

103^D CONGRESS
2^D SESSION

H. R. 916

To establish in the Food and Drug Administration the Patented Medicine Prices Review Board to regulate the prices of certain prescription drugs, to amend the Internal Revenue Code to recapture certain tax benefits, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 16, 1993

Mr. STARK introduced the following bill; which was referred jointly to the Committees on Energy and Commerce, the Judiciary, and Ways and Means

FEBRUARY 28, 1994

Additional sponsors: Mrs. COLLINS of Illinois, Mr. SANDERS, Mr. DE LUGO, Mr. FRANK of Massachusetts, Mr. BARRETT of Wisconsin, Mr. LAFALCE, Mr. MARTINEZ, Ms. PELOSI, Mr. STRICKLAND, Mr. OWENS, Mr. SABO, Mr. BLACKWELL, Mr. HASTINGS, Ms. FURSE, Miss COLLINS of Michigan, Ms. KAPTUR, Mr. EVANS, Mr. BARLOW, Mr. FOGLIETTA, Mr. HALL of Ohio, Mr. FLAKE, Mr. BAESLER, Mr. TORRICELLI, Mr. DEFazio, Ms. SLAUGHTER, Mr. MILLER of California, Mrs. CLAYTON, Mr. KLECZKA, Mr. PASTOR, Mr. GIBBONS, Mr. DELLUMS, Mr. WASHINGTON, and Mr. ROMERO-BARCELÓ

Deleted sponsors: Mr. CLYBURN (added March 24, 1993; deleted April 22, 1993)

A BILL

To establish in the Food and Drug Administration the Patented Medicine Prices Review Board to regulate the prices of certain prescription drugs, to amend the Internal Revenue Code to recapture certain tax 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Prescription Drug
5 Prices Review Board Act of 1993”.

6 **SEC. 2. ESTABLISHMENT.**

7 There is established in the Food and Drug Adminis-
8 tration a board to be known as the Patented Medicine
9 Prices Review Board (in this Act referred to as the
10 “Board”).

11 **SEC. 3. MEMBERSHIP.**

12 (a) NUMBER AND APPOINTMENT.—The Board shall
13 be composed of 5 members appointed by the President,
14 by and with the advice and consent of the Senate, from
15 among individuals—

16 (1) who are recognized experts in the fields of
17 consumer advocacy, medicine, pharmacology, phar-
18 macy, and prescription drug reimbursement; and

19 (2) who have not worked in the pharmaceutical
20 industry during the 1-year period ending on the date
21 of appointment.

22 (b) INITIAL APPOINTMENTS.—Initial appointments
23 under subsection (a) shall be made not later than 90 days
24 after the date of the enactment of this Act.

25 (c) TERMS.—

1 (1) IN GENERAL.—Except as provided in para-
2 graphs (2) and (3), each member shall be appointed
3 for a term of 5 years.

4 (2) TERMS OF INITIAL APPOINTEES.—As des-
5 ignated by the President at the time of appointment,
6 of the members first appointed—

7 (A) 1 member shall be appointed for a
8 term of 1 year;

9 (B) 1 member shall be appointed for a
10 term of 2 years;

11 (C) 1 member shall be appointed for a
12 term of 3 years;

13 (D) 1 member shall be appointed for a
14 term of 4 years; and

15 (E) 1 member shall be appointed for a
16 term of 5 years.

17 (3) VACANCIES.—A vacancy in the Board shall
18 be filled in the manner in which the original appoint-
19 ment was made. Any member appointed to fill a va-
20 cancy occurring before the expiration of the term for
21 which the member's predecessor was appointed shall
22 be appointed only for the remainder of that term. A
23 member may serve after the expiration of the mem-
24 ber's term until a successor has taken office.

1 (d) INITIAL MEETING.—The initial meeting of the
2 Board shall be held not later than 90 days after the date
3 on which the first appointments of the members have been
4 completed.

5 (e) CHAIRPERSON.—The President shall designate 1
6 member of the Board to serve as the chairperson.

7 (f) BASIC PAY.—

8 (1) IN GENERAL.—Members shall be paid at a
9 rate not to exceed the daily equivalent of the maxi-
10 mum annual rate of basic pay payable for grade
11 GS–18 of the General Schedule under section 5332
12 of title 5, United States Code, for each day during
13 which the members are engaged in the actual per-
14 formance of the duties of the Board.

15 (2) TRAVEL EXPENSES.—Members shall receive
16 travel expenses, including per diem in lieu of subsist-
17 ence, in accordance with sections 5702 and 5703 of
18 title 5, United States Code.

19 **SEC. 4. DIRECTOR AND STAFF.**

20 (a) DIRECTOR.—The Board shall have a director who
21 shall be appointed by the chairperson, subject to rules pre-
22 scribed by the Board.

23 (b) STAFF.—The chairperson may appoint and fix
24 the pay of such additional personnel as the chairperson

1 considers appropriate, subject to rules prescribed by the
2 Board.

