

Maggi Hassan
Hassan S. 4348 Amendment # 4

AMENDMENT NO. _____ Calendar No. _____

Purpose: To restrict the awarding of FDA contracts to entities that do not have in place certain internal policies regarding 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 ____ . RESTRICTIONS ON FDA CONTRACTORS.**

4 (a) PROHIBITION AGAINST CERTAIN CONTRACTS.—

5 (1) IN GENERAL.—Subject to paragraph (2),
6 the Secretary of Health and Human Services (re-
7 ferred to in this section as the “Secretary”) shall
8 not award a contract relating to the duties of the
9 Food and Drug Administration to any person pro-
10 viding consulting services (referred to in this section

1 as a "consulting firm") unless such contract pro-
2 vides that, during the restricted period described in
3 paragraph (3), subject to paragraph (2), no indi-
4 vidual employee or subcontractor of such consulting
5 firm may provide services to both—

6 (A) the Food and Drug and Administra-
7 tion under the consulting firm's contract; and

8 (B)(i) a person engaged in the develop-
9 ment or manufacturing of a device, drug, or bi-
10 ological product; or

11 (ii) any other private entity engaged in ac-
12 tivities regulated by the Food and Drug Admin-
13 istration.

14 (2) EXCEPTION.—

15 (A) IN GENERAL.—The Secretary may
16 issue an exception to the requirement under
17 paragraph (1) with respect to an employee or
18 subcontractor of a consulting firm only if the
19 Secretary or designee determines in writing
20 that there is a compelling reason to award a
21 contract with such consulting firm with such
22 exception. The Secretary shall not delegate the
23 authority to issue exceptions under this sub-
24 paragraph below the level of head of a con-
25 tracting activity.

1 (B) REPORTING.—Not later than 14 days
2 after issuing an exception under subparagraph
3 (A), the Secretary shall publish, on the website
4 of the Food and Drug Administration, a notifi-
5 cation of the exception. Such notification shall
6 be made publicly available in an easily acces-
7 sible format, and shall include—

8 (i) the name of the contract;

9 (ii) the consulting firm receiving the
10 exception, and the employee or subcon-
11 tractor to whom the exception applies;

12 (iii) the other contracts or clients that
13 would, in the absence of the exception,
14 cause the consulting firm to be in violation
15 of paragraph (1); and

16 (iv) the efforts that the consulting
17 firm plans to take to mitigate any potential
18 or actual conflict of interest arising from
19 the other work of its employees or sub-
20 contractors.

21 (3) RESTRICTED PERIOD.—

22 (A) IN GENERAL.—For purposes of para-
23 graph (1), the restricted period is the period
24 that—

1 (i) begins when the applicable em-
2 ployee or subcontractor of the consulting
3 firm first provides services under the con-
4 sulting firm's contract; and

5 (ii) ends not less than the applicable
6 period specified in subparagraph (B) after
7 the last date on which such employee or
8 subcontractor provides services under the
9 consulting firm's contract.

10 (B) APPLICABLE PERIOD SPECIFIED.—For
11 purposes of subparagraph (A)(ii), the applicable
12 period specified in this subparagraph is—

13 (i) 30 days; or

14 (ii) such longer period of time as the
15 Secretary may specify after consultation
16 with the Federal Acquisition Regulatory
17 Council, which shall apply with respect to
18 all exceptions issued under paragraph (2).

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