## [DISCUSSION DRAFT]

117TH CONGRESS 1ST SESSION	H.R.	
-------------------------------	------	--

To prevent conflicts of interest arising from Government employees receiving bonuses or other compensation arrangements from non-Government sources, from the revolving door that raises concerns about the independence of certain employees of the Food and Drug Administration, from the revolving door that casts aspersions over the awarding of Government contracts and other financial benefits, and for other purposes.

## IN THE HOUSE OF REPRESENTATIVES

Ms. S	SPEIER intro	duced th	e following	bill;	which	was	referred	to	the	Comm	ittee
		on _									

## A BILL

To prevent conflicts of interest arising from Government employees receiving bonuses or other compensation arrangements from non-Government sources, from the revolving door that raises concerns about the independence of certain employees of the Food and Drug Administration, from the revolving door that casts aspersions over the awarding of Government contracts and other financial benefits, 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,

1	SECTION 1. SHORT TITLE.
2	This Act may be cited as the "FDA Conflict of Inter-
3	est Act".
4	SEC. 2. RESTRICTIONS ON PRIVATE SECTOR PAYMENT FOR
5	GOVERNMENT SERVICE.
6	Section 209 of title 18, United States Code, is
7	amended—
8	(1) in subsection (a)—
9	(A) by striking "any salary" and inserting
10	"any bonus, salary"; and
11	(B) by striking "his services" and inserting
12	"services rendered or to be rendered"; and
13	(2) in subsection (b)—
14	(A) by inserting "(1)" after "(b)"; and
15	(B) by adding at the end the following:
16	"(2) For purposes of paragraph (1), a pension,
17	retirement, group life, health or accident insurance,
18	profit-sharing, stock bonus, or other employee wel-
19	fare or benefit plan that makes payment of com-
20	pensation contingent on accepting a position in the
21	Federal Government shall not be considered bona
22	fide.
23	"(3) For purposes of paragraph (2), compensa-
24	tion includes a retention award or bonus, severance
25	pay, and any other payment linked to future service
26	in the Federal Government in any way.".

1	SEC. 3. REQUIREMENTS RELATING TO SLOWING THE RE-
2	VOLVING DOOR AMONG COVERED FDA EM-
3	PLOYEES.
4	(a) In General.—The Ethics in Government Act of
5	1978 (5 U.S.C. App.) is amended by adding at the end
6	the following:
7	"TITLE VI—SPECIAL REQUIRE-
8	MENTS FOR COVERED FDA
9	<b>EMPLOYEES</b>
10	"SEC. 601. DEFINITIONS.
11	"In this title:
12	"(1) COVERED AGENCY.—The term 'covered
13	agency' means the U.S. Food and Drug Administra-
14	tion.
15	"(2) Covered fda employee.—The term
16	'covered FDA employee' means an officer or em-
17	ployee of the covered agency who occupies—
18	"(A) a position classified above GS-15 of
19	the General Schedule;
20	"(B) in the case of a position not under
21	the General Schedule, a position for which the
22	rate of basic pay is not less than 120 percent
23	of the minimum rate of basic pay for GS-15 of
24	the General Schedule: or

1	"(C) any other supervisory position deter-
2	mined to be of equal classification by the Direc-
3	tor of the Office of Government Ethics.
4	"(3) Designated agency ethics official.—
5	The term 'designated agency ethics official' has the
6	meaning given that term under section 109.
7	"(4) Executive agency.—The term 'executive
8	branch' has the meaning given that term under sec-
9	tion 109.
10	"(5) Former client.—The term 'former cli-
11	ent'—
12	"(A) means a person for whom a covered
13	FDA employee served personally as an agent,
14	attorney, or consultant during the 2-year period
15	ending on the date (after such service) on which
16	the covered FDA employee begins service in the
17	Federal Government; and
18	"(B) does not include—
19	"(i) instances in which the service
20	provided was limited to a speech or similar
21	appearance; or
22	"(ii) a client of the former employer
23	of the covered FDA employee to whom the
24	covered FDA employee did not personally
25	provide such services.

