

108TH CONGRESS
2D SESSION

H. R. 4899

To amend the Public Health Service Act and the Internal Revenue Code of 1986 to require agreements regarding the wholesale price of brand-name prescription drugs as a condition of the allowance of certain tax deductions and credits.

IN THE HOUSE OF REPRESENTATIVES

JULY 22, 2004

Mr. BROWN of Ohio 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

To amend the Public Health Service Act and the Internal Revenue Code of 1986 to require agreements regarding the wholesale price of brand-name prescription drugs as a condition of the allowance of certain tax deductions and credits.

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 “Sustainable Drug Pric-
5 ing Act”.

1 **SEC. 2. AGREEMENTS REGARDING PRICES OF BRAND-NAME**
 2 **PRESCRIPTION DRUGS; RELATION TO CER-**
 3 **TAIN TAX DEDUCTIONS AND CREDITS.**

4 Part D of title III of the Public Health Service Act
 5 (42 U.S.C. 254b et seq.) is amended by adding at the end
 6 the following subpart:

7 **“Subpart XI—Sustainable Drug Pricing**

8 **“SEC. 340H. AGREEMENTS REGARDING PRICES OF BRAND-**
 9 **NAME PRESCRIPTION DRUGS; RELATION TO**
 10 **CERTAIN TAX DEDUCTIONS AND CREDITS.**

11 **“(a) IN GENERAL.—**

12 **“(1) AGREEMENT.—**The Secretary may in ac-
 13 cordance with this section enter into an agreement
 14 with any manufacturer of a brand-name prescription
 15 drug for purposes of—

16 **“(A)** section 280I of the Internal Revenue
 17 Code of 1986 (relating to the allowance of a de-
 18 duction for expenditures relating to the adver-
 19 tising, promoting, or marketing of such drug);
 20 and

21 **“(B)** section 901(l) of such Code (relating
 22 to the allowance of a foreign tax credit for in-
 23 come, war profits, or excess profits taxes paid
 24 or accrued with respect to such drug).

25 **“(2) COORDINATION WITH TAX PROVISIONS.—**

26 For purposes of the provisions of the Internal Rev-

1 enue Code of 1986 referred to in paragraph (1), an
2 agreement under this section shall be considered to
3 be in effect with respect to a brand-name prescrip-
4 tion drug unless the Secretary transmits to the Sec-
5 retary of the Treasury a notice in writing that such
6 an agreement is not in effect.

7 “(3) NEGOTIATIONS.—The Secretary shall ne-
8 gotiate with any manufacturer of a brand-name pre-
9 scription drug that in good faith seeks an agreement
10 under paragraph (1), and shall make reasonable ef-
11 forts to enter into such an agreement with the man-
12 ufacturer.

13 “(b) PUBLIC HEALTH OBJECTIVES OF AGREE-
14 MENT.—The purpose of an agreement under subsection
15 (a) regarding a drug is to establish the maximum price
16 at which the drug may be sold at wholesale under the
17 agreement, reasonably taking into account—

18 “(1) the affordability of the drug in relation to
19 the public-health need for the drug; and

20 “(2) the need for the manufacturer to invest in
21 research and development activities toward the de-
22 velopment of new drugs that will benefit the public
23 health.

24 “(c) DURATION OF AGREEMENT; RENEGOTIATION.—

1 “(1) IN GENERAL.—With respect to taxable
2 years of a manufacturer, the Secretary may enter
3 into an agreement under subsection (a) regarding a
4 drug only if the agreement contains provisions in ac-
5 cordance with the following:

6 “(A) In the case of the agreement as first
7 in effect, the agreement will be in effect for not
8 fewer than four successive taxable years.

9 “(B) In the case of taxable years following
10 such four taxable years, the agreement may be
11 periodically renegotiated at the initiative of the
12 manufacturer or the Secretary, except that any
13 agreement that takes effect pursuant to such a
14 renegotiation will remain in effect for not fewer
15 than four taxable years.

16 “(C) Each agreement will apply to the en-
17 tirety of the taxable years with which the agree-
18 ment is concerned, except that in the case of
19 the taxable year during which the drug first en-
20 ters the commercial market, the applicability of
21 the agreement will begin on the date during the
22 taxable year on which commercial marketing of
23 the drug begins.

24 “(2) VARIATION IN MAXIMUM PRICE UNDER
25 AGREEMENT.—With respect to the maximum price

1 established for a drug under an agreement under
2 subsection (a), this section may not be construed as
3 requiring that the agreement provide that a single
4 maximum price be in effect throughout the taxable
5 years with which the agreement is concerned. The
6 maximum price may vary under the agreement ac-
7 cording to the terms of the agreement.

8 “(d) VIOLATION OF AGREEMENT; LIQUIDATED PEN-
9 ALTY.—

10 “(1) IN GENERAL.—The Secretary may enter
11 into an agreement under subsection (a) regarding a
12 drug only if—

13 “(A) the agreement specifies the amount
14 that, as a liquidated penalty, the Secretary may
15 require the manufacturer involved to pay to the
16 United States for failing to maintain substan-
17 tial compliance with the agreement; and

18 “(B) such amount is sufficient to deter
19 violations of the agreement.

20 “(2) HEARING; LOSS OF EFFECTIVE STATUS OF
21 AGREEMENT.—

22 “