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

13 **SEC. 5. REGULATION OF PRESCRIPTION DRUG PRICING.**

14 (a) ANNUAL INFORMATION REQUIREMENT.—The
15 Board shall require each patentee of a prescription drug
16 to provide the Board with information on an annual
17 basis—

18 (1) identifying the type of prescription drug
19 sold by the patentee; and

20 (2) identifying the price at which the prescrip-
21 tion drug is being sold in the United States.

22 The Board shall also require each such patentee to provide
23 the Board with information describing the costs of produc-
24 ing and marketing the prescription drug for sale in the
25 United States. Such information shall be provided at a

1 level of specificity necessary for the Board to make its de-
2 termination under subsection (b).

3 (b) DECREASE IN LENGTH OF PATENT TERM.—

4 (1) IN GENERAL.—The Board shall decrease
5 the length of a term of a patent issued under section
6 151 of title 35, United States Code, for a prescrip-
7 tion drug, after notice and an opportunity for a
8 hearing, if the patentee of such drug charges an ex-
9 cessive price for such drug. If the patentee charged
10 an excessive price for a drug which has gone off pat-
11 ent, the Board may select another drug of the pat-
12 entee to have its length of patent term reduced.

13 (2) EXCESSIVE PRICE.—

14 (A) IN GENERAL.—For purposes of para-
15 graph (1), the term “excessive price” means the
16 average price charged by the patentee for a pre-
17 scription drug during the calendar year preced-
18 ing the date on which the Board gives notice to
19 the patentee under paragraph (1), if such price
20 for such calendar year, adjusted for cost-of-liv-
21 ing, as determined by the Board, exceeds the
22 average price for such drug charged by the pat-
23 entee for the calendar year preceding such year
24 in an amount determined by the Board to be
25 excessive under subparagraph (B).

1 (B) EXCESSIVE AMOUNT.—In determining
2 if an amount of increase in a drug price is ex-
3 cessive, the Board shall consider—

4 (i) the average price at which the pat-
5 entee sold the drug during the 5-year pe-
6 riod ending on the date on which the
7 Board gives notice to the patentee under
8 paragraph (1);

9 (ii) the average prices of other pre-
10 scription drugs in the same therapeutic
11 class sold in the United States during such
12 period;

13 (iii) the average price at which the
14 prescription drug and other prescription
15 drugs in the same therapeutic class have
16 been sold in countries other than the
17 United States during such period;

18 (iv) the costs associated with produc-
19 ing and marketing the prescription drug
20 during such period and the value of any
21 support provided by Federal agencies, the
22 value of any tax benefit provided to the
23 patentee in the development of the drug,
24 the amount of compensation provided to
25 officers of the patentee, and other factors

1 determinative as to the true cost of pro-
2 duction; and

3 (v) if the price of the drug exceeds the
4 CPI increase percentage (as defined in sec-
5 tion 215(i) of the Social Security Act) by
6 more than 2 percent.

7 (3) LENGTH OF TERM DECREASE.—The Board
8 shall determine the length of the decrease of a term
9 of a patent for a prescription drug described in
10 paragraph (1).

11 (c) AUTHORITY TO RECAPTURE CERTAIN TAX BEN-
12 EFITS.—

13 (1) IN GENERAL.—If the Board determines,
14 after notice and an opportunity for a hearing, that
15 the patentee of any prescription drug charges an ex-
16 cessive price for such drug, the Board may require
17 the recapture of tax benefits provided to the pat-
18 entee with respect to such drug.

19 (2) RECAPTURE.—

20 (A) IN GENERAL.—If the Board requires
21 the recapture of tax benefits with respect to any
22 prescription drug, the patentee's tax under
23 chapter 1 of the Internal Revenue Code of 1986
24 for each taxable year specified by the Board
25 shall be increased by the aggregate of the re-

1 capture amounts with respect to sales of such
2 drug during such taxable year.

3 (B) RECAPTURE AMOUNT.—For purposes
4 of subparagraph (A), the recapture amount
5 with respect to the sale of any prescription drug
6 is the lesser of—

7 (i) the portion of the price of such
8 drug which the Board determines is exces-
9 sive, or

10 (ii) the amount which the Board de-
11 termines is such sales pro rata share of the
12 tax benefits received by the patentee in
13 connection with the research for, and de-
14 velopment of, such drug.

15 (3) NO CREDITS AGAINST TAX, ETC.—Any in-
16 crease in tax by reason of this subsection shall not
17 be treated as a tax imposed by chapter 1 of such
18 Code for purposes of determining—

19 (A) the amount of any credit under sub-
20 part A, B, D, or G of part IV of subchapter A
21 of such chapter, or

22 (B) the minimum tax under section 55 of
23 such Code.

24 (d) MANUFACTURE AND SALE OF DRUGS.—If the
25 Board determines, after notice and an opportunity for a

1 hearing, that the patentee of any prescription drug
2 charges an excessive price for such drug, the Board may,
3 either directly or by contract, manufacture and sell such
4 drug.

