I

114TH CONGRESS
2D SESSION

H. R. 6501

To establish within the Food and Drug Administration the Prescription Drug and Medical Device Price Review Board to regulate the prices of certain prescription drugs and medical devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 8, 2016

Ms. DELAURO (for herself, Ms. SCHAKOWSKY, Mr. DOGGETT, Mr. MCDERMOTT, Mr. HONDA, Ms. MOORE, Ms. KAPTUR, and Mr. WELCH) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To establish within the Food and Drug Administration the Prescription Drug and Medical Device Price Review Board to regulate the prices of certain prescription drugs and medical devices, 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 ''Prescription Drug and Medical Device Price Review Board Act of 2016''.

SEC. 2. ESTABLISHMENT.

There is established in the Food and Drug Administration a board to be known as the Prescription Drug and Medical Device Price Review Board (in this Act referred to as the ''Board'').

SEC. 3. MEMBERSHIP; STAFF.

(a) MEMBERS.—The Board shall be composed of 5 members as follows:

(1) The Commissioner of Food and Drugs (or the Commissioner's designee).

(2) The Administrator of the Centers for Medicare & Medicaid Services (or the Administrator's designee).

(3) The Director of the National Institutes of Health (or the Director's designee).

(4) The Secretary of Defense (or the Secretary's designee).

(5) The Secretary of Veterans Affairs (or the Secretary's designee).

(b) CHAIRPERSON.—The Board shall designate 1 member of the Board to serve as the chairperson.

(c) DIRECTOR AND STAFF.—

(1) DIRECTOR.—The Board shall have a director who shall be appointed by the chairperson of the Board, subject to rules prescribed by the Board.

(2) STAFF.—The director may appoint and fix the pay of such additional personnel as the chairperson considers appropriate, subject to rules prescribed by the Board.

(3) APPLICABILITY OF CERTAIN CIVIL SERVICE LAWS.—The director and staff of the Board shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the requirements of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates; except that an individual so appointed may not receive pay in excess of the maximum annual rate of basic pay payable for grade GS–15 of the General Schedule.

(d) ASSISTANCE FOR THE BOARD.—Subject to section 8(g), in carrying out this Act, the Board may seek assistance from outside experts in the fields of consumer advocacy, medicine, pharmacology, pharmacy, and prescription drug reimbursement.

(e) INITIAL MEETING.—The Board shall hold its initial meeting not later than 90 days after the date of the enactment of this Act.

SEC. 4. REPORTING REQUIREMENT.

The Board shall require each manufacturer of a prescription drug or medical device that is sold in the United States to submit to the Board on a periodic basis, at a level of specificity determined by the Board to be necessary to make a determination under section 6, the following information with respect to the reporting period:

(1) Each type of prescription drug and medical device that is sold by the manufacturer or an affiliate of the manufacturer—

(A) in the United States; or

(B) in a country that is a member of the Organization for Economic Co-operation and Development.

(2) The price charged by the manufacturer and the affiliate for the prescription drug or medical device in the United States and in any such country, as applicable.

(3) The costs of the manufacturer and the affiliate to produce and market the prescription drug or medical device for sale in the United States and in any such country, as applicable.

SEC. 5. PROHIBITION AGAINST EXCESSIVE PRICE.

(a) PROHIBITION.—Beginning on the effective date of the regulation required by subsection (b), the manufacturer of a prescription drug or medical device shall not

charge an excessive price, as determined pursuant to such regulation, for such drug or device.

(b) FORMULA.—The Board shall by regulation prescribe a formula for determining whether the average manufacturer price of such drug or device over an annual quarter is an excessive price.

(c) DETERMINATION OF EXCESSIVE PRICE.—If the Board determines, on its own initiative or in response to a petition submitted under subsection (d), that the manufacturer of a prescription drug or medical device charges an excessive price for such drug or device in violation of subsection (a)—

(1) the Board shall give the manufacturer—

(A) notice of such violation; and

(B) subject to subsection (d), a period to correct such violation; and

(2) if the manufacturer fails to correct the violation by the end of such period, the manufacturer shall be subject to section 6 of this Act, section 1927(c)(2)(E) of the Social Security Act, as added by subsection (c) of such section 6, and section 4192 of the Internal Revenue Code of 1986, as added by subsection (d) of such section 6.

