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108TH CONGRESS
1ST SESSION

H. R. 1400

To provide for substantial reductions in the price of prescription drugs for Medicare beneficiaries.

IN THE HOUSE OF REPRESENTATIVES

MARCH 20, 2003

Mr. ALLEN (for himself, Mr. BROWN of Ohio, Mr. BERRY, Ms. SCHAKOWSKY, Mr. CONYERS, Ms. ROYBAL-ALLARD, Mr. STARK, Ms. CORRINE BROWN of Florida, Mr. SERRANO, Mr. WAXMAN, Mr. KLECZKA, Mr. PALLONE, Mrs. MCCARTHY of New York, Ms. NORTON, Mr. KENNEDY of Rhode Island, Mr. HINCHEY, Mr. PASTOR, Mr. CASE, Ms. WOOLSEY, Mr. GREEN of Texas, Mrs. MALONEY, Mr. OBERSTAR, Mr. FROST, Mr. WEXLER, Mr. SABO, Mr. NADLER, Mr. MCNULTY, Mr. MICHAUD, and Mr. KUCINICH) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 provide for substantial reductions in the price of prescription drugs for Medicare beneficiaries.

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 Fairness for Seniors Act of 2003''.

SEC. 2. FINDINGS AND PURPOSES.

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

(1) Manufacturers of prescription drugs engage in price discrimination practices that compel many older Americans to pay substantially more for prescription drugs than consumers in foreign nations and the drug manufacturers' most favored U.S. customers, such as health insurers, health maintenance organizations, and the Federal Government.

(2) Older Americans who buy their own prescription drugs often pay twice as much for prescription drugs as consumers in foreign nations and the drug manufacturers' most favored U.S. customers. In some cases, older Americans pay 10 times more for prescription drugs than such customers.

(3) The discriminatory pricing by major drug manufacturers sustains their high profits (for example, $27,300,000,000 in 1999), but causes financial hardship and impairs the health and well-being of millions of older Americans. Many older Americans are forced to choose between buying their food and buying their medicines.

(4) Foreign nations and U.S. federally funded health care programs use purchasing power to obtain prescription drugs at low prices. Medicare beneficiaries are denied this benefit and cannot obtain

their prescription drugs at the lower prices available to such nations and programs.

(5) Implementation of the policy set forth in this Act will reduce prices for brand name prescription drugs for many Medicare beneficiaries by an average of 40 percent.

(6) In addition to substantially lowering the costs of prescription drugs for older Americans, implementation of the policy set forth in this Act will significantly improve the health and well-being of older Americans and lower the costs to the Federal taxpayer of the Medicare program.

(7) Older Americans who are terminally ill and receiving hospice care services represent some of the most vulnerable individuals in our nation. Making prescription drugs available to Medicare beneficiaries under the care of Medicare-certified hospices will assist in extending the benefits of lower prescription drug prices to those most vulnerable and in need.

(b) PURPOSE.—The purpose of this Act is to protect Medicare beneficiaries from discriminatory pricing by drug manufacturers and to make prescription drugs available to Medicare beneficiaries at substantially reduced prices.

SEC. 3. PARTICIPATING MANUFACTURERS.

(a) IN GENERAL.—Each participating manufacturer of a covered outpatient drug shall make available for purchase by each pharmacy such covered outpatient drug in the amount described in subsection (b) at the price described in subsection (c).

(b) DESCRIPTION OF AMOUNT OF DRUGS.—The amount of a covered outpatient drug that a participating manufacturer shall make available for purchase by a pharmacy is an amount equal to the aggregate amount of the covered outpatient drug sold or distributed by the pharmacy to Medicare beneficiaries.

(c) DESCRIPTION OF PRICE.—The price at which a participating manufacturer shall make a covered outpatient drug available for purchase by a pharmacy is a price no greater than the manufacturer's average foreign price.

(d) ENFORCEMENT.—The United States shall debar a manufacturer of drugs or biologicals that does not comply with the provisions of this Act.

SEC. 4. SPECIAL PROVISION WITH RESPECT TO HOSPICE PROGRAMS.

For purposes of determining the amount of a covered outpatient drug that a participating manufacturer shall make available for purchase by a pharmacy under section 3, there shall be included in the calculation of such

amount the amount of the covered outpatient drug sold or distributed by a pharmacy to a hospice program. In calculating such amount, only amounts of the covered outpatient drug furnished to a Medicare beneficiary enrolled in the hospice program shall be included.

SEC. 5. ADMINISTRATION.

The Secretary shall issue such regulations as may be necessary to implement this Act.

SEC. 6. REPORTS TO CONGRESS REGARDING EFFECTIVENESS OF ACT.

(a) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, and annually thereafter, the Secretary shall report to the Congress regarding the effectiveness of this Act in—

(1) protecting Medicare beneficiaries from discriminatory pricing by drug manufacturers, and

(2) making prescription drugs available to Medicare beneficiaries at substantially reduced prices.

(b) CONSULTATION.—In preparing such reports, the Secretary shall consult with public health experts, affected industries, organizations representing consumers and older Americans, and other interested persons.

(c) RECOMMENDATIONS.—The Secretary shall include in such reports any recommendations the Secretary

considers appropriate for changes in this Act to further reduce the cost of covered outpatient drugs to Medicare beneficiaries.

SEC. 7. DEFINITIONS.

In this Act:

(1) AVERAGE FOREIGN PRICE.—

(A) IN GENERAL.—The term ''average foreign price'' means, with respect to a covered outpatient drug, the average price that the manufacturer of the drug realizes on the sale of drugs with the same active ingredient or ingredients that are consumed in covered foreign nations, taking into account—

(i) any rebate, contract term or condition, or other arrangement (whether with the purchaser or other persons) that has the effect of reducing the amount realized by the manufacturer on the sale of the drugs; and

(ii) adjustments for any differences in dosage, formulation, or other relevant characteristics of the drugs.

(B) EXEMPT TRANSACTIONS.—The Secretary may, by regulation, exempt from the calculation of the average foreign price of a drug

those prices realized by a manufacturer in transactions that are entered into for charitable purposes, for research purposes, or under other unusual circumstances, if the Secretary determines that the exemption is in the public interest and is consistent with the purposes of this Act.

(2) COVERED FOREIGN NATION.—The term ''covered foreign nation' means Canada, France, Germany, Italy, Japan, and the United Kingdom.

(3) COVERED OUTPATIENT DRUG.—The term ''covered outpatient drug'' has the meaning given that term in section 1927(k)(2) of the Social Security Act (42 U.S.C. 1396r–8(k)(2)).

(4) DEBAR.—The term ''debar'' means to exclude, pursuant to established administrative procedures, from Government contracting and subcontracting for a specified period of time commensurate with the seriousness of the failure or offense or the inadequacy of performance.

(5) HOSPICE PROGRAM.—The term ''hospice program'' has the meaning given that term under section 1861(dd)(2) of the Social Security Act (42 U.S.C. 1395x(dd)(2)).

(6) MEDICARE BENEFICIARY.—The term ''Medicare beneficiary'' means an individual entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title, or both.

(7) PARTICIPATING MANUFACTURER.—The term ''participating manufacturer'' means any manufacturer of drugs or biologicals that, on or after the date of the enactment of this Act, enters into a contract or agreement with the United States for the sale or distribution of covered outpatient drugs to the United States.

(8) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 8. EFFECTIVE DATE.

The Secretary shall implement this Act as expeditiously as practicable and in a manner consistent with the obligations of the United States.

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