107TH 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

April 4, 2001

Mr. Allen (for himself, Mr. Waxman, Mr. Stark, Mr. Berry, Mr. Bonior, Mr. FROST, Mr. OBEY, Mrs. THURMAN, Mr. DOGGETT, Mr. BROWN of Ohio, Mr. GREEN of Texas, Ms. DELAURO, Mr. PALLONE, Mr. SHOWS, Mr. SANDERS, Ms. SCHAKOWSKY, Mr. CROWLEY, Mr. HINCHEY, Mr. BALDACCI, Mr. ABERCROMBIE, Mr. ANDREWS, Mr. BACA, Mr. BAIRD, Ms. BALDWIN, Mr. BARRETT, Ms. BERKLEY, Mr. BLAGOJEVICH, Mr. BLUMENAUER, Mr. BORSKI, Mr. BOYD, Mr. BRADY of Pennsylvania, Ms. BROWN of Florida, Ms. CARSON of Indiana, Mrs. CLAYTON, Mr. CLEM-ENT, Mr. CONYERS, Mr. CUMMINGS, Mr. DAVIS of Illinois, Mr. DEFAZIO, Ms. DEGETTE, Mr. DELAHUNT, Mr. EVANS, Mr. FALEOMAVAEGA, Mr. FILNER, Mr. HASTINGS of Florida, Ms. HOOLEY of Oregon, Ms. JACK-SON-LEE of Texas, Mr. JEFFERSON, Mrs. JONES of Ohio, Ms. KAPTUR, Mr. KENNEDY of Rhode Island, Mr. KILDEE, Mr. KLECZKA, Mr. KUCINICH, Mr. LAMPSON, Mr. LANTOS, Mr. LARSON of Connecticut, Ms. LEE, Mr. LEWIS of Georgia, Mrs. LOWEY, Mrs. MCCARTHY of New York, Ms. McCollum, Mr. McGovern, Ms. McKinney, Mr. McNulty, Mrs. MALONEY of New York, Mr. MARKEY, Mr. MASCARA, Mr. MEEHAN, Mrs. MEEK of Florida, Mr. MEEKS of New York, Ms. MILLENDER-MCDON-ALD, Mr. GEORGE MILLER of California, Mrs. MINK of Hawaii, Mr. MOAKLEY, Mr. NADLER, Mrs. NAPOLITANO, Ms. NORTON, Mr. OBER-STAR, Mr. OLVER, Mr. ORTIZ, Mr. OWENS, Mr. PASTOR, Mr. PAYNE, Ms. PELOSI, Mr. PHELPS, Mr. POMEROY, Mr. RAHALL, Mr. REYES, Ms. RIV-ERS, MS. ROYBAL-ALLARD, Mr. SANDLIN, Mr. SAYWER, Mr. SERRANO, Ms. SLAUGHTER, Mr. STRICKLAND, Mr. STUPAK, Mr. THOMPSON of Mississippi, Mr. TIERNEY, Mr. UDALL of New Mexico, Mr. UNDERWOOD, Ms. VELÁZQUEZ, Ms. WATERS, Mr. WEINER, Mr. WEXLER, Ms. WOOL-SEY, and Mr. WYNN) 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

A BILL

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

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 Drug5 Fairness for Seniors Act of 2001".

6 SEC. 2. FINDINGS AND PURPOSES.

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

8 (1) Manufacturers of prescription drugs engage 9 in price discrimination practices that compel many 10 older Americans to pay substantially more for pre-11 scription drugs than consumers in foreign nations 12 and the drug manufacturers' most favored U.S. cus-13 tomers, such as health insurers, health maintenance 14 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.

21 (3) The discriminatory pricing by major drug
22 manufacturers sustains their high profits (for exam-

ple, \$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.

6 (4) Foreign nations and U.S. federally funded 7 health care programs use purchasing power to ob-8 tain prescription drugs at low prices. Medicare bene-9 ficiaries are denied this benefit and cannot obtain 10 their prescription drugs at the lower prices available 11 to such nations and programs.

12 (5) Implementation of the policy set forth in
13 this Act will reduce prices for brand name prescrip14 tion drugs for many Medicare beneficiaries by an av15 erage of 40 percent.

16 (6) In addition to substantially lowering the
17 costs of prescription drugs for older Americans, im18 plementation of the policy set forth in this Act will
19 significantly improve the health and well-being of
20 older Americans and lower the costs to the Federal
21 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 as sist in extending the benefits of lower prescription
 drug prices to those most vulnerable and in need.

4 (b) PURPOSE.—The purpose of this Act is to protect
5 Medicare beneficiaries from discriminatory pricing by drug
6 manufacturers and to make prescription drugs available
7 to Medicare beneficiaries at substantially reduced prices.
8 SEC. 3. PARTICIPATING MANUFACTURERS.