(d) PETITIONS.—Any person may petition the Board to make a determination under subsection (c) regarding

the pricing of a prescription drug or medical device. Not later than 90 days after the date of receipt of such a petition, the Board shall—

(1) make a determination under subsection (c) regarding such pricing; or

(2) decline to make such a determination.

(e) CONTINUING VIOLATION.—The Board shall not be required to give a manufacturer an opportunity to correct a violation, as described in subsection (c)(1)(B), before the manufacturer becomes subject to the provisions described in subsection (c)(2) for such violation, if—

(1) the Board has already provided such an opportunity to correct to the manufacturer; and

(2) the Board finds that the violation of subsection (a) is a continuation of an earlier violation with respect to which such an opportunity was provided.

(f) CONSIDERATIONS.—The formula required by subsection (a) shall at a minimum take into consideration—

(1) the average manufacturer price of the prescription drug or medical device over the respective annual quarter or quarters;

(2) the average manufacturer price of other prescription drugs or medical devices in the same therapeutic class over the same quarter or quarters;

(3) the average price at which the prescription drug or medical device and other prescription drugs and medical devices in the same therapeutic class have been sold by manufacturers in countries other than the United States;

(4) the costs associated with producing and marketing the prescription drug or medical device, the value of the drug or device to patients where sufficient data is available to determine such value, the total Federal investment in the development of the drug or device, the size of the patient population receiving the drug or device, and other factors determinative as to the true cost of production; and

(5) whether the price of the prescription drug or medical device increased during any annual quarter by a percentage that is more than 2 percent greater than the CPI increase percentage (as defined in section 215(i) of the Social Security Act (42 U.S.C. 415)) for the respective annual quarter.

SEC. 6. ENFORCEMENT PROVISIONS.

(a) REDUCED PATENT TERM.—If the Board finds that the manufacturer of a prescription drug or medical device, who is also an owner of a patent for such drug or device, charged an excessive price for such drug or device in violation of section 5(a), the Board may—

(1) reduce the term, by not more than 5 years, of any patent issued under title 35, United States Code, relating to such drug or device; or

(2) if the term of each patent for such drug or device has expired, reduce the term, by not more than 5 years, of another patent owned by the patent owner relating to a prescription drug or medical device.

(b) CIVIL PENALTIES.—If the Board determines under section 5(c) that a manufacturer of a prescription drug or medical device charged an excessive price for a prescription drug or medical device in violation of section 5(a), the Board may impose a civil penalty on the manufacturer of not more than 10 percent of the manufacturer's gross sales of the drug or device during the period beginning on the date on which an excessive price is first charged and ending on the date on which the manufacturer ceases to charge an excessive price.

(c) ENFORCEMENT THROUGH INCREASED MEDICAID REBATES.—

(1) IN GENERAL.—Section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)) is amended—

(A) in subparagraph (A), by inserting ", subject to subparagraph (E)," after "increased by"; and

(B) by adding at the end the following new subparagraph:

"(E) DISCOURAGING EXCESSIVE PRICES.—

"(i) IN GENERAL.—In the case of a manufacturer of a single source drug or an innovator multiple source drug with a rebate agreement under this section, if the Prescription Drug and Medical Device Price Review Board established under section 2 of the Prescription Drug and Medical Device Price Review Board Act of 2016 determines under section 5(a) of such Act that such manufacturer charged, with respect to a 30-day period, an excessive price for such drug, and the Board determines under clause (ii) to apply an increase amount described in such clause with respect to such manufacturer and drug, the amount of the rebate determined under subparagraph (A) for such manufacturer and drug shall be, subject to subparagraph (D), increased by such amount

for the 4 rebate periods following such 30-day period.

