

105TH CONGRESS
2D SESSION

H. R. 3925

To establish the Prescription Drug Price Monitoring Commission.

IN THE HOUSE OF REPRESENTATIVES

MAY 21, 1998

Mr. BERRY (for himself, Mr. DINGELL, Mr. STARK, Mr. CLEMENT, Mr. DEFAZIO, Mr. LEWIS of Georgia, Ms. FURSE, Mr. BOUCHER, and Mr. ALLEN) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, 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 the Prescription Drug Price Monitoring Commission.

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; FINDINGS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Prescription Drug Price Monitoring Commission Act of
6 1998”.

7 (b) FINDINGS.—The Congress finds the following:

1 (1) Although prescription drugs represent one
2 of the most frequently used medical care interven-
3 tions in treating common acute and chronic diseases,
4 many Americans, especially elderly and other vulner-
5 able populations, are unable to afford necessary
6 medications because of excessive and persistent pre-
7 scription drug price inflation.

8 (2) Between 1981 and 1998, the rate of infla-
9 tion for prescription drugs has increased at over 2.5
10 times the general rate of inflation.

11 (3) Because of the limited availability of private
12 or public prescription drug coverage for the elderly,
13 prescription drugs represent the highest out-of-pock-
14 et medical care cost for 75 percent of elderly pa-
15 tients, surpassed only by costs of long-term care
16 services.

17 (4) The Federal Government and the American
18 taxpayer provide substantial subsidies to the phar-
19 maceutical industry in the form of tax incentives,
20 tax write-offs, and grants for nonresearch activities.

21 (5) According to the most current edition of the
22 Internal Revenue Service Corporation Source Book
23 of Statistics of Income, the 1994–95 edition, the
24 pharmaceutical industry claimed \$6,061,807,000 in

1 deductions for advertising and marketing of their
2 products.

3 (6) The statistic described in paragraph (5) is
4 not indicative of the current amounts deducted by
5 prescription drug manufacturers, since the Food and
6 Drug Administration Reform Act of 1996, effective
7 taxable year 1996, substantially expanded the adver-
8 tising activities the costs of which are deductible by
9 the pharmaceutical industry.

10 (7) According to the Internal Revenue Service
11 Corporation Source Book of Statistics of Income,
12 the pharmaceutical industry claimed \$2,115,690,000
13 in tax credits to locate their production facilities in
14 United States possessions.

15 (8) There is a need to determine whether Fed-
16 eral subsidies are used in the most efficient manner
17 by the pharmaceutical industry to develop drugs
18 which represent true therapeutic advances over those
19 products already on the market.

20 **SEC. 2. ESTABLISHMENT.**

21 There is established a commission to be known as the
22 “Prescription Drug Price Monitoring Commission” (in
23 this Act referred to as the “Commission”).

1 **SEC. 3. DUTIES OF COMMISSION.**

2 (a) STUDIES.—The Commission shall conduct the fol-
3 lowing studies:

4 (1) A study of the impact of a pharmaceutical
5 price review board on containing inflation on the
6 cost of prescription pharmaceutical products in the
7 United States.

8 (2) A study on how Federal tax credits and
9 subsidies, as well as market exclusivity given to the
10 pharmaceutical industry, can be used to modify an
11 individual manufacturer's pricing behavior and re-
12 search priorities.

13 (3) A study on drug prices in other industri-
14 alized nations.

15 (4)(A) A study on the feasibility of establishing
16 in the United States a pharmaceutical products price
17 review board.

18 (B) In conducting the study under subpara-
19 graph (A), the Commission shall—

20 (i) assess the impact of such a board in
21 other industrialized nations, such as Canada, on
22 containing the costs of prescription drugs and
23 the introductory prices of new drugs;

24 (ii) recommend how such a board might
25 operate in the United States, including the
26 membership of the Board;

1 (iii) recommend guidelines that might be
2 used by the board in determining whether
3 prices or price increases for prescription drugs
4 are excessive and whether the introductory
5 prices of new drugs are excessive; and

6 (iv) recommend incentives for drug manu-
7 facturers to price their products fairly in the
8 United States, including a system of compul-
9 sory licensing of pharmaceutical products or a
10 reduction in the period of market exclusivity as
11 a penalty for excessive inflation.

