115TH CONGRESS
1ST SESSION

S. _____

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

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

A BILL

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

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 ''Pharmaceutical Regulation Conflict of Interest Act''.

SEC. 2. REQUIREMENTS RELATING TO SLOWING THE REVOLVING DOOR AMONG PHARMACEUTICAL REGULATORS.

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

"TITLE VI—SPECIAL REQUIREMENTS FOR PHARMACEUTICAL REGULATORS

"SEC. 601. DEFINITIONS.

''(a) IN GENERAL.—In this title, the terms 'designated agency ethics official' and 'executive branch' have the meanings given those terms under section 109.

''(b) OTHER DEFINITIONS.—In this title:

''(1) COVERED PHARMACEUTICAL REGULATOR.—The term 'covered pharmaceutical regulator' means an officer or employee of a covered pharmaceutical regulatory agency who occupies—

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

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

''(C) any other supervisory position determined to be of equal classification by the Director.

''(2) COVERED PHARMACEUTICAL REGULATORY AGENCY.—The term 'covered pharmaceutical regulatory agency'—

"(A) means an agency whose primary responsibility is to regulate the manufacture, distribution, or sale of drugs (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) or biological products (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262)); and

"(B) includes—

"(i) the Drug Enforcement Administration; and

"(ii) the Food and Drug Administration;

"(3) DIRECTOR.—The term 'Director' means the Director of the Office of Government Ethics.

"(4) FORMER CLIENT.—The term 'former client'—

"(A) means a person for whom the covered pharmaceutical regulator served personally as an agent, attorney, or consultant during the 2-year period ending on the date (after such service) on which the covered pharmaceutical regulator begins service in the Federal Government; and

"(B) does not include—

"(i) instances in which the service provided was limited to a speech or similar appearance; or

"(ii) a client of the former employer of the covered pharmaceutical regulator to whom the covered pharmaceutical regulator did not personally provide such services.

"(5) FORMER EMPLOYER.—The term 'former employer'—

"(A) means a person for whom a covered pharmaceutical regulator served as an employee, officer, director, trustee, or general partner during the 2-year period ending on the date (after such service) on which the covered pharmaceutical regulator begins service in the Federal Government; and

"(B) does not include—

"(i) any entity in the Federal Government, including an executive branch agency;

"(ii) a State or local government;

"(iii) the District of Columbia;

"(iv) an Indian tribe, as defined in section 4 of the Indian Self-Determination

and Education Assistance Act (25 U.S.C. 5304); or

''(v) the government of a territory or possession of the United States.

''SEC. 602. CONFLICT OF INTEREST AND ELIGIBILITY STANDARDS FOR PHARMACEUTICAL REGULATORS.

''(a) IN GENERAL.—A covered pharmaceutical regulator shall not make, participate in making, or in any way attempt to use the official position of the covered pharmaceutical regulator to influence a particular matter that provides a direct and substantial pecuniary benefit for a former employer or former client of the covered pharmaceutical regulator.

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

''(c) WAIVER.—

''(1) IN GENERAL.—The head of the covered pharmaceutical regulatory agency employing a covered pharmaceutical regulator, in consultation with the Director, may grant a written waiver of the restrictions under subsection (a) if, and to the extent that, the head of the covered pharmaceutical regulatory agency certifies in writing that—

"(A) the application of the restriction to the particular matter is inconsistent with the purposes of the restriction; or

"(B) it is in the public interest to grant the waiver.

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

"SEC. 603. NEGOTIATING FUTURE PRIVATE SECTOR EMPLOYMENT.

"(a) PROHIBITION.—Except as provided in subsection (c), and notwithstanding any other provision of law, a covered pharmaceutical regulator may not participate in any particular matter which involves, to the knowledge of the covered pharmaceutical regulator, an individual or entity with whom the covered pharmaceutical regulator is in negotiations of future employment or has an arrangement concerning prospective employment.

"(b) DISCLOSURE OF EMPLOYMENT NEGOTIATIONS.—

"(1) IN GENERAL.—If a covered pharmaceutical regulator begins any negotiations of future employment with another person, or an agent or intermediary of another person, or other discussion or communication with another person, or an agent or

intermediary of another person, mutually conducted with a view toward reaching an agreement regarding possible employment of the covered pharmaceutical regulator, the covered pharmaceutical regulator shall notify the designated agency ethics official of the covered pharmaceutical regulatory agency employing the covered pharmaceutical regulator regarding the negotiations, discussions, or communications.

''(2) INFORMATION.—A designated agency ethics official receiving notice under paragraph (1), after consultation with the Director, shall inform the covered pharmaceutical regulator of any potential conflicts of interest involved in any negotiations, discussions, or communications with the other person and the applicable prohibitions.

''(3) PUBLICATION.—The Director, after receiving notice under paragraph (1), shall make publicly available on the Web site of the Office of Government Ethics the name of the covered pharmaceutical regulator and the name of the private person involved in the negotiations or arrangement concerning prospective employment of the covered pharmaceutical regulator.

''(c) WAIVERS ONLY WHEN EXCEPTIONAL CIRCUMSTANCES EXIST.—

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

"(2) REVIEW AND PUBLICATION.—For any waiver granted under paragraph (1), the Director shall—

"(A) review the circumstances relating to the waiver and the determination that exceptional circumstances exist; and

"(B) make the waiver publicly available on the Web site of the Office of Government Ethics, which shall include—

"(i) the name of the private person involved in the negotiations or arrangement concerning prospective employment of the covered pharmaceutical regulator; and

"(ii) the date on which the negotiations or arrangement commenced.

