

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.

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 “Prescription Drug and
5 Medical Device Price Review Board Act of 2016”.

1 **SEC. 2. ESTABLISHMENT.**

2 There is established in the Food and Drug Adminis-
3 tration a board to be known as the Prescription Drug and
4 Medical Device Price Review Board (in this Act referred
5 to as the “Board”).

6 **SEC. 3. MEMBERSHIP; STAFF.**

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

9 (1) The Commissioner of Food and Drugs (or
10 the Commissioner’s designee).

11 (2) The Administrator of the Centers for Medi-
12 care & Medicaid Services (or the Administrator’s
13 designee).

14 (3) The Director of the National Institutes of
15 Health (or the Director’s designee).

16 (4) The Secretary of Defense (or the Sec-
17 retary’s designee).

18 (5) The Secretary of Veterans Affairs (or the
19 Secretary’s designee).

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

22 (c) DIRECTOR AND STAFF.—

23 (1) DIRECTOR.—The Board shall have a direc-
24 tor who shall be appointed by the chairperson of the
25 Board, subject to rules prescribed by the Board.

1 (2) STAFF.—The director may appoint and fix
2 the pay of such additional personnel as the chair-
3 person considers appropriate, subject to rules pre-
4 scribed by the Board.

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

16 (d) ASSISTANCE FOR THE BOARD.—Subject to sec-
17 tion 8(g), in carrying out this Act, the Board may seek
18 assistance from outside experts in the fields of consumer
19 advocacy, medicine, pharmacology, pharmacy, and pre-
20 scription drug reimbursement.

21 (e) INITIAL MEETING.—The Board shall hold its ini-
22 tial meeting not later than 90 days after the date of the
23 enactment of this Act.

1 **SEC. 4. REPORTING REQUIREMENT.**

2 The Board shall require each manufacturer of a pre-
3 scription drug or medical device that is sold in the United
4 States to submit to the Board on a periodic basis, at a
5 level of specificity determined by the Board to be nec-
6 essary to make a determination under section 6, the fol-
7 lowing information with respect to the reporting period:

8 (1) Each type of prescription drug and medical
9 device that is sold by the manufacturer or an affil-
10 iate of the manufacturer—

11 (A) in the United States; or

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

15 (2) The price charged by the manufacturer and
16 the affiliate for the prescription drug or medical de-
17 vice in the United States and in any such country,
18 as applicable.

19 (3) The costs of the manufacturer and the affil-
20 iate to produce and market the prescription drug or
21 medical device for sale in the United States and in
22 any such country, as applicable.

23 **SEC. 5. PROHIBITION AGAINST EXCESSIVE PRICE.**

24 (a) PROHIBITION.—Beginning on the effective date
25 of the regulation required by subsection (b), the manufac-
26 turer of a prescription drug or medical device shall not

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

3 (b) FORMULA.—The Board shall by regulation pre-
4 scribe a formula for determining whether the average
5 manufacturer price of such drug or device over an annual
6 quarter is an excessive price.

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

13 (1) the Board shall give the manufacturer—

14 (A) notice of such violation; and

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

17 (2) if the manufacturer fails to correct the vio-
18 lation by the end of such period, the manufacturer
19 shall be subject to section 6 of this Act, section
20 1927(e)(2)(E) of the Social Security Act, as added
21 by subsection (c) of such section 6, and section 4192
22 of the Internal Revenue Code of 1986, as added by
23 subsection (d) of such section 6.

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

1 the pricing of a prescription drug or medical device. Not
2 later than 90 days after the date of receipt of such a peti-
3 tion, the Board shall—

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

6 (2) decline to make such a determination.

7 (e) CONTINUING VIOLATION.—The Board shall not
8 be required to give a manufacturer an opportunity to cor-
9 rect a violation, as described in subsection (c)(1)(B), be-
10 fore the manufacturer becomes subject to the provisions
11 described in subsection (c)(2) for such violation, if—

12 (1) the Board has already provided such an op-
13 portunity to correct to the manufacturer; and

14 (2) the Board finds that the violation of sub-
15 section (a) is a continuation of an earlier violation
16 with respect to which such an opportunity was pro-
17 vided.

