118TH CONGRESS	$\mathbf{C}$	
2D Session		
	<b>D</b> •	

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.

- 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 "Fixing Administrations
- 5 Unethical Corrupt Influence Act" or the "'FAUCI Act'".

1	SEC. 2. PROHIBITION AGAINST SERVICE BY FORMER EM-
2	PLOYEES OF COVERED HEALTH AGENCIES
3	ON BOARDS OF ENTITIES INVOLVED IN DE-
4	VELOPMENT AND RESEARCH OF A DRUG, BI-
5	OLOGICAL PRODUCT, OR DEVICE.
6	(a) Prohibition Against Service on Boards of
7	Entities.—Title 18, United States Code, is amended by
8	inserting after section 207 the following:
9	"§ 207A. Prohibition against service by former em-
10	ployees of covered health agencies on
11	boards of entities involved in develop-
12	ment and research of a drug, biological
13	product, or device.
14	"(a) Definitions.—In this section:
15	"(1) BIOLOGICAL PRODUCT.—The term 'bio-
16	logical product' has the meaning given such term in
17	section 351(i) of the Public Health Service Act (42
18	U.S.C. 262(i)).
19	"(2) COVERED HEALTH AGENCY.—The term
20	'covered health agency' means any of the following:
21	"(A) The National Institutes of Health.
22	"(B) The Food and Drug Administration.
23	"(C) The Centers for Disease Control and
<ul><li>23</li><li>24</li></ul>	"(C) The Centers for Disease Control and Prevention.

1	tion 201 of the Federal Food, Drug, and Cosmetic
2	Act (21 U.S.C. 321).
3	"(4) Top official.—The term 'top official'
4	means—
5	"(A) any officer or employee in the execu-
6	tive branch who occupies a position classified at
7	or above GS-13 of the General Schedule or, in
8	the case of any position not under the General
9	Schedule, for which the rate of basic pay is
10	equal to or greater than the minimum rate of
11	basic pay payable for GS-13 of the General
12	Schedule; or
13	"(B) any employee of the Federal Govern-
14	ment who directly or indirectly has input or any
15	authority to determine or help determine the
16	authorization for use or emergency use author-
17	ization of a drug, biological product, or device.
18	"(b) Prohibition Against Service by Former
19	Employees of Covered Health Agencies on
20	BOARDS OF ENTITIES INVOLVED IN DEVELOPMENT AND
21	RESEARCH OF A DRUG, BIOLOGICAL PRODUCT, OR DE-
22	VICE.—Any person who is a top official of a covered health
23	agency of the United States, and who, within 8 years after
24	the termination of the service or employment of the top
25	official with the United States, serves as an officer or

- 1 member of the board of any association, corporation, or
- 2 entity that directly manufactures or researches a drug, bi-
- 3 ological product, or device shall be punished as provided
- 4 in section 216 of this title.
- 5 "(c) Prohibition Against Profiting From A
- 6 Drug, Biological Product, or Device by Former
- 7 Employees of Covered Health Agencies Involved
- 8 IN THE APPROVAL OF RELATED GRANT APPLICATIONS.—
- 9 Any person who is a former Federal employee of a covered
- 10 health agency who profits from a drug, biological product,
- 11 or device if such employee at any point during the course
- 12 of service or employment with the United States was di-
- 13 rectly involved in determining whether a grant application
- 14 for such drug, biological product, or device was approved
- 15 shall be subject to a civil penalty of \$250,000 and impris-
- 16 oned for not more than five years nor less than one year.".
- 17 (b) Penalties and Injunctions.—Section 216(a)
- 18 of title 18, United States Code, is amended, in the matter
- 19 preceding paragraph (1), by inserting "207A," after
- 20 "207,".
- 21 (c) Table of Chapters.—Chapter of 11 of title 18,
- 22 United States Code, is amended by inserting after the
- 23 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.".

1 (d) Effective Date.—Except as provided in sub-2 section (d), the amendments made by this section shall 3 apply with respect to an individual whose service or em-4 ployment with the United States terminates on or after 5 the date of the enactment of this Act. 6 (e) Special Rule for Certain Former Federal 7 EMPLOYEES OF COVERED HEALTH AGENCIES.— 8 (1) APPLICATION.—Section 207A(c) of title 18, 9 United States Code, as added by subsection (a), 10 shall apply to an individual who at any point served 11 or was employed with the United States. (2) COMPLIANCE PERIOD.—With respect to the 12 13 prohibition under section 207A(c) of title 18, United 14 States Code, as added by subsection (a), the compli-15 ance period for a former Federal employee whose 16 service or employment with the United States termi-17 nated prior to the date of enactment of this Act 18 shall be 6 months from such date of enactment. SEC. 3. PROHIBITION AGAINST OWNERSHIP OR FINANCIAL 19 20 INTEREST IN CERTAIN PATENTS. 21 Section 208 of title 18 is amended by adding at the 22 end the following: 23 "(e) Prohibition Against Ownership or Finan-CIAL INTEREST IN CERTAIN PATENTS.— 25 "(1) Definitions.—In this subsection:

1	(A) BIOLOGICAL PRODUCT.—The term
2	'biological product' has the meaning given such
3	term in section 351(i) of the Public Health
4	Service Act (42 U.S.C. 262(i)).
5	"(B) COVERED PATENT.—The term 'cov-
6	ered patent' means a patent issued by the
7	United States for a drug, biological product, or
8	device.
9	"(C) DEVICE; DRUG.—The terms 'device'
10	and 'drug' have the meanings given those terms
11	in section 201 of the Federal Food, Drug, and
12	Cosmetic Act (21 U.S.C. 321).
13	"(D) Top official.—The term 'top offi-
14	cial' means—
15	"(i) each officer or employee in the
16	executive branch who occupies a position
17	classified at or above GS-13 of the Gen-
18	eral Schedule or, in the case of any posi-
19	tion not under the General Schedule, for
20	which the rate of basic pay is equal to or
21	greater than the minimum rate of basic
22	pay payable for GS-13 of the General
23	Schedule; or
24	"(ii) any employee of the Federal
25	Government who directly or indirectly has

1	input or any authority to determine or help
2	determine the authorization for use or
3	emergency use authorization of a drug, bi-
4	ological product, or device.
5	"(2) IN GENERAL.—A person who is a top offi-
6	cial may not submit an application for a covered
7	patent (or be included in the application for a cov-
8	ered patent)—
9	"(A) in the case of a drug, biological prod-
10	uct, or device invented by the person during the
11	course of employment as a top official, at any
12	point during employment as a top official; and
13	"(B) in the case of a drug, biological prod-
14	uct, or device invented by the person outside
15	the course of employment as a top official, at
16	any point during employment as a top official.
17	"(3) Disclosure.—
18	"(A) REQUIREMENT AS OF DATE OF EN-
19	ACTMENT OF THE FAUCI ACT.—A person who is
20	a top official or a spouse of a top official on the
21	date of enactment of the FAUCI Act shall dis-
22	close not later than 180 days after the date of
23	enactment of such Act any ownership of, or any
24	rights or interest in, a covered patent.

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"(B) REQUIREMENT AFTER DATE OF EN-1 2 ACTMENT OF THE FAUCI ACT.—A person who is 3 a top official or a spouse of a top official after 4 the date of enactment of the FAUCI Act shall 5 disclose not later than 90 days after becoming 6 a top official or the spouse of a top official any 7 ownership of, or any rights or interest in, a cov-8 ered patent.".