"(d) SCOPE.—For the purposes of this section, the term 'negotiations of future employment' is not limited to discussions of specific terms or conditions of employment in a specific position.

"SEC. 604. RECORDKEEPING.

''The Director shall—

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

''(2) promulgate rules and regulations, in consultation with the Director of the Office of Personnel Management and the Attorney General, to implement this title;

''(3) provide guidance and assistance where appropriate to facilitate compliance with this title;

''(4) review and, where necessary, assist designated agency ethics officials in providing advice to covered pharmaceutical regulators regarding compliance with this title; and

''(5) if the Director determines that a violation of this title may have occurred, and in consultation with the designated agency ethics official and the Counsel to the President, refer the compliance case to the United States Attorney for the District of Columbia for enforcement action.

"SEC. 605. PENALTIES AND INJUNCTIONS.

''(a) CRIMINAL PENALTIES.—

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

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

''(b) CIVIL ENFORCEMENT.—

''(1) IN GENERAL.—The Attorney General may bring a civil action in an appropriate district court of the United States against any person who violates, or whom the Attorney General has reason to believe is engaging in conduct that violates, section 602 or 603.

''(2) CIVIL PENALTY.—

''(A) IN GENERAL.—Upon proof by a preponderance of the evidence that a person violated section 602 or 603, the court shall impose a civil penalty of not more than the greater of—

''(i) $100,000 for each violation; or

''(ii) the amount of compensation the person received or was offered for the conduct constituting the violation.

"(B) RULE OF CONSTRUCTION.—A civil penalty under this subsection shall be in addition to any other criminal or civil statutory, common law, or administrative remedy available to the United States or any other person.

"(3) INJUNCTIVE RELIEF.—

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

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

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

SEC. 3. SLOWING THE REVOLVING DOOR FROM PHARMACEUTICAL REGULATORY AGENCY INTO PRIVATE SECTOR REPRESENTATIONAL ACTIVITIES.

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

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

(2) by inserting after subsection (d) the following:

''(e) RESTRICTIONS ON EMPLOYMENT FOR PHARMACEUTICAL REGULATORS.—

''(1) IN GENERAL.—In addition to the restrictions set forth in subsections (a), (b), (c), and (d), a covered pharmaceutical regulator shall not—

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

''(i) knowingly act as agent or attorney for, or otherwise represent, any other person for compensation (except the United States) in any formal or informal appearance before;

''(ii) with the intent to influence, make any oral or written communication

on behalf of any other person (except the United States) to; or

"(iii) knowingly aid, advise, or assist in—

"(I) representing any other person (except the United States) in any formal or informal appearance before; or

"(II) making, with the intent to influence, any oral or written communication on behalf of any other person (except the United States) to,

any court of the United States, or any officer or employee thereof, in connection with any judicial or other proceeding, which was actually pending under his or her official responsibility as a covered pharmaceutical regulator during the 1-year period ending on the date on which his or her employment as a covered pharmaceutical regulator ceases or in which he or she participated personally and substantially as a covered pharmaceutical regulator; or

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

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

"(ii) with the intent to influence, make any oral or written communication or conduct any lobbying activities on behalf of any other person (except the United States) to; or

"(iii) knowingly aid, advise, or assist in—

"(I) representing any other person (except the United States) in any formal or informal appearance before; or

"(II) making, with the intent to influence, any oral or written communication or conduct any lobbying activities on behalf of any other person (except the United States) to,

any department or agency of the executive branch or Congress (including any committee of Congress), or any officer or employee thereof, in connection with any matter that is pending before the department, the agency, or Congress.

''(2) PENALTY.—Any person who violates paragraph (1) shall be punished as provided in section 216.

''(3) DEFINITIONS.—In this subsection—

''(A) the term 'covered pharmaceutical regulator' has the meaning given that term in section 601 of the Ethics in Government Act of 1978 (5 U.S.C. App.); and

''(B) the terms 'lobbying activities' and 'lobbyist' have the meanings given those terms in section 3 of the Lobbying Disclosure Act of 1995 (2 U.S.C. 1602).''.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) Section 103(a) of the Honest Leadership and Open Government Act of 2007 (2 U.S.C. 4702(a)) is amended by striking ''section 207(e)'' 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)''; and

(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)''; and

(iv) in paragraph (7)—

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

(II) in subparagraph (B)(ii), in the matter preceding subclause (I), by striking ''subsections (c), (d), or (e)'' and inserting ''subsection (c), (d), (e), or (f)''.

(3) Section 141(b)(4) of the Trade Act of 1974 (19 U.S.C. 2171(b)(4)) is amended by striking ''section 207(f)(3)'' and inserting ''207(g)(3)''.

(4) Section 7802(b)(3)(B) of the Internal Revenue Code of 1986 is amended by striking ''and (f) of section 207'' and inserting ''and (g) of section 207''.

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

(6) Section 106(p)(6)(I)(ii) of title 49, United States Code, is amended by striking ''and (f) of section 207'' and inserting ''and (g) of section 207''.

SEC. 4. SEVERABILITY.

If any provision of this Act or any amendment made by this Act, or any application of such provision or amendment to any person or circumstance, is held to be unconstitutional, the remainder of the provisions of this Act and the amendments made by this Act and the application of the provision or amendment to any other person or circumstance shall not be affected.