18 (f) CONSIDERATIONS.—The formula required by sub-
19 section (a) shall at a minimum take into consideration—

20 (1) the average manufacturer price of the pre-
21 scription drug or medical device over the respective
22 annual quarter or quarters;

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

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

6 (4) the costs associated with producing and
7 marketing the prescription drug or medical device,
8 the value of the drug or device to patients where suf-
9 ficient data is available to determine such value, the
10 total Federal investment in the development of the
11 drug or device, the size of the patient population re-
12 ceiving the drug or device, and other factors deter-
13 minative as to the true cost of production; and

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

20 **SEC. 6. ENFORCEMENT PROVISIONS.**

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

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

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

9 (b) CIVIL PENALTIES.—If the Board determines
10 under section 5(c) that a manufacturer of a prescription
11 drug or medical device charged an excessive price for a
12 prescription drug or medical device in violation of section
13 5(a), the Board may impose a civil penalty on the manu-
14 facturer of not more than 10 percent of the manufactur-
15 er's gross sales of the drug or device during the period
16 beginning on the date on which an excessive price is first
17 charged and ending on the date on which the manufac-
18 turer ceases to charge an excessive price.

19 (c) ENFORCEMENT THROUGH INCREASED MEDICAID
20 REBATES.—

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

1 (A) in subparagraph (A), by inserting “,
2 subject to subparagraph (E),” after “increased
3 by”; and

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

6 “(E) DISCOURAGING EXCESSIVE PRICES.—

7 “(i) IN GENERAL.—In the case of a
8 manufacturer of a single source drug or an
9 innovator multiple source drug with a re-
10 bate agreement under this section, if the
11 Prescription Drug and Medical Device
12 Price Review Board established under sec-
13 tion 2 of the Prescription Drug and Med-
14 ical Device Price Review Board Act of
15 2016 determines under section 5(a) of
16 such Act that such manufacturer charged,
17 with respect to a 30-day period, an exces-
18 sive price for such drug, and the Board de-
19 termines under clause (ii) to apply an in-
20 crease amount described in such clause
21 with respect to such manufacturer and
22 drug, the amount of the rebate determined
23 under subparagraph (A) for such manufac-
24 turer and drug shall be, subject to sub-
25 paragraph (D), increased by such amount

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

3 “(ii) INCREASED AMOUNT DETER-
4 MINATION.—For purposes of clause (i), if
5 the Board described in such clause makes
6 such a determination under such section
7 5(a), with respect to a manufacturer and
8 drug described in such clause, the Board
9 may determine an increase amount to
10 apply with respect to such manufacturer
11 and drug and rebate period described in
12 such clause. Such increase amount may
13 not exceed the rebate amount that would
14 otherwise be applied to such manufacturer
15 and drug under this section for such rebate
16 period, without regard to this subpara-
17 graph.”.

18 (2) EFFECTIVE DATE.—This subsection and the
19 amendments made by this subsection shall apply
20 with respect to rebate agreements entered into after
21 the date that is 60 days after the date of the enact-
22 ment of this Act.

23 (d) TAX ON EXCESS PRESCRIPTION DRUG AND MED-
24 ICAL DEVICE PROFITS.—

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

9 (2) IMPOSITION OF TAX.—

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

13 **“SEC. 4192. EXCESSIVE PRESCRIPTION DRUG AND MEDICAL**
14 **DEVICE PRICE.**

15 “(a) IN GENERAL.—There is hereby imposed on the
16 sale of any prescription drug or medical device by the
17 manufacturer, producer, or importer a tax equal to the
18 difference between the price at which such drug or device
19 is so sold and the reasonable price determined by the Pre-
20 scription Drug and Medical Device Price Review Board
21 under section 6(d)(1) of the Prescription Drug and Med-
22 ical Device Price Review Board Act of 2016 for such drug
23 or device for the taxable year for sales after the determina-
24 tion.

1 “(b) PRESCRIPTION DRUG OR MEDICAL DEVICE.—
2 For purposes of this section, the term ‘prescription drug
3 or medical device’ means any prescription drug (as defined
4 in section 9008 of the Patient Protection and Affordable
5 Care Act) or device (as defined in section 201(h) of the
6 Federal Food, Drug, and Cosmetic Act) intended for hu-
7 mans.”.

8 (B) CLERICAL AMENDMENT.—The table of
9 parts for chapter 32 of such Code is amended—
10 (i) in the item relating to subchapter
11 E, by striking “Medical” and inserting
12 “Drugs and medical”, and
13 (ii) by inserting after the item relating
14 to section 4191 the following new item:

“Sec. 4192. Excessive prescription drug and medical device price.”.