12 (b) REPORTS.—

13 (1) ANNUAL REPORTS.—The Commission shall
14 submit to the Congress an annual report (by not
15 later than January 1 of each year beginning with
16 1999) which shall include information and rec-
17 ommendations regarding national and international
18 drug policy issues, such as—

19 (A) trends and changes in prices for pre-
20 scription and nonprescription drugs in the inpa-
21 tient and outpatient setting in the United
22 States;

23 (B) trends and changes in prices for pre-
24 scription drugs in other industrialized nations,

1 such as Canada, Japan, Mexico, and countries
2 of the European Union;

3 (C) the scope of coverage, reimbursement,
4 and financing under titles XVIII and XIX of
5 the Social Security Act and other programs
6 that directly provide or receive Federal funds
7 to provide coverage for or reimbursement of
8 prescription drugs, such as the Department of
9 Veterans Affairs, the Department of Defense,
10 and Public Health Service clinics;

11 (D) the availability and affordability of
12 prescription drugs for various population
13 groups in the United States, and the accessibil-
14 ity and affordability of public and private insur-
15 ance programs for prescription drugs for such
16 population groups;

17 (E) changes in the level and nature of use
18 of prescription drugs by recipients of benefits
19 under titles XVIII and XIX of the Social Secu-
20 rity Act, taking into account the impact of such
21 changes on aggregate expenditures under these
22 titles;

23 (F) recommendations to make prescription
24 drugs more affordable and cost-effective for
25 third-party insurers, including State-based

1 pharmaceutical assistance and general assist-
2 ance programs;

3 (G) evaluation of technologies available for
4 efficient third-party prescription drug program
5 administration, such as electronic claims man-
6 agement and payment technologies;

7 (H) methods of providing reimbursement
8 under Federal health care programs to provid-
9 ers for drug products;

10 (I) evaluation of the use and efficiency of
11 all Federal tax credits and subsidies given to
12 the pharmaceutical industry for various pur-
13 poses, including the tax credit allowed under
14 section 936 of the Internal Revenue Code of
15 1986; and

16 (J) evaluation of the effect of direct mar-
17 keting on price, the volume of sales, and adver-
18 tising deductions.

19 (2) SPECIAL REPORT.—The Commission shall
20 submit to the Committee on Finance of the United
21 States Senate, the Committee on Commerce and the
22 Committee on Ways and Means of the House of
23 Representatives, and the Special Committee on
24 Aging of the United States Senate, by not later than

1 October 1, 1999, a report on the study conducted
2 under subsection (a)(4).

3 **SEC. 4. MEMBERSHIP.**

4 (a) NUMBER AND APPOINTMENT.—The Commission
5 shall be composed of 7 members appointed as follows:

6 (1) The President shall appoint three members.

7 (2) The Speaker of the House of Representa-
8 tives shall appoint one member.

9 (3) The minority leader of the House of Rep-
10 resentatives shall appoint one member.

11 (4) The majority leader of the Senate shall ap-
12 point one member.

13 (5) The minority leader of the Senate shall ap-
14 point one member.

15 (b) QUALIFICATIONS.—

16 (1) IN GENERAL.—The membership of the
17 Commission shall include the following:

18 (A) Individuals with national recognition
19 for their expertise in the provision and financ-
20 ing of inpatient and outpatient drugs and
21 biologicals.

22 (B) Individuals with national recognition
23 for their expertise in the fields of health care
24 economics and quality assurance, medicine,

1 pharmacology, pharmacy, and prescription drug
2 reimbursement.

3 (C) Other health care professionals.

4 (D) At least one individual who is an advo-
5 cate for medicare and medicaid recipients.

6 (2) LIMITATION.—No more than 2 individuals
7 who are, or have been, in the full- or part-time em-
8 ploy of a pharmaceutical company within one year
9 from the date of appointment under subsection (a)
10 may be appointed to the Commission at any time.

11 (c) CHAIRMAN.—The Chairman shall be elected by
12 the members.

13 (d) DEADLINE FOR APPOINTMENT.—Members of the
14 Commission shall be appointed not later than October 1,
15 1998.

16 (e) TERMS.—

17 (1) IN GENERAL.—Each member shall be ap-
18 pointed for the life of the Commission.

19 (2) VACANCIES.—A vacancy in the Commission
20 shall be filled in the manner in which the original
21 appointment was made.

22 (f) MEETINGS.—The Commission shall meet at the
23 call of the Chairperson or a majority of its members.

1 (g) QUORUM.—Four members of the Commission
2 shall constitute a quorum but a lesser number may hold
3 hearings.

4 (h) WAIVER OF LIMITATION ON EXECUTIVE SCHED-
5 ULE POSITIONS.—Appointments may be made under this
6 section without regard to the provisions of title 5, United
7 States Code, governing appointments in the competitive
8 service.

