

115TH CONGRESS
1ST SESSION

S. 2057

To prevent conflicts of interest that stem from the revolving door that raises concerns about the independence of pharmaceutical regulators.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 1, 2017

Ms. BALDWIN (for herself, Mrs. FEINSTEIN, Ms. HARRIS, Ms. HASSAN, Mr. MARKEY, Mrs. SHAHEEN, and Mr. UDALL) introduced the following bill; which was read twice and referred to the Committee on Homeland Security and Governmental Affairs

A BILL

To prevent conflicts of interest that stem from the revolving door that raises concerns about the independence of pharmaceutical regulators.

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 “Pharmaceutical Regu-
5 lation Conflict of Interest Act”.

1 **SEC. 2. REQUIREMENTS RELATING TO SLOWING THE RE-**
 2 **VOLVING DOOR AMONG PHARMACEUTICAL**
 3 **REGULATORS.**

4 The Ethics in Government Act of 1978 (5 U.S.C.
 5 App.) is amended by adding at the end the following:

6 **“TITLE VI—SPECIAL REQUIRE-**
 7 **MENTS FOR PHARMA-**
 8 **CEUTICAL REGULATORS**

9 **“SEC. 601. DEFINITIONS.**

10 “(a) IN GENERAL.—In this title, the terms ‘des-
 11 ignated agency ethics official’ and ‘executive branch’ have
 12 the meanings given those terms under section 109.

13 “(b) OTHER DEFINITIONS.—In this title:

14 “(1) COVERED PHARMACEUTICAL REGU-
 15 LATOR.—The term ‘covered pharmaceutical regu-
 16 lator’ means an officer or employee of a covered
 17 pharmaceutical regulatory agency who occupies—

18 “(A) a supervisory position classified at or
 19 above GS–13 of the General Schedule;

20 “(B) in the case of a position not under
 21 the General Schedule, a supervisory position for
 22 which the rate of basic pay is not less than the
 23 minimum rate of basic pay for GS–13 of the
 24 General Schedule; or

1 “(C) any other supervisory position deter-
2 mined to be of equal classification by the Direc-
3 tor.

4 “(2) COVERED PHARMACEUTICAL REGULATORY
5 AGENCY.—The term ‘covered pharmaceutical regu-
6 latory agency’—

7 “(A) means an agency whose primary re-
8 sponsibility is to regulate the manufacture, dis-
9 tribution, or sale of drugs (as defined in section
10 201 of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 321)) or biological products (as
12 defined in section 351 of the Public Health
13 Service Act (42 U.S.C. 262)); and

14 “(B) includes—

15 “(i) the Drug Enforcement Adminis-
16 tration; and

17 “(ii) the Food and Drug Administra-
18 tion.

19 “(3) DIRECTOR.—The term ‘Director’ means
20 the Director of the Office of Government Ethics.

21 “(4) FORMER CLIENT.—The term ‘former cli-
22 ent’—

23 “(A) means a person for whom the covered
24 pharmaceutical regulator served personally as
25 an agent, attorney, or consultant during the 2-

1 year period ending on the date (after such serv-
2 ice) on which the covered pharmaceutical regu-
3 lator begins service in the Federal Government;
4 and

5 “(B) does not include—

6 “(i) instances in which the service
7 provided was limited to a speech or similar
8 appearance; or

9 “(ii) a client of the former employer
10 of the covered pharmaceutical regulator to
11 whom the covered pharmaceutical regu-
12 lator did not personally provide such serv-
13 ices.

14 “(5) FORMER EMPLOYER.—The term ‘former
15 employer’—

16 “(A) means a person for whom a covered
17 pharmaceutical regulator served as an em-
18 ployee, officer, director, trustee, or general part-
19 ner during the 2-year period ending on the date
20 (after such service) on which the covered phar-
21 maceutical regulator begins service in the Fed-
22 eral Government; and

23 “(B) does not include—

1 “(i) any entity in the Federal Govern-
 2 ment, including an executive branch agen-
 3 cy;

4 “(ii) a State or local government;

5 “(iii) the District of Columbia;

6 “(iv) an Indian tribe, as defined in
 7 section 4 of the Indian Self-Determination
 8 and Education Assistance Act (25 U.S.C.
 9 5304); or

10 “(v) the government of a territory or
 11 possession of the United States.