9 (a) IN GENERAL.—Each participating manufacturer 10 of a covered outpatient drug shall make available for pur-11 chase by each pharmacy such covered outpatient drug in 12 the amount described in subsection (b) at the price de-13 scribed 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.

20 (c) DESCRIPTION OF PRICE.—The price at which a
21 participating manufacturer shall make a covered out22 patient drug available for purchase by a pharmacy is a
23 price no greater than the manufacturer's average foreign
24 price.

1 (d) ENFORCEMENT.—The United States shall debar 2 a manufacturer of drugs or biologicals that does not com-3 ply with the provisions of this Act.

4 SEC. 4. SPECIAL PROVISION WITH RESPECT TO HOSPICE 5 PROGRAMS.

6 For purposes of determining the amount of a covered 7 outpatient drug that a participating manufacturer shall 8 make available for purchase by a pharmacy under section 9 3, there shall be included in the calculation of such 10 amount the amount of the covered outpatient drug sold or distributed by a pharmacy to a hospice program. In 11 12 calculating such amount, only amounts of the covered out-13 patient drug furnished to a Medicare beneficiary enrolled in the hospice program shall be included. 14

15 **SEC. 5. ADMINISTRATION.**

16 The Secretary shall issue such regulations as may be 17 necessary to implement this Act.

18 SEC. 6. REPORTS TO CONGRESS REGARDING EFFECTIVE-19

NESS OF ACT.

20 (a) IN GENERAL.—Not later than 2 years after the 21 date of the enactment of this Act, and annually thereafter, 22 the Secretary shall report to the Congress regarding the 23 effectiveness of this Act in—

24 (1) protecting Medicare beneficiaries from dis-25 criminatory pricing by drug manufacturers, and

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

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

8 (c) RECOMMENDATIONS.—The Secretary shall in-9 clude in such reports any recommendations the Secretary 10 considers appropriate for changes in this Act to further 11 reduce the cost of covered outpatient drugs to Medicare 12 beneficiaries.

13 SEC. 7. DEFINITIONS.

14 In this Act:

15 (1) AVERAGE FOREIGN PRICE.—

16 (A) IN GENERAL.—The term "average for-17 eign price" means, with respect to a covered 18 outpatient drug, the average price that the 19 manufacturer of the drug realizes on the sale of 20 drugs with the same active ingredient or ingre-21 dients that are consumed in covered foreign na-22 tions, taking into account—

(i) any rebate, contract term or condition, or other arrangement (whether with
the purchaser or other persons) that has

1	the effect of reducing the amount realized
2	by the manufacturer on the sale of the
3	drugs; and
4	(ii) adjustments for any differences in
5	dosage, formulation, or other relevant
6	characteristics of the drugs.
7	(B) EXEMPT TRANSACTIONS.—The Sec-
8	retary may, by regulation, exempt from the cal-
9	culation of the average foreign price of a drug
10	those prices realized by a manufacturer in
11	transactions that are entered into for charitable
12	purposes, for research purposes, or under other
13	unusual circumstances, if the Secretary deter-
14	mines that the exemption is in the public inter-
15	est and is consistent with the purposes of this
16	Act.
17	(2) COVERED FOREIGN NATION.—The term
18	"covered foreign nation' means Canada, France,
19	Germany, Italy, Japan, and the United Kingdom.
20	(3) COVERED OUTPATIENT DRUG.—The term
21	"covered outpatient drug" has the meaning given
22	that term in section $1927(k)(2)$ of the Social Secu-
23	rity Act (42 U.S.C. 1396r-8(k)(2)).
24	(4) DEBAR.—The term "debar" means to ex-
25	clude, pursuant to established administrative proce-

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dures, from Government contracting and subcon tracting for a specified period of time commensurate
 with the seriousness of the failure or offense or the
 inadequacy of performance.

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

9 (6) MEDICARE BENEFICIARY.—The term 10 "Medicare beneficiary" means an individual entitled 11 to benefits under part A of title XVIII of the Social 12 Security Act or enrolled under part B of such title, 13 or both.

14 (7)PARTICIPATING MANUFACTURER.—The 15 term "participating manufacturer" means any man-16 ufacturer of drugs or biologicals that, on or after the 17 date of the enactment of this Act, enters into a con-18 tract or agreement with the United States for the 19 sale or distribution of covered outpatient drugs to 20 the United States.

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

1 SEC. 8. EFFECTIVE DATE.

2 The Secretary shall implement this Act as expedi-3 tiously as practicable and in a manner consistent with the4 obligations of the United States.

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