1	"(6) FORMER EMPLOYER.—The term 'former
2	employer'—
3	"(A) means a person for whom a covered
4	FDA employee served as an employee, officer,
5	director, trustee, or general partner during the
6	2-year period ending on the date (after such
7	service) on which the covered FDA employee
8	begins service in the Federal Government; and
9	"(B) does not include—
10	"(i) an entity in the Federal Govern-
11	ment, including an executive branch agen-
12	cy;
13	"(ii) a State or local government;
14	"(iii) the District of Columbia;
15	"(iv) an Indian tribe, as defined in
16	section 4 of the Indian Self-Determination
17	and Education Assistance Act (25 U.S.C.
18	450b); or
19	"(v) the government of a territory or
20	possession of the United States.
21	"SEC. 602. CONFLICT OF INTEREST AND ELIGIBILITY
22	STANDARDS FOR COVERED FDA EMPLOYEES.
23	"(a) IN GENERAL.—A covered FDA employee may
24	not make, participate in making, or in any way attempt
25	to use the official position of the covered FDA employee

1	to influence a particular matter that provides a direct and
2	substantial pecuniary benefit for a former employer or
3	former client of the covered FDA employee.
4	"(b) Recusal.—A covered FDA employee shall
5	recuse himself or herself from any official action that
6	would violate subsection (a).
7	"(c) Waiver.—
8	"(1) In General.—The Commissioner or Act-
9	ing Commissioner of the covered agency, in consulta-
10	tion with the Director of the Office of Government
11	Ethics, may grant a written waiver of the restric-
12	tions under subsection (a) if, and to the extent that,
13	the Commissioner or Acting Commissioner certifies
14	in writing that—
15	"(A) the application of the restriction to
16	the particular matter is inconsistent with the
17	purposes of the restriction; or
18	"(B) it is in the public interest to grant
19	the waiver.
20	"(2) Publication.—The Director of the Office
21	of Government Ethics shall make each waiver under
22	paragraph (1) publicly available on the website of
23	the Office of Government Ethics.

1	"SEC. 603. NEGOTIATING FUTURE PRIVATE SECTOR EM-
2	PLOYMENT.
3	"(a) Prohibition.—Except as provided in sub-
4	section (c), and notwithstanding any other provision of
5	law, a covered FDA employee may not participate in any
6	particular matter which involves, to the knowledge of the
7	covered FDA employee, an individual or entity with whom
8	the covered FDA employee is in negotiations for future
9	employment or has an arrangement concerning prospec-
10	tive employment.
11	"(b) Disclosure of Employment Negotia-
12	TIONS.—
13	"(1) IN GENERAL.—If a covered FDA employee
14	begins any negotiations for future employment with
15	another person, or an agent or intermediary of an-
16	other person, or other discussion or communication
17	with another person, or an agent or intermediary of
18	another person, mutually conducted with a view to-
19	ward reaching an agreement regarding possible em-
20	ployment of the covered FDA employee, the covered
21	FDA employee shall notify the designated agency
22	ethics official of the covered agency regarding the
23	negotiations, discussions, or communications.
24	"(2) Information.—A designated agency eth-
25	ics official receiving notice under paragraph (1),
26	after consultation with the Director of the Office of

1	Government Ethics, shall inform the covered FDA
2	employee of any potential conflicts of interest in-
3	volved in any negotiations, discussions, or commu-
4	nications with the other person and the prohibitions
5	applicable.
6	"(c) Waivers Only When Exceptional Cir-
7	CUMSTANCES EXIST.—
8	"(1) In General.—The Commissioner or Act-
9	ing Commissioner of the covered agency may only
10	grant a waiver of subsection (a) if it is determined
11	that exceptional circumstances exist.
12	"(2) Review and publication.—For any
13	waiver granted under paragraph (1), the Director of
14	the Office of Government Ethics shall—
15	"(A) review the circumstances relating to
16	the waiver and the determination that excep-
17	tional circumstances exist; and
18	"(B) make the waiver publicly available on
19	the website of the Office of Government Ethics,
20	which shall include—
21	"(i) the name of the private person or
22	persons involved in the negotiations or ar-
23	rangement concerning prospective employ-
24	ment; and