12 **“SEC. 602. CONFLICT OF INTEREST AND ELIGIBILITY**
 13 **STANDARDS FOR PHARMACEUTICAL REGU-**
 14 **LATORS.**

15 “(a) IN GENERAL.—A covered pharmaceutical regu-
 16 lator shall not make, participate in making, or in any way
 17 attempt to use the official position of the covered pharma-
 18 ceutical regulator to influence a particular matter that
 19 provides a direct and substantial pecuniary benefit for a
 20 former employer or former client of the covered pharma-
 21 ceutical regulator.

22 “(b) RECUSAL.—A covered pharmaceutical regulator
 23 shall recuse himself or herself from any official action that
 24 would violate subsection (a).

25 “(c) WAIVER.—

1 “(1) IN GENERAL.—The head of the covered
 2 pharmaceutical regulatory agency employing a cov-
 3 ered pharmaceutical regulator, in consultation with
 4 the Director, may grant a written waiver of the re-
 5 strictions under subsection (a) if, and to the extent
 6 that, the head of the covered pharmaceutical regu-
 7 latory agency certifies in writing that—

8 “(A) the application of the restriction to
 9 the particular matter is inconsistent with the
 10 purposes of the restriction; or

11 “(B) it is in the public interest to grant
 12 the waiver.

13 “(2) PUBLICATION.—The Director shall make
 14 each waiver under paragraph (1) publicly available
 15 on the Web site of the Office of Government Ethics.

16 **“SEC. 603. NEGOTIATING FUTURE PRIVATE SECTOR EM-**
 17 **PLOYMENT.**

18 “(a) PROHIBITION.—Except as provided in sub-
 19 section (c), and notwithstanding any other provision of
 20 law, a covered pharmaceutical regulator may not partici-
 21 pate in any particular matter which involves, to the knowl-
 22 edge of the covered pharmaceutical regulator, an indi-
 23 vidual or entity with whom the covered pharmaceutical
 24 regulator is in negotiations of future employment or has
 25 an arrangement concerning prospective employment.

1 “(b) DISCLOSURE OF EMPLOYMENT NEGOTIA-
2 TIONS.—

3 “(1) IN GENERAL.—If a covered pharmaceutical
4 regulator begins any negotiations of future employ-
5 ment with another person, or an agent or inter-
6 mediary of another person, or other discussion or
7 communication with another person, or an agent or
8 intermediary of another person, mutually conducted
9 with a view toward reaching an agreement regarding
10 possible employment of the covered pharmaceutical
11 regulator, the covered pharmaceutical regulator shall
12 notify the designated agency ethics official of the
13 covered pharmaceutical regulatory agency employing
14 the covered pharmaceutical regulator regarding the
15 negotiations, discussions, or communications.

16 “(2) INFORMATION.—A designated agency eth-
17 ics official receiving notice under paragraph (1),
18 after consultation with the Director, shall inform the
19 covered pharmaceutical regulator of any potential
20 conflicts of interest involved in any negotiations, dis-
21 cussions, or communications with the other person
22 and the applicable prohibitions.

23 “(3) PUBLICATION.—The Director, after receiv-
24 ing notice under paragraph (1), shall make publicly
25 available on the Web site of the Office of Govern-

1 ment Ethics the name of the covered pharmaceutical
 2 regulator and the name of the private person in-
 3 volved in the negotiations or arrangement con-
 4 cerning prospective employment of the covered phar-
 5 maceutical regulator.

6 “(c) WAIVERS ONLY WHEN EXCEPTIONAL CIR-
 7 CUMSTANCES EXIST.—

8 “(1) IN GENERAL.—The head of a covered
 9 pharmaceutical regulatory agency may only grant a
 10 waiver of the prohibition under subsection (a) if the
 11 head determines that exceptional circumstances
 12 exist.

13 “(2) REVIEW AND PUBLICATION.—For any
 14 waiver granted under paragraph (1), the Director
 15 shall—

16 “(A) review the circumstances relating to
 17 the waiver and the determination that excep-
 18 tional circumstances exist; and

19 “(B) make the waiver publicly available on
 20 the Web site of the Office of Government Eth-
 21 ics, which shall include—

22 “(i) the name of the private person in-
 23 volved in the negotiations or arrangement
 24 concerning prospective employment of the
 25 covered pharmaceutical regulator; and

1 “(ii) the date on which the negotia-
2 tions or arrangement commenced.

3 “(d) SCOPE.—For the purposes of this section, the
4 term ‘negotiations of future employment’ is not limited to
5 discussions of specific terms or conditions of employment
6 in a specific position.