5 (e) INCREASE IN LENGTH OF PATENT TERM.—

6 (1) IN GENERAL.—Upon application of the pat-
7 entee, the Board may increase the length of a term
8 of a patent issued under section 151 of title 35,
9 United States Code, for a prescription drug, if—

10 (A) the Board determines that the pat-
11 entee of such drug has not charged an excessive
12 price for such drug during the 5-year period
13 ending on the date the patentee applies to the
14 Board, as determined by the Board using rules
15 similar to the rules applicable under subsection
16 (b); and

17 (B) the patentee provides assurances satis-
18 factory to the Board that it will not charge an
19 excessive price for such drug for any period
20 during the extension of the term.

21 (2) LENGTH OF TERM INCREASE.—

22 (A) IN GENERAL.—Subject to subpara-
23 graph (B), the Board shall determine the length
24 of the increase of a term of a patent for a pre-
25 scription drug described in paragraph (1).

1 (B) LIMITATION.—The Board may not in-
2 crease the length of a term of such patent in
3 excess of 10 percent of the length of the origi-
4 nal term of such patent.

5 (f) REGULATIONS.—

6 (1) IN GENERAL.—Not later than 1 year after
7 the date of the initial meeting held under section
8 3(e), the Board shall develop regulations to carry
9 out subsections (a), (b), (c), (d), and (e).

10 (2) NOTICE AND COMMENT REQUIREMENT.—
11 The regulations developed under paragraph (1) shall
12 be issued in accordance with the notice and com-
13 ment procedures established under section 553 of
14 title 5, United States Code.

15 (g) DEFINITIONS.—For purposes of this section, the
16 following definitions apply:

17 (1) PATENTEE.—The term “patentee” has the
18 meaning given such term in section 100(d) of title
19 35, United States Code.

20 (2) PRESCRIPTION DRUG.—The term “prescrip-
21 tion drug” means a drug (as defined in section
22 201(g)(1) of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 321 (g)(1))) which is subject to reg-
24 ulation under section 503(b) of such Act.

1 **SEC. 6. PROVISION OF REPORT TO FEDERAL AGENCIES RE-**
2 **LATING TO PRESCRIPTION DRUGS SOLD AT**
3 **EXCESSIVE PRICES.**

4 (a) IN GENERAL.—The Board shall provide on an an-
5 nual basis to each Federal agency which dispenses or
6 makes payments for the dispensing of prescription drugs
7 a report containing—

8 (1) a list of each prescription drug which is sold
9 at an excessive price, as determined by the Board
10 under section 5(b)(2);

11 (2) recommendations to the Federal agency
12 against dispensing or making payments for the dis-
13 pensing of the prescription drug; and

14 (3) recommendations to the Federal agency to
15 substitute the drug with a similar prescription drug
16 which is not sold at an excessive price.

17 (b) PRESCRIPTION DRUG DEFINED.—For purposes
18 of this section, the term “prescription drug” has the
19 meaning given such term in section 5(e)(2).

20 **SEC. 7. POWERS.**

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

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

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

9 (d) **CONTRACT AUTHORITY.**—The chairperson may
10 contract with and compensate government and private
11 agencies or persons for the purpose of conducting re-
12 search, surveys, and other services necessary to enable the
13 Board to carry out its duties.

14 (e) **INVESTIGATIONS.**—The Board may make such in-
15 vestigations as it considers necessary to determine whether
16 there is or may be a violation of any regulation promul-
17 gated under this Act and may require or permit any per-
18 son to file with it a statement in writing, under oath or
19 otherwise as the Board shall determine, as to all the facts
20 and circumstances concerning the matter to be inves-
21 tigated.

22 (f) **SUBPOENA POWER.**—

23 (1) **IN GENERAL.**—The Board may issue sub-
24 poenas requiring the attendance and testimony of
25 witnesses and the production of any evidence relat-

1 ing to any matter under investigation by the Board.
2 The attendance of witnesses and the production of
3 evidence may be required from any place within the
4 United States at any designated place of hearing
5 within the United States.

6 (2) FAILURE TO OBEY A SUBPOENA.—If a per-
7 son refuses to obey a subpoena issued under para-
8 graph (1), the Board may apply to a United States
9 district court for an order requiring that person to
10 appear before the Board to give testimony, produce
11 evidence, or both, relating to the matter under inves-
12 tigation. The application may be made within the ju-
13 dicial district where the hearing is conducted or
14 where that person is found, resides, or transacts
15 business. Any failure to obey the order of the court
16 may be punished by the court as civil contempt.

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

22 (4) SERVICE OF PROCESS.—All process of any
23 court to which application is made under paragraph
24 (2) may be served in the judicial district in which

1 the person required to be served resides or may be
2 found.

3 **SEC. 8. ASSISTANCE FOR THE BOARD.**

4 The Director of the National Institutes of Health, the
5 Commissioner of the Food and Drug Administration, and
6 the Director of the Center for Disease Control shall report
7 to the Board the amount of any subsidy paid through such
8 agency to a patentee.

9 **SEC. 9. REPORT.**

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

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