1	"(ii) the date on which the negotia-
2	tions or arrangements commenced.
3	"(d) Scope.—For purposes of this section, the term
4	'negotiations of future employment' is not limited to dis-
5	cussions of specific terms or conditions of employment in
6	a specific position.
7	"SEC. 604. RECORDKEEPING.
8	"The Director of the Office of Government Ethics
9	shall—
10	"(1) receive all employment histories, recusal
11	and waiver records, and other disclosure records for
12	covered FDA employees necessary for monitoring
13	compliance to this title;
14	"(2) promulgate rules and regulations, in con-
15	sultation with the Director of the Office of Per-
16	sonnel Management and the Attorney General, for
17	implementation of this title;
18	"(3) provide guidance and assistance where ap-
19	propriate to facilitate compliance with this title;
20	"(4) review and, where necessary, assist des-
21	ignated agency ethics officers in providing advice to
22	covered FDA employees regarding compliance with
23	this title; and
24	"(5) if the Director determines that a serious
25	violation of this title may have occurred that cannot

1	be corrected through administrative remedies, and in
2	consultation with the designated agency ethics offi-
3	cer and the Commissioner or Acting Commissioner
4	of the covered agency, refer the compliance case to
5	the United States Attorney for the District of Co-
6	lumbia for enforcement action. The Attorney Gen-
7	eral may also prosecute violations with or without
8	referral.
9	"SEC. 605. PENALTIES AND INJUNCTIONS.
10	"(a) Criminal Penalties.—
11	"(1) In General.—Any person who violates
12	section 602 or 603 shall be fined under title 18,
13	United States Code, imprisoned for not more than
14	1 year, or both.
15	"(2) WILLFUL VIOLATIONS.—Any person who
16	willfully violates section 602 or 603 shall be fined
17	under title 18, United States Code, imprisoned for
18	not more than 5 years, or both.
19	"(b) CIVIL ENFORCEMENT.—
20	"(1) In General.—The Attorney General or
21	the United States Attorney for the District of Co-
22	lumbia may bring a civil action in the appropriate
23	United States district court against any person who
24	violates, or who the Attorney General or United

1	States Attorney has reason to believe is engaging in
2	conduct that violates, section 602 or 603.
3	"(2) CIVIL PENALTY.—
4	"(A) IN GENERAL.—Upon proof by a pre-
5	ponderance of the evidence that a person vio-
6	lated section 602 or 603, the court shall impose
7	a civil penalty of not more than the greater
8	of—
9	"(i) \$100,000 for each violation; or
10	"(ii) the amount of compensation the
11	person received or was offered for the con-
12	duct constituting the violation.
13	"(B) RULE OF CONSTRUCTION.—A civil
14	penalty under this subsection shall be in addi-
15	tion to any other criminal or civil statutory,
16	common law, or administrative remedy, avail-
17	able to the United States or any other person.
18	"(3) Injunctive relief.—
19	"(A) IN GENERAL.—In a civil action
20	brought under paragraph (1) against a person,
21	the Attorney General or United States Attorney
22	may petition the court for an order prohibiting
23	the person from engaging in conduct that vio-
24	lates section 602 or 603. The court may issue
25	such an order if the court finds by a preponder-

1	ance of the evidence that the conduct of the
2	person violates section 602 or 603.
3	"(B) RULE OF CONSTRUCTION.—The filing
4	of a petition seeking injunctive relief under this
5	paragraph shall not preclude any other remedy
6	which is available by law to the United States
7	or any other person.".
8	SEC. 4. PROHIBITION OF PROCUREMENT OFFICERS AC-
9	CEPTING EMPLOYMENT FROM GOVERNMENT
10	CONTRACTORS.
11	(a) Expansion of Prohibition on Acceptance
12	BY FORMER OFFICIALS OF COMPENSATION FROM CON-
13	TRACTORS.—Section 2104 of title 41, United States Code,
14	is amended—
15	(1) in subsection (a)—
16	(A) in the matter preceding paragraph
17	(1)—
18	(i) by striking "or consultant" and in-
19	serting "consultant, lawyer, or lobbyist";
20	and
21	(ii) by striking "one year" and insert-
22	ing "2 years"; and
<ul><li>22</li><li>23</li></ul>	ing "2 years"; and (B) in paragraph (3), by striking "person-