''(ii) INCREASED AMOUNT DETERMINATION.—For purposes of clause (i), if the Board described in such clause makes such a determination under such section 5(a), with respect to a manufacturer and drug described in such clause, the Board may determine an increase amount to apply with respect to such manufacturer and drug and rebate period described in such clause. Such increase amount may not exceed the rebate amount that would otherwise be applied to such manufacturer and drug under this section for such rebate period, without regard to this subparagraph.''.

(2) EFFECTIVE DATE.—This subsection and the amendments made by this subsection shall apply with respect to rebate agreements entered into after the date that is 60 days after the date of the enactment of this Act.

(d) TAX ON EXCESS PRESCRIPTION DRUG AND MEDICAL DEVICE PROFITS.—

(1) DETERMINATION OF AMOUNT.—If the Board determines under section 5(a) that a manufacturer, producer, or importer of a prescription drug or medical device charged an excessive price for such prescription drug or medical device during a taxable year, the Board may determine under this paragraph a reasonable price for such drug or device for such taxable year.

(2) IMPOSITION OF TAX.—

(A) IN GENERAL.—The Internal Revenue Code of 1986 is amended by inserting after section 4191 the following new section:

"SEC. 4192. EXCESSIVE PRESCRIPTION DRUG AND MEDICAL DEVICE PRICE.

''(a) IN GENERAL.—There is hereby imposed on the sale of any prescription drug or medical device by the manufacturer, producer, or importer a tax equal to the difference between the price at which such drug or device is so sold and the reasonable price determined by the Prescription Drug and Medical Device Price Review Board under section 6(d)(1) of the Prescription Drug and Medical Device Price Review Board Act of 2016 for such drug or device for the taxable year for sales after the determination.

''(b) PRESCRIPTION DRUG OR MEDICAL DEVICE.—For purposes of this section, the term 'prescription drug or medical device' means any prescription drug (as defined in section 9008 of the Patient Protection and Affordable Care Act) or device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) intended for humans.''.

(B) CLERICAL AMENDMENT.—The table of parts for chapter 32 of such Code is amended—

(i) in the item relating to subchapter E, by striking ''Medical'' and inserting ''Drugs and medical'', and

(ii) by inserting after the item relating to section 4191 the following new item:

''Sec. 4192. Excessive prescription drug and medical device price.''.

(3) EFFECTIVE DATE.—This subsection and the amendments made by this subsection shall apply with respect to sales after December 31, 2016.

(e) SAFE AND AFFORDABLE DRUGS FROM APPROVED COUNTRIES.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

"SEC. 810. IMPORTATION BY INDIVIDUALS OF PRESCRIPTION DRUGS, AND DEVICES, FROM AN APPROVED COUNTRY IF MANUFACTURERS ARE CHARGING AN EXCESSIVE PRICE FOR COMPARABLE PRODUCTS IN THE UNITED STATES.

''(a) IN GENERAL.—Notwithstanding any other provision of this Act, not later than 180 days after the date of enactment of this section, the Prescription Drug and Medical Device Price Review Board (in this section referred to as the 'Board') shall promulgate regulations permitting individuals to safely import from an approved country into the United States prescription drugs, and devices, that are comparable to prescription drugs, and devices, for which the Board makes a final determination that the manufacturer is charging or has charged an excessive price in violation of section 5(a) of the Prescription Drug and Medical Device Price Review Board Act of 2016.

''(b) COMPARABLE DEFINED.—For purposes of this section, the term 'comparable' means—

''(1) with respect to a drug, having the same active ingredient or ingredients, route of administration, dosage form, and strength; and

''(2) with respect to a device, being substantially equivalent.

''(c) ASSURANCE OF SAFETY.—For purposes of this section, the term 'approved country' means a country that is determined by the Secretary to have in effect standards to ensure the safety of prescription drugs, and of devices, that are at least as protective as the standards applicable under Federal law in the United States.''.

SEC. 7. AUTHORITY.

(a) OBTAINING OFFICIAL DATA.—The chairperson of the Board may secure directly from any Federal agency information necessary to enable the Board to carry out its duties. Upon request of the chairperson, the head of the agency shall furnish such information to the Board to the extent such information is not prohibited from disclosure by law.

