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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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''FDA Ethics Act of 2022''.

SEC. 2. REQUIREMENTS REGARDING ONGOING REPORTING OF CONTRACTOR CONFLICTS OF INTEREST.

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

(1) to disclose, on an ongoing basis during the term of the contract, any information related to potential and actual conflicts of interest, including conflicts of interest concerning the contractor's personnel, consultants, and subcontractors; and

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

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

SEC. 3. REQUIREMENTS REGARDING WAIVERS RELATING TO ORGANIZATIONAL CONFLICTS OF INTEREST.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall, not later than 14 days after awarding a contract relating to the Food and Drug Administration, publish, on the website of the Food and Drug Administration, a notification of any waiver of any requirements re-

garding a potential or actual organizational conflict of interest granted to the contractor. Such notification shall be made publicly available in an easily accessible format, and shall include the name of the contract, the contractor receiving the waiver, the other contracts or clients that created the potential or actual organizational conflict of interest, and the efforts that the contractor plans to take to mitigate the potential or actual organizational conflict of interest.

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

SEC. 4. RESTRICTIONS ON CONSULTING FIRMS SERVING AS FDA CONTRACTORS.

(a) PROHIBITION AGAINST CERTAIN CONTRACTS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall not award a contract relating to the duties of the Food and Drug Administration to any person providing consulting services (referred to in this section as a ''consulting firm'') unless such contract provides that, during the restricted period described in 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

of the Food and Drug Administration, a notification of the exception. Such notification shall be made publicly available in an easily accessible format, and shall include—

(i) the name of the contract;

(ii) the consulting firm receiving the exception, and the employee or subcontractor to whom the exception applies;

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

(iv) the efforts that the consulting firm plans to take to mitigate any potential or actual conflict of interest arising from the other work of its employees or subcontractors.

(3) RESTRICTED PERIOD.—

(A) IN GENERAL.—For purposes of paragraph (1), the restricted period is the period that—

(i) begins when the applicable employee or subcontractor of the consulting firm first provides services under the consulting firm's contract; and

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

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

(i) 30 days; or

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

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

(c) DEFINITION.—In this section, the term ''consulting services''—

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

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

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

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