7 **“SEC. 604. RECORDKEEPING.**

8 “The Director shall—

9 “(1) receive all employment histories, recusal
10 and waiver records, and other disclosure records for
11 covered pharmaceutical regulators necessary for
12 monitoring compliance with this title, and make
13 those records publicly available on the Web site of
14 the Office of Government Ethics;

15 “(2) promulgate rules and regulations, in con-
16 sultation with the Director of the Office of Per-
17 sonnel Management and the Attorney General, to
18 implement this title;

19 “(3) provide guidance and assistance where ap-
20 propriate to facilitate compliance with this title;

21 “(4) review and, where necessary, assist des-
22 ignated agency ethics officials in providing advice to
23 covered pharmaceutical regulators regarding compli-
24 ance with this title; and

1 “(5) if the Director determines that a violation
2 of this title may have occurred, and in consultation
3 with the designated agency ethics official and the
4 Counsel to the President, refer the compliance case
5 to the United States Attorney for the District of Co-
6 lumbia for enforcement action.

7 **“SEC. 605. PENALTIES AND INJUNCTIONS.**

8 “(a) CRIMINAL PENALTIES.—

9 “(1) IN GENERAL.—Any person who violates
10 section 602 or 603 shall be fined under title 18,
11 United States Code, imprisoned for not more than
12 1 year, or both.

13 “(2) WILLFUL VIOLATIONS.—Any person who
14 willfully violates section 602 or 603 shall be fined
15 under title 18, United States Code, imprisoned for
16 not more than 5 years, or both.

17 “(b) CIVIL ENFORCEMENT.—

18 “(1) IN GENERAL.—The Attorney General may
19 bring a civil action in an appropriate district court
20 of the United States against any person who vio-
21 lates, or whom the Attorney General has reason to
22 believe is engaging in conduct that violates, section
23 602 or 603.

24 “(2) CIVIL PENALTY.—

1 “(A) IN GENERAL.—Upon proof by a pre-
 2 ponderance of the evidence that a person vio-
 3 lated section 602 or 603, the court shall impose
 4 a civil penalty of not more than the greater
 5 of—

6 “(i) \$100,000 for each violation; or

7 “(ii) the amount of compensation the
 8 person received or was offered for the con-
 9 duct constituting the violation.

10 “(B) RULE OF CONSTRUCTION.—A civil
 11 penalty under this subsection shall be in addi-
 12 tion to any other criminal or civil statutory,
 13 common law, or administrative remedy available
 14 to the United States or any other person.

15 “(3) INJUNCTIVE RELIEF.—

16 “(A) IN GENERAL.—In a civil action
 17 brought under paragraph (1) against a person,
 18 the Attorney General may petition the court for
 19 an order prohibiting the person from engaging
 20 in conduct that violates section 602 or 603.

21 “(B) STANDARD.—The court may issue an
 22 order under subparagraph (A) if the court finds
 23 by a preponderance of the evidence that the
 24 conduct of the person violates section 602 or
 25 603.

1 “(C) RULE OF CONSTRUCTION.—The filing
 2 of a petition seeking injunctive relief under this
 3 paragraph shall not preclude any other remedy
 4 that is available by law to the United States or
 5 any other person.”.

6 **SEC. 3. SLOWING THE REVOLVING DOOR FROM PHARMA-**
 7 **CEUTICAL REGULATORY AGENCY INTO PRI-**
 8 **VATE SECTOR REPRESENTATIONAL ACTIVI-**
 9 **TIES.**

10 (a) IN GENERAL.—Section 207 of title 18, United
 11 States Code, is amended—

12 (1) by redesignating subsections (e) through (l)
 13 as subsections (f) through (m), respectively; and

14 (2) by inserting after subsection (d) the fol-
 15 lowing:

16 “(e) RESTRICTIONS ON EMPLOYMENT FOR PHARMA-
 17 CEUTICAL REGULATORS.—

18 “(1) IN GENERAL.—In addition to the restric-
 19 tions set forth in subsections (a), (b), (c), and (d),
 20 a covered pharmaceutical regulator shall not—

21 “(A) during the 2-year period beginning on
 22 the date on which his or her employment as a
 23 covered pharmaceutical regulator ceases—

24 “(i) knowingly act as agent or attor-
 25 ney for, or otherwise represent, any other

1 person for compensation (except the
2 United States) in any formal or informal
3 appearance before;

4 “(ii) with the intent to influence,
5 make any oral or written communication
6 on behalf of any other person (except the
7 United States) to; or

8 “(iii) knowingly aid, advise, or assist
9 in—

10 “(I) representing any other per-
11 son (except the United States) in any
12 formal or informal appearance before;
13 or

