

117TH CONGRESS
2D SESSION

H. R. 8828

To address potential conflicts of interest among entities serving as Food and Drug Administration contractors, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 14, 2022

Ms. KUSTER introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To address potential conflicts of interest among entities serving as Food and Drug Administration contractors, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “FDA Ethics Act of
5 2022”.

6 **SEC. 2. REQUIREMENTS REGARDING ONGOING REPORTING**
7 **OF CONTRACTOR CONFLICTS OF INTEREST.**

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

1 (1) to disclose, on an ongoing basis during the
2 term of the contract, any information related to po-
3 tential and actual conflicts of interest, including con-
4 flicts of interest concerning the contractor's per-
5 sonnel, consultants, and subcontractors; and

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

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

17 **SEC. 3. REQUIREMENTS REGARDING WAIVERS RELATING**
18 **TO ORGANIZATIONAL CONFLICTS OF INTER-**
19 **EST.**

20 (a) IN GENERAL.—The Secretary of Health and
21 Human Services (referred to in this section as the “Sec-
22 retary”) shall, not later than 14 days after awarding a
23 contract relating to the Food and Drug Administration,
24 publish, on the website of the Food and Drug Administra-
25 tion, a notification of any waiver of any requirements re-

1 guarding a potential or actual organizational conflict of in-
2 terest granted to the contractor. Such notification shall
3 be made publicly available in an easily accessible format,
4 and shall include the name of the contract, the contractor
5 receiving the waiver, the other contracts or clients that
6 created the potential or actual organizational conflict of
7 interest, and the efforts that the contractor plans to take
8 to mitigate the potential or actual organizational conflict
9 of interest.

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).

14 **SEC. 4. RESTRICTIONS ON CONSULTING FIRMS SERVING AS**
15 **FDA CONTRACTORS.**

16 (a) PROHIBITION AGAINST CERTAIN CONTRACTS.—

17 (1) IN GENERAL.—Subject to paragraph (2),
18 the Secretary of Health and Human Services (re-
19 ferred to in this section as the “Secretary”) shall
20 not award a contract relating to the duties of the
21 Food and Drug Administration to any person pro-
22 viding consulting services (referred to in this section
23 as a “consulting firm”) unless such contract pro-
24 vides that, during the restricted period described in
25 paragraph (3), subject to paragraph (2), no indi-

vidual employee or subcontractor of such consulting firm may provide services to both—

(A) the Food and Drug and Administration under the consulting firm's contract; and

(B)(i) a person engaged in the development or manufacturing of a device, drug, or biological product; or

(ii) any other private entity engaged in activities regulated by the Food and Drug Administration.

(2) EXCEPTION.—

(A) IN GENERAL.—The Secretary may issue an exception to the requirement under paragraph (1) with respect to an employee or subcontractor of a consulting firm only if the Secretary or designee determines in writing that there is a compelling reason to award a contract with such consulting firm with such exception. The Secretary shall not delegate the authority to issue exceptions under this subparagraph below the level of head of a contracting activity.

(B) REPORTING.—Not later than 14 days after issuing an exception under subparagraph (A), the Secretary shall publish, on the website

1 of the Food and Drug Administration, a notifi-
2 cation of the exception. Such notification shall
3 be made publicly available in an easily acces-
4 sible format, and shall include—

5 (i) the name of the contract;

6 (ii) the consulting firm receiving the
7 exception, and the employee or subcon-
8 tractor to whom the exception applies;

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

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

18 (3) RESTRICTED PERIOD.—

19 (A) IN GENERAL.—For purposes of para-
20 graph (1), the restricted period is the period
21 that—

22 (i) begins when the applicable em-
23 ployee or subcontractor of the consulting
24 firm first provides services under the con-
25 sulting firm’s contract; and

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

6 (B) APPLICABLE PERIOD SPECIFIED.—For
7 purposes of subparagraph (A)(ii), the applicable
8 period specified in this subparagraph is—

9 (i) 30 days; or

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

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

19 (c) DEFINITION.—In this section, the term “con-
20 sulting services”—

21 (1) means providing advice or recommendations
22 to improve organizational effectiveness; and

23 (2) does not include services provided pursuant
24 to a contract related to regulatory science research,

- 1 public health surveillance, or information technology,
- 2 or services provided by a small business concern.

