARDING ONGOING RE-**
4 **PORTING OF CONTRACTOR CONFLICTS OF IN-**
5 **TEREST.**

6 (a) IN GENERAL.—The Secretary of Health and
7 Human Services shall require entities that contract with
8 the Food and Drug Administration—

9 (1) to disclose, on an ongoing basis during the
10 term of the contract, any information related to po-
11 tential and actual conflicts of interest, including con-

1 flicts of interest concerning the contractor's per-
2 sonnel, consultants, and subcontractors; and

3 (2) during the term of the contract, to refrain
4 from entering into consulting or other contractual
5 arrangements with any person to perform work that
6 may reasonably create a potential or actual conflict
7 of interest, without receiving the written approval of
8 the contracting officer before the execution of the
9 contractual arrangement.

10 (b) REGULATIONS.—Not later than 18 months after
11 the date of enactment of this Act, the Secretary, in con-
12 sultation with the Federal Acquisition Regulatory Council,
13 shall issue regulations to carry out subsection (a).