(b) MAILS.—The Board may use the United States mails in the same manner and under the same conditions as other Federal agencies.

(c) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the chairperson of the Board, the Administrator of General Services shall provide to the Board, on a reimbursable basis, the administrative support services necessary for the Board to carry out its duties.

(d) CONTRACT AUTHORITY.—The Board may contract with and compensate government and private agencies or persons for the purpose of conducting research,

surveys, and other services necessary to enable the Board to carry out its duties.

(e) INVESTIGATIONS.—The Board may make such investigations as it considers necessary to determine whether there is or may be a violation of any regulation promulgated under this Act and may require or permit any person to file with it a statement in writing, under oath or otherwise as the Board shall determine, as to all the facts and circumstances concerning the matter to be investigated.

(f) SUBPOENA POWER.—

(1) IN GENERAL.—The Board may issue subpoenas requiring the attendance and testimony of witnesses and the production of any evidence relating to any matter under investigation by the Board. The attendance of witnesses and the production of evidence may be required from any place within the United States at any designated place of hearing within the United States.

(2) FAILURE TO OBEY A SUBPOENA.—If a person refuses to obey a subpoena issued under paragraph (1), the Board may apply to a United States district court for an order requiring that person to appear before the Board to give testimony, produce evidence, or both, relating to the matter under inves-

tigation. The application may be made within the judicial district where the hearing is conducted or where that person is found, resides, or transacts business. Any failure to obey the order of the court may be punished by the court as civil contempt.

(3) SERVICE OF SUBPOENAS.—The subpoenas of the Board shall be served in the manner provided for subpoenas issued by a United States district court under the Federal Rules of Civil Procedure for the United States district courts.

(4) SERVICE OF PROCESS.—All process of any court to which application is made under paragraph (2) may be served in the judicial district in which the person required to be served resides or may be found.

(5) NOTICE.—Upon issuing any subpoena under this subsection, the Board shall give notice of such issuance to the appropriate committees of Congress, including the Committee on Appropriations of the House of Representatives and the Committee on Appropriations of the Senate.

(g) CONFIDENTIALITY.—Nothing in this Act shall be construed as authorizing the Board to disclose any information that is a trade secret or confidential information

subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

SEC. 8. REGULATIONS.

(a) IN GENERAL.—Not later than 1 year after the date of the initial meeting held under section 4(e), the Board shall issue final regulations to carry out this Act.

(b) NOTICE AND COMMENT REQUIREMENT.—The regulations developed under subsection (a) shall be issued in accordance with the notice and comment procedures established under section 553 of title 5, United States Code.

SEC. 9. REPORT TO FEDERAL AGENCIES .

Not later than 1 year after the effective date of the regulations under section 9 and annually thereafter, the Board shall submit to each Federal agency that dispenses or makes payments for the dispensing of prescription drugs or medical devices a report containing—

(1) a list of each prescription drug and medical device for which an excessive price was charged during the preceding calendar year, as determined by the Board under section 5;

(2) recommendations to the Federal agency against dispensing or making payments for the dispensing of the prescription drug or medical device; and

(3) recommendations to the Federal agency to substitute, in place of any drug or device listed pursuant to paragraph (1), a similar prescription drug or medical device that is not sold at an excessive price.

SEC. 10. REPORT TO CONGRESS.

Not later than 1 year after the initial meeting of the Board under section 3(e), and annually thereafter, the Board shall submit to the Congress a report describing the activities of the Board for the preceding year.

SEC. 11. DEFINITIONS.

In this Act:

(1) The term ''affiliate'' means, with respect to a manufacturer, any entity that controls, is controlled by, or is under common control with such manufacturer.

(2) The term ''average manufacturer price'' means the average price charged by the manufacturer of a prescription drug or medical device, as applicable, for sales of the drug or device by the manufacturer in the United States over the respective annual quarter.

(3) The term ''medical device'' means a device (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)).

(4) The term ''prescription drug'' means a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that is subject to section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)).

○