118TH CONGRESS
2D SESSION

S. _____

To amend title 18, United States Code, to prohibit former employees of covered health agencies from serving on the board of entities involved in development and research of a drug, biological product, or device and from profiting from a drug, biological product, or device, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. VANCE introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend title 18, United States Code, to prohibit former employees of covered health agencies from serving on the board of entities involved in development and research of a drug, biological product, or device and from profiting from a drug, biological product, or device, 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 ''Fixing Administrations Unethical Corrupt Influence Act'' or the '' 'FAUCI Act' ''.

SEC. 2. PROHIBITION AGAINST SERVICE BY FORMER EMPLOYEES OF COVERED HEALTH AGENCIES ON BOARDS OF ENTITIES INVOLVED IN DEVELOPMENT AND RESEARCH OF A DRUG, BIOLOGICAL PRODUCT, OR DEVICE.

(a) PROHIBITION AGAINST SERVICE ON BOARDS OF ENTITIES.—Title 18, United States Code, is amended by inserting after section 207 the following:

"§ 207A. Prohibition against service by former employees of covered health agencies on boards of entities involved in development and research of a drug, biological product, or device.

''(a) DEFINITIONS.—In this section:

''(1) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

''(2) COVERED HEALTH AGENCY.—The term 'covered health agency' means any of the following:

''(A) The National Institutes of Health.

''(B) The Food and Drug Administration.

''(C) The Centers for Disease Control and Prevention.

''(3) DEVICE; DRUG.—The terms 'device' and 'drug' have the meanings given those terms in sec-

tion 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

''(4) TOP OFFICIAL.—The term 'top official' means—

''(A) any officer or employee in the executive branch who occupies a position classified at or above GS–13 of the General Schedule or, in the case of any position not under the General Schedule, for which the rate of basic pay is equal to or greater than the minimum rate of basic pay payable for GS–13 of the General Schedule; or

''(B) any employee of the Federal Government who directly or indirectly has input or any authority to determine or help determine the authorization for use or emergency use authorization of a drug, biological product, or device.

''(b) PROHIBITION AGAINST SERVICE BY FORMER EMPLOYEES OF COVERED HEALTH AGENCIES ON BOARDS OF ENTITIES INVOLVED IN DEVELOPMENT AND RESEARCH OF A DRUG, BIOLOGICAL PRODUCT, OR DEVICE.—Any person who is a top official of a covered health agency of the United States, and who, within 8 years after the termination of the service or employment of the top official with the United States, serves as an officer or

member of the board of any association, corporation, or entity that directly manufactures or researches a drug, biological product, or device shall be punished as provided in section 216 of this title.

''(c) PROHIBITION AGAINST PROFITING FROM A DRUG, BIOLOGICAL PRODUCT, OR DEVICE BY FORMER EMPLOYEES OF COVERED HEALTH AGENCIES INVOLVED IN THE APPROVAL OF RELATED GRANT APPLICATIONS.—Any person who is a former Federal employee of a covered health agency who profits from a drug, biological product, or device if such employee at any point during the course of service or employment with the United States was directly involved in determining whether a grant application for such drug, biological product, or device was approved shall be subject to a civil penalty of $250,000 and imprisoned for not more than five years nor less than one year.''.

(b) PENALTIES AND INJUNCTIONS.—Section 216(a) of title 18, United States Code, is amended, in the matter preceding paragraph (1), by inserting ''207A,'' after ''207,''.

(c) TABLE OF CHAPTERS.—Chapter of 11 of title 18, United States Code, is amended by inserting after the item relating to section 207 the following:

''Sec. 207A. Prohibition against service by former employees of covered health agencies on boards of entities involved in development and research of a drug, biological product, or device.''.

(d) EFFECTIVE DATE.—Except as provided in subsection (d), the amendments made by this section shall apply with respect to an individual whose service or employment with the United States terminates on or after the date of the enactment of this Act.

(e) SPECIAL RULE FOR CERTAIN FORMER FEDERAL EMPLOYEES OF COVERED HEALTH AGENCIES.—

(1) APPLICATION.—Section 207A(c) of title 18, United States Code, as added by subsection (a), shall apply to an individual who at any point served or was employed with the United States.

(2) COMPLIANCE PERIOD.—With respect to the prohibition under section 207A(c) of title 18, United States Code, as added by subsection (a), the compliance period for a former Federal employee whose service or employment with the United States terminated prior to the date of enactment of this Act shall be 6 months from such date of enactment.

SEC. 3. PROHIBITION AGAINST OWNERSHIP OR FINANCIAL INTEREST IN CERTAIN PATENTS.

Section 208 of title 18 is amended by adding at the end the following:

''(e) PROHIBITION AGAINST OWNERSHIP OR FINANCIAL INTEREST IN CERTAIN PATENTS.—

''(1) DEFINITIONS.—In this subsection:

"(A) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

"(B) COVERED PATENT.—The term 'covered patent' means a patent issued by the United States for a drug, biological product, or device.

"(C) DEVICE; DRUG.—The terms 'device' and 'drug' have the meanings given those terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

"(D) TOP OFFICIAL.—The term 'top official' means—

"(i) each officer or employee in the executive branch who occupies a position classified at or above GS–13 of the General Schedule or, in the case of any position not under the General Schedule, for which the rate of basic pay is equal to or greater than the minimum rate of basic pay payable for GS–13 of the General Schedule; or

"(ii) any employee of the Federal Government who directly or indirectly has

input or any authority to determine or help determine the authorization for use or emergency use authorization of a drug, biological product, or device.

''(2) IN GENERAL.—A person who is a top official may not submit an application for a covered patent (or be included in the application for a covered patent)—

''(A) in the case of a drug, biological product, or device invented by the person during the course of employment as a top official, at any point during employment as a top official; and

''(B) in the case of a drug, biological product, or device invented by the person outside the course of employment as a top official, at any point during employment as a top official.

''(3) DISCLOSURE.—

''(A) REQUIREMENT AS OF DATE OF ENACTMENT OF THE FAUCI ACT.—A person who is a top official or a spouse of a top official on the date of enactment of the FAUCI Act shall disclose not later than 180 days after the date of enactment of such Act any ownership of, or any rights or interest in, a covered patent.

''(B) REQUIREMENT AFTER DATE OF ENACTMENT OF THE FAUCI ACT.—A person who is a top official or a spouse of a top official after the date of enactment of the FAUCI Act shall disclose not later than 90 days after becoming a top official or the spouse of a top official any ownership of, or any rights or interest in, a covered patent.''.