1	"participated personally and substantially in"
2	and
3	(2) by amending subsection (b) to read as fol-
4	lows:
5	"(b) Prohibition on Compensation From Affili-
6	ATES AND SUBCONTRACTORS.—A former official respon-
7	sible for a Government contract referred to in paragraph
8	(1), (2), or (3) of subsection (a) shall be prohibited from
9	accepting compensation for 2 years after awarding such
10	contract from any division, affiliate, or subcontractor of
11	the contractor.".
12	(b) Requirement for Procurement Officers to
13	DISCLOSE JOB OFFERS MADE ON BEHALF OF REL-
14	ATIVES.—Section 2103(a) of title 41, United States Code
15	is amended in the matter preceding paragraph (1) by in-
16	serting after "that official" the following: ", or for a rel-
17	ative (as defined in section 3110 of title 5) of that offi-
18	cial,".
19	(c) Requirement on Award of Government
20	CONTRACTS TO FORMER EMPLOYERS.—
21	(1) In General.—Chapter 21 of title 41
22	United States Code, is amended by adding at the
23	end the following:

1	"§ 2108. Prohibition on involvement by certain
2	former contractor employees in procure-
3	ments
4	"An employee of the Federal Government may not
5	be personally and substantially involved with any award
6	of a contract to, or the administration of a contract award-
7	ed to, a contractor that is a former employer of the em-
8	ployee during the 2-year period beginning on the date on
9	which the employee leaves the employment of the con-
10	tractor.".
11	(2) Technical and conforming amend-
12	MENT.—The table of sections for chapter 21 of title
13	41, United States Code, is amended by adding after
14	the item relating to section 2107 the following:
	"2108. Prohibition on involvement by certain former contractor employees in procurements.".
15	(d) REGULATIONS.—The Administrator for Federal
16	Procurement Policy and the Director of the Office of Man-
17	agement and Budget shall—
18	(1) in consultation with the Director of the Of-
19	fice of Personnel Management and the Counsel to
20	the President, promulgate regulations to carry out
21	and ensure the enforcement of chapter 21 of title
22	41, United States Code, as amended by this section;
23	and

1	(2) in consultation with designated agency eth-
2	ics officers (as defined under section 601 of the Eth-
3	ics in Government Act of 1978 (5 U.S.C. App.)),
4	monitor compliance with such chapter by individuals
5	and agencies.
6	SEC. 5. REVOLVING DOOR RESTRICTIONS ON FORMER COV-
7	ERED FDA EMPLOYEES REPRESENTING PRI-
8	VATE INTERESTS.
9	(a) In General.—Section 207 of title 18, United
10	States Code, is amended—
11	(1) by redesignating subsections (e) through (l)
12	as subsections (f) through (m), respectively; and
13	(2) by inserting after subsection (d) the fol-
14	lowing:
15	"(e) Restrictions on Employment for Covered
16	FDA EMPLOYEES.—
17	"(1) In general.—In addition to the restric-
18	tions set forth in subsections (a), (b), (c), and (d),
19	a covered FDA employee shall not—
20	"(A) during the 2-year period beginning on
21	the date his or her employment as a covered
22	FDA employee ceases—
23	"(i) knowingly act as agent or attor-
24	ney for, or otherwise represent, any other
25	person for compensation (except the

1	United States) in any formal or informal
2	appearance before;
3	"(ii) with the intent to influence,
4	make any oral or written communication
5	on behalf of any other person (except the
6	United States) to; or
7	"(iii) knowingly aid, advise, or assist
8	in—
9	"(I) representing any other per-
10	son (except the United States) in any
11	formal or informal appearance before;
12	or
13	"(II) making, with the intent to
14	influence, any oral or written commu-
15	nication on behalf of any other person
16	(except the United States) to,
17	any court of the United States, or any officer
18	or employee thereof, in connection with any ju-
19	dicial or other proceeding, which was actually
20	pending under his or her official responsibility
21	as a covered FDA employee during the 2-year
22	period ending on the date his or her employ-
23	ment as a covered FDA employee ceases or in
24	which he or she participated personally and
25	substantially as a covered FDA employee; or