14 “(II) making, with the intent to
15 influence, any oral or written commu-
16 nication on behalf of any other person
17 (except the United States) to,
18 any court of the United States, or any offi-
19 cer or employee thereof, in connection with
20 any judicial or other proceeding, which was
21 actually pending under his or her official
22 responsibility as a covered pharmaceutical
23 regulator during the 1-year period ending
24 on the date on which his or her employ-
25 ment as a covered pharmaceutical regu-

1 lator ceases or in which he or she partici-
2 pated personally and substantially as a
3 covered pharmaceutical regulator; or

4 “(B) during the 2-year period beginning on
5 the date on which his or her employment as a
6 covered pharmaceutical regulator ceases—

7 “(i) knowingly act as a lobbyist or
8 agent for, or otherwise represent, any
9 other person for compensation (except the
10 United States) in any formal or informal
11 appearance before;

12 “(ii) with the intent to influence,
13 make any oral or written communication
14 or conduct any lobbying activities on behalf
15 of any other person (except the United
16 States) to; or

17 “(iii) knowingly aid, advise, or assist
18 in—

19 “(I) representing any other per-
20 son (except the United States) in any
21 formal or informal appearance before;
22 or

23 “(II) making, with the intent to
24 influence, any oral or written commu-
25 nication or conduct any lobbying ac-

1 tivities on behalf of any other person
 2 (except the United States) to,
 3 any department or agency of the executive
 4 branch or Congress (including any com-
 5 mittee of Congress), or any officer or em-
 6 ployee thereof, in connection with any mat-
 7 ter that is pending before the department,
 8 the agency, or Congress.

9 “(2) PENALTY.—Any person who violates para-
 10 graph (1) shall be punished as provided in section
 11 216.

12 “(3) DEFINITIONS.—In this subsection—

13 “(A) the term ‘covered pharmaceutical reg-
 14 ulator’ has the meaning given that term in sec-
 15 tion 601 of the Ethics in Government Act of
 16 1978 (5 U.S.C. App.); and

17 “(B) the terms ‘lobbying activities’ and
 18 ‘lobbyist’ have the meanings given those terms
 19 in section 3 of the Lobbying Disclosure Act of
 20 1995 (2 U.S.C. 1602).”.

21 (b) TECHNICAL AND CONFORMING AMENDMENTS.—

22 (1) Section 103(a) of the Honest Leadership
 23 and Open Government Act of 2007 (2 U.S.C.
 24 4702(a)) is amended by striking “section 207(e)”
 25 each place it appears and inserting “section 207(f)”.

(2) Section 207 of title 18, United States Code,
as amended by subsection (a), is amended—

(A) in subsection (g)(1), as so redesignated, by striking “or (e)” and inserting “or (f)”;

(B) in subsection (j)(1)(B), as so redesignated, by striking “subsection (f)” and inserting “subsection (g)”;

(C) in subsection (k), as so redesignated—

(i) in paragraph (1)(B), by striking “(25 U.S.C. 450i(j))” and inserting “(25 U.S.C. 5323(j))”;

(ii) in paragraph (2), in the matter preceding subparagraph (A), by striking “and (e)” and inserting “(e), and (f)”;

(iii) in paragraph (4), by striking “and (e)” and inserting “(e), and (f)”;

(iv) in paragraph (7)—

(I) in subparagraph (A), by striking “and (e)” and inserting “(e), and (f)”;

(II) in subparagraph (B)(ii), in the matter preceding subclause (I), by striking “subsections (c), (d), or (e)”

1 and inserting “subsection (c), (d), (e),
2 or (f)”.

3 (3) Section 141(b)(4) of the Trade Act of 1974
4 (19 U.S.C. 2171(b)(4)) is amended by striking “sec-
5 tion 207(f)(3)” and inserting “207(g)(3)”.

6 (4) Section 7802(b)(3)(B) of the Internal Rev-
7 enue Code of 1986 is amended by striking “and (f)
8 of section 207” and inserting “and (g) of section
9 207”.

10 (5) Section 3105(c) of the USEC Privatization
11 Act (42 U.S.C. 2297h–3(c)) is amended by striking
12 “and (d)” and inserting “(d), and (e)”.

13 (6) Section 106(p)(6)(I)(ii) of title 49, United
14 States Code, is amended by striking “and (f) of sec-
15 tion 207” and inserting “and (g) of section 207”.

16 **SEC. 4. SEVERABILITY.**

17 If any provision of this Act or any amendment made
18 by this Act, or any application of such provision or amend-
19 ment to any person or circumstance, is held to be uncon-
20 stitutional, the remainder of the provisions of this Act and
21 the amendments made by this Act and the application of
22 the provision or amendment to any other person or cir-
23 cumstance shall not be affected.

○