9 **SEC. 5. ADMINISTRATIVE PROVISIONS.**

10 (a) IN GENERAL.—The following provisions of sec-
11 tion 1805 of the Social Security Act (42 U.S.C. 1395b-
12 6) shall apply to the Commission in the same manner as
13 they apply to the Medicare Payment Advisory Commis-
14 sion:

15 (1) Subsection (c)(4) (relating to compensation
16 of members).

17 (2) Subsection (d) (relating to staffing and ad-
18 ministration).

19 (3) Subsection (e) (relating to powers of the
20 Commission generally).

21 (b) TECHNICAL ASSISTANCE.—Upon the request of
22 the Commission, the head of a Federal agency shall pro-
23 vide such technical assistance to the Commission as the
24 Commission determines to be necessary to carry out its
25 duties.

1 **SEC. 6. TERMINATION.**

2 The Commission shall terminate on October 1, 2003.

3 **SEC. 7. STUDY AND REPORT ON FEDERAL SUBSIDIES AND**
4 **INCENTIVES PROVIDED TO THE PHARMA-**
5 **CEUTICAL INDUSTRY.**

6 (a) STUDY.—The Secretary of Health and Human
7 Services, in consultation with Secretary of the Treasury,
8 shall conduct a study on Federal subsidies and incentives
9 provided to the pharmaceutical industry. Matters studied
10 shall include—

11 (1) a determination of the total cost over the 5
12 preceding fiscal years to Federal taxpayers of all
13 Federal subsidies provided to the pharmaceutical in-
14 dustry (including tax incentives, subsidies, grants,
15 and any other financial support);

16 (2)(A) the purposes for which such Federal
17 subsidies are used by the pharmaceutical industry;

18 (B) the Federal role in researching and develop-
19 ing patented pharmaceutical products and the extent
20 to which the Federal Government should co-license
21 certain drugs and biologicals;

22 (C) the extent to which pharmaceutical industry
23 marketing research costs are incorporated into al-
24 lowable Federal tax credits;

25 (D) comparable financial incentives, subsidies,
26 and tax credits provided to the pharmaceutical in-

1 industry by other industrialized nations and the use of
2 such incentives, subsidies, and credits by such indus-
3 try;

4 (E) the relationship between the total Federal
5 financial support provided to the pharmaceutical in-
6 dustry by the United States and other industrialized
7 nations and the prices paid by the citizens of such
8 respective nations for prescription drugs; and

9 (F) the extent to which tax credits provided by
10 the Federal Government subsidize total worldwide
11 pharmaceutical industry research and development;
12 and

13 (3) the relation of Federal tax credits to phar-
14 maceutical manufacturers and marketing exclusivity
15 for drug products to—

16 (A) an individual manufacturer's pricing
17 behavior in the marketplace; and

18 (B) the relative therapeutic value of new
19 pharmaceutical products researched, developed,
20 and marketed in the United States.

21 (b) REPORT.—Not later than July 1, 1999, the Sec-
22 retary of Health and Human Services, after consultation
23 with the Secretary of the Treasury, shall submit a report
24 to the Committee on Finance of the United States Senate,
25 the Committee on Commerce and the Committee on Ways

1 and Means of the United States House of Representatives,
2 and the Special Committee on Aging of the United States
3 Senate, on the study conducted under subsection (a), and
4 shall include such recommendations as the Secretary of
5 Health and Human Services deems appropriate.

6 **SEC. 8. MANUFACTURER INTERNATIONAL DRUG PRICE RE-**
7 **PORTING REQUIREMENTS.**

8 (a) IN GENERAL.—Subparagraph (A) of section
9 1927(b)(3) of the Social Security Act (42 U.S.C. 1396r–
10 8(b)(3)) is amended—

11 (1) by striking “and” at the end of clause (i),

12 (2) by striking the period at the end of clause

13 (ii) and inserting “, and”, and

14 (3) by adding at the end thereof the following
15 new clause:

16 “(iii) not later than 30 days after the
17 end of each calendar year, the average
18 price at which the manufacturer sold each
19 covered outpatient drug in such calendar
20 year in the following countries: Canada,
21 Australia, Mexico, and the countries of the
22 European Union.”.

1 (b) TECHNICAL AMENDMENT.—Clause (ii) of section
2 1927(b)(3)(A) of such Act (42 U.S.C. 1396r-8(b)(3)(A))
3 is amended by inserting a comma after “1990”.

○