1	"(B) during the 2-year period beginning on
2	the date his or her employment as a covered
3	FDA employee ceases—
4	"(i) knowingly act as a lobbyist or
5	agent for, or otherwise represent, any
6	other person for compensation (except the
7	United States) in any formal or informal
8	appearance before;
9	"(ii) with the intent to influence,
10	make any oral or written communication
11	or conduct any lobbying activities on behalf
12	of any other person (except the United
13	States) to; or
14	"(iii) knowingly aid, advise, or assist
15	in—
16	"(I) representing any other per-
17	son (except the United States) in any
18	formal or informal appearance before;
19	or
20	"(II) making, with the intent to
21	influence, any oral or written commu-
22	nication or conduct any lobbying ac-
23	tivities on behalf of any other person
24	(except the United States) to,

1	any department or agency of the executive
2	branch or Congress (including any committee of
3	Congress), or any officer or employee thereof,
4	in connection with any matter which is pending
5	before the department, agency, or Congress.
6	"(2) Penalty.—Any person who violates para-
7	graph (1) shall be punished as provided in section
8	216.
9	"(3) Definitions.—In this subsection—
10	"(A) the term 'covered FDA employee' has
11	the meaning given that term under the new sec-
12	tion 601 of the Ethics in Government Act of
13	1978 (5 U.S.C. App.); and
14	"(B) the terms 'lobbyist' and 'lobbying ac-
15	tivities' have the meanings given such terms in
16	section 3 of the Lobbying Disclosure Act of
17	1995 (2 U.S.C. 1602).".
18	(b) Technical and Conforming Amendments.—
19	(1) Section 103(a) of the Honest Leadership
20	and Open Government Act of 2007 (2 U.S.C.
21	4702(a)) is amended by striking "section 207(e)"
22	each place it appears and inserting "section 207(f)".
23	(2) Section 207 of title 18, United States Code,
24	as amended by subsection (a), is amended—

1	(A) in subsection (g), as so redesignated,
2	by striking "or (e)" and inserting "or (f)";
3	(B) in subsection $(j)(1)(B)$ , as so redesig-
4	nated, by striking "subsection (f)" and insert-
5	ing "subsection (g)"; and
6	(C) in subsection (k), as so redesignated—
7	(i) in paragraph (2), in the matter
8	preceding subparagraph (A), by striking
9	"and (e)" and inserting "(e), and (f)";
10	(ii) in paragraph (4), by striking "and
11	(e)" and inserting "(e), and (f)"; and
12	(iii) in paragraph (7)—
13	(I) in subparagraph (A), by strik-
14	ing "and (e)" and inserting "(e), and
15	(f)"; and
16	(II) in subparagraph (B)(ii), in
17	the matter preceding subclause (I), by
18	striking "subsections (c), (d), or (e)"
19	and inserting "subsection (c), (d), (e),
20	or (f)".
21	(3) Section 141(b)(3) of the Trade Act of 1974
22	(19 U.S.C. 2171(b)(3)) is amended by striking "sec-
23	tion $207(f)(3)$ " and inserting " $207(g)(3)$ ".
24	(4) Section 7802(b)(3)(B) of the Internal Rev-
25	enue Code of 1986 is amended by striking "and (f)

