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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

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A BILL

To establish the Prescription Drug Price Monitoring Commission.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This Act may be cited as the ''Prescription Drug Price Monitoring Commission Act of 1998''.

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

(1) Although prescription drugs represent one of the most frequently used medical care interventions in treating common acute and chronic diseases, many Americans, especially elderly and other vulnerable populations, are unable to afford necessary medications because of excessive and persistent prescription drug price inflation.

(2) Between 1981 and 1998, the rate of inflation for prescription drugs has increased at over 2.5 times the general rate of inflation.

(3) Because of the limited availability of private or public prescription drug coverage for the elderly, prescription drugs represent the highest out-of-pocket medical care cost for 75 percent of elderly patients, surpassed only by costs of long-term care services.

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

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

deductions for advertising and marketing of their products.

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

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

(8) There is a need to determine whether Federal subsidies are used in the most efficient manner by the pharmaceutical industry to develop drugs which represent true therapeutic advances over those products already on the market.

SEC. 2. ESTABLISHMENT.

There is established a commission to be known as the ''Prescription Drug Price Monitoring Commission'' (in this Act referred to as the ''Commission'').

SEC. 3. DUTIES OF COMMISSION.

(a) STUDIES.—The Commission shall conduct the following studies:

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

(2) A study on how Federal tax credits and subsidies, as well as market exclusivity given to the pharmaceutical industry, can be used to modify an individual manufacturer's pricing behavior and research priorities.

(3) A study on drug prices in other industrialized nations.

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

(B) In conducting the study under subparagraph (A), the Commission shall—

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

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

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

(iv) recommend incentives for drug manufacturers to price their products fairly in the United States, including a system of compulsory licensing of pharmaceutical products or a reduction in the period of market exclusivity as a penalty for excessive inflation.

(b) REPORTS.—

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

(A) trends and changes in prices for prescription and nonprescription drugs in the inpatient and outpatient setting in the United States;

(B) trends and changes in prices for prescription drugs in other industrialized nations,

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

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

(D) the availability and affordability of prescription drugs for various population groups in the United States, and the accessibility and affordability of public and private insurance programs for prescription drugs for such population groups;

(E) changes in the level and nature of use of prescription drugs by recipients of benefits under titles XVIII and XIX of the Social Security Act, taking into account the impact of such changes on aggregate expenditures under these titles;

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

pharmaceutical assistance and general assistance programs;

(G) evaluation of technologies available for efficient third-party prescription drug program administration, such as electronic claims management and payment technologies;

(H) methods of providing reimbursement under Federal health care programs to providers for drug products;

(I) evaluation of the use and efficiency of all Federal tax credits and subsidies given to the pharmaceutical industry for various purposes, including the tax credit allowed under section 936 of the Internal Revenue Code of 1986; and

(J) evaluation of the effect of direct marketing on price, the volume of sales, and advertising deductions.

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

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

SEC. 4. MEMBERSHIP.

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

(1) The President shall appoint three members.

(2) The Speaker of the House of Representatives shall appoint one member.

(3) The minority leader of the House of Representatives shall appoint one member.

(4) The majority leader of the Senate shall appoint one member.

(5) The minority leader of the Senate shall appoint one member.

(b) QUALIFICATIONS.—

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

(A) Individuals with national recognition for their expertise in the provision and financing of inpatient and outpatient drugs and biologicals.

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

pharmacology, pharmacy, and prescription drug reimbursement.

(C) Other health care professionals.

(D) At least one individual who is an advocate for medicare and medicaid recipients.

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

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

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

(e) TERMS.—

(1) IN GENERAL.—Each member shall be appointed for the life of the Commission.

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

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

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

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

SEC. 5. ADMINISTRATIVE PROVISIONS.

(a) IN GENERAL.—The following provisions of section 1805 of the Social Security Act (42 U.S.C. 1395b–6) shall apply to the Commission in the same manner as they apply to the Medicare Payment Advisory Commission:

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

(2) Subsection (d) (relating to staffing and administration).

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

(b) TECHNICAL ASSISTANCE.—Upon the request of the Commission, the head of a Federal agency shall provide such technical assistance to the Commission as the Commission determines to be necessary to carry out its duties.

SEC. 6. TERMINATION.

The Commission shall terminate on October 1, 2003.

SEC. 7. STUDY AND REPORT ON FEDERAL SUBSIDIES AND INCENTIVES PROVIDED TO THE PHARMACEUTICAL INDUSTRY.

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

(1) a determination of the total cost over the 5 preceding fiscal years to Federal taxpayers of all Federal subsidies provided to the pharmaceutical industry (including tax incentives, subsidies, grants, and any other financial support);

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

(B) the Federal role in researching and developing patented pharmaceutical products and the extent to which the Federal Government should co-license certain drugs and biologicals;

(C) the extent to which pharmaceutical industry marketing research costs are incorporated into allowable Federal tax credits;

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

dustry by other industrialized nations and the use of such incentives, subsidies, and credits by such industry;

(E) the relationship between the total Federal financial support provided to the pharmaceutical industry by the United States and other industrialized nations and the prices paid by the citizens of such respective nations for prescription drugs; and

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

(3) the relation of Federal tax credits to pharmaceutical manufacturers and marketing exclusivity for drug products to—

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

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

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

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

SEC. 8. MANUFACTURER INTERNATIONAL DRUG PRICE REPORTING REQUIREMENTS.

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

(1) by striking ''and'' at the end of clause (i),

(2) by striking the period at the end of clause (ii) and inserting '', and'', and

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

''(iii) not later than 30 days after the end of each calendar year, the average price at which the manufacturer sold each covered outpatient drug in such calendar year in the following countries: Canada, Australia, Mexico, and the countries of the European Union.''.

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

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