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

18 (e) SAFE AND AFFORDABLE DRUGS FROM AP-
19 PROVED COUNTRIES.—Chapter VIII of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amend-
21 ed by adding at the end the following:

1 **“SEC. 810. IMPORTATION BY INDIVIDUALS OF PRESCRIP-**
2 **TION DRUGS, AND DEVICES, FROM AN AP-**
3 **PROVED COUNTRY IF MANUFACTURERS ARE**
4 **CHARGING AN EXCESSIVE PRICE FOR COM-**
5 **PARABLE PRODUCTS IN THE UNITED STATES.**

6 “(a) IN GENERAL.—Notwithstanding any other pro-
7 vision of this Act, not later than 180 days after the date
8 of enactment of this section, the Prescription Drug and
9 Medical Device Price Review Board (in this section re-
10 ferred to as the ‘Board’) shall promulgate regulations per-
11 mitting individuals to safely import from an approved
12 country into the United States prescription drugs, and de-
13 vices, that are comparable to prescription drugs, and de-
14 vices, for which the Board makes a final determination
15 that the manufacturer is charging or has charged an ex-
16 cessive price in violation of section 5(a) of the Prescription
17 Drug and Medical Device Price Review Board Act of
18 2016.

19 “(b) COMPARABLE DEFINED.—For purposes of this
20 section, the term ‘comparable’ means—

21 “(1) with respect to a drug, having the same
22 active ingredient or ingredients, route of administra-
23 tion, dosage form, and strength; and

24 “(2) with respect to a device, being substan-
25 tially equivalent.

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

7 **SEC. 7. AUTHORITY.**

8 (a) OBTAINING OFFICIAL DATA.—The chairperson of
9 the Board may secure directly from any Federal agency
10 information necessary to enable the Board to carry out
11 its duties. Upon request of the chairperson, the head of
12 the agency shall furnish such information to the Board
13 to the extent such information is not prohibited from dis-
14 closure by law.

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

18 (c) ADMINISTRATIVE SUPPORT SERVICES.—Upon the
19 request of the chairperson of the Board, the Administrator
20 of General Services shall provide to the Board, on a reim-
21 bursable basis, the administrative support services nec-
22 essary for the Board to carry out its duties.

23 (d) CONTRACT AUTHORITY.—The Board may con-
24 tract with and compensate government and private agen-
25 cies or persons for the purpose of conducting research,

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

3 (e) INVESTIGATIONS.—The Board may make such in-
4 vestigations as it considers necessary to determine whether
5 there is or may be a violation of any regulation promul-
6 gated under this Act and may require or permit any per-
7 son to file with it a statement in writing, under oath or
8 otherwise as the Board shall determine, as to all the facts
9 and circumstances concerning the matter to be inves-
10 tigated.

11 (f) SUBPOENA POWER.—

12 (1) IN GENERAL.—The Board may issue sub-
13 poenas requiring the attendance and testimony of
14 witnesses and the production of any evidence relat-
15 ing to any matter under investigation by the Board.
16 The attendance of witnesses and the production of
17 evidence may be required from any place within the
18 United States at any designated place of hearing
19 within the United States.

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

1 tigation. The application may be made within the ju-
2 dicial district where the hearing is conducted or
3 where that person is found, resides, or transacts
4 business. Any failure to obey the order of the court
5 may be punished by the court as civil contempt.

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

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

16 (5) NOTICE.—Upon issuing any subpoena
17 under this subsection, the Board shall give notice of
18 such issuance to the appropriate committees of Con-
19 gress, including the Committee on Appropriations of
20 the House of Representatives and the Committee on
21 Appropriations of the Senate.

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

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

3 **SEC. 8. REGULATIONS.**

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

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

11 **SEC. 9. REPORT TO FEDERAL AGENCIES .**

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

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

21 (2) recommendations to the Federal agency
22 against dispensing or making payments for the dis-
23 pensing of the prescription drug or medical device;
24 and

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

6 **SEC. 10. REPORT TO CONGRESS.**

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

11 **SEC. 11. DEFINITIONS.**

12 In this Act:

13 (1) The term “affiliate” means, with respect to
14 a manufacturer, any entity that controls, is con-
15 trolled by, or is under common control with such
16 manufacturer.

17 (2) The term “average manufacturer price”
18 means the average price charged by the manufac-
19 turer of a prescription drug or medical device, as ap-
20 plicable, for sales of the drug or device by the manu-
21 facturer in the United States over the respective an-
22 nual quarter.

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

1 (4) The term “prescription drug” means a drug
2 (as defined in section 201 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 321)) that is
4 subject to section 503(b)(1) of such Act (21 U.S.C.
5 353(b)(1)).

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