1	of section 207" and inserting "and (g) of section
2	207".
3	(5) Section 106(p)(6)(I)(ii) of title 49, United
4	States Code, is amended by striking "and (f) of sec-
5	tion 207" and inserting "and (g) of section 207".
6	SEC. 6. ADDITIONAL RESTRICTIONS ON PRIVATE SECTOR
7	EMPLOYMENT BY COVERED FDA REGU-
8	LATORS.
9	Subchapter A of chapter VII of the Federal Food,
10	Drug, and Cosmetic Act (42 U.S.C. 371 et seq.) is amend-
11	ed by adding at the end the following:
12	"SEC. 716. EMPLOYMENT RESTRICTIONS FROM REGULATED
13	BUSINESSES OR ENTITIES.
14	"(a) Definition.—In this section, the term 'covered
15	FDA regulator' means an officer or employee of the Food
16	and Drug Administration who occupies—
17	"(1) a position of inspector or investigator for
18	the agency;
19	"(2) a position of auditor or reviewer of agency
20	inspections or investigations; $[and][or?]$
21	"(3) a supervisory position over an inspector,
22	investigator, auditor or reviewer classified above GS-
23	15 of the General Schedule or its equivalent.
24	"(b) Prohibition.—During the 2-year period fol-
25	lowing the employment of a covered FDA regulator with

1	the Food and Drug Administration, the covered FDA reg-
2	ulator shall not accept compensation with any business or
3	entity, or any division or affiliate thereof, as an employee,
4	officer, director, or consultant of the business, entity, divi-
5	sion, or affiliate if the covered FDA regulator has directly
6	and substantially—
7	"(1) participated in an inspection or investiga-
8	tion of the business or entity; or
9	"(2) audited or supervised such an inspection
10	or investigation.
11	"(c) Implementing Regulations and Guid-
12	ANCE.—The Commissioner of Food and Drugs [Struck
13	references to the acting commissioner. Why were those need-
14	ed? Wouldn't the Acting Commissioner automatically as-
15	sume the duties of the Commissioner?], in consultation
16	with the Director of the Office of Personnel Management
17	and the Attorney General, shall promulgate regulations
18	and issue guidance for implementation and enforcement
19	of this section.
20	"(d) Application of Penalties.—
21	"(1) Referral.—If the Commissioner of Food
22	and Drugs determines that a serious violation of this
23	section may have occurred [that cannot be corrected
24	through administrative remedies
25	to civil enforcement under paragraph (2)? Or a refer-

1	ral for prosecution? If prosecution, for what crime?
2	This section does not establish any criminal pen-
3	alties?], then the Commissioner, in consultation
4	with the [designated agency ethics officer] [what's
5	this? clarify? define?], [shall? may?] refer [the
6	compliance case I [Is this the correct term? Check
7	with CRS? to the United States Attorney for the
8	District of Columbia for [enforcement action] [Does
9	this mean prosecution? ]. The Attorney General may
10	[prosecute] [Is this the correct term? The penalties
11	below appear to be exclusively civil, not criminal.]
12	violations of this section with or without such a re-
13	ferral. [If the previous sentence is referring to civil
14	enforcement, would it be better to incorporate this
15	concept into paragraph (2)(A) below per the brackets
16	below ?  bracket
17	"(2) CIVIL ENFORCEMENT.—
18	"(A) In general.—[add if (1) is referring
19	to civil not criminal enforcement?: With or with-
20	out a referral under paragraph (1) The Attor-
21	ney General or the United States Attorney for
22	the District of Columbia may bring a civil ac-
23	tion in the appropriate United States district
24	court against any person who violates, or who
25	the Attorney General or United States Attorney

1	has reason to believe is engaging in conduct
2	that violates, this section.
3	"(B) Penalty.—Upon proof by a prepon-
4	derance of the evidence that a person violated
5	this section [in an action initiated pursuant to
6	subparagraph (A)?], the court shall impose a
7	civil penalty of not more than the greater of—
8	"(i) \$100,000 for each violation; or
9	"(ii) the amount of compensation the
10	person received or was offered for the con-
11	duct constituting the violation.
12	"(C) Rule of construction.—A civil
13	penalty under this paragraph shall be in addi-
14	tion to any other criminal or civil statutory,
15	common law, or administrative remedy, avail-
16	able to the United States or any other person.".
17	SEC. 7. SEVERABILITY.
18	If any provision of this Act or any amendment made
19	by this Act, or any application of such provision or amend-
20	ment to any person or circumstance, is held to be uncon-
21	stitutional, the remainder of the provisions of this Act and
22	the amendments made by this Act and the application of
23	the provision or amendment to any other person or cir-
24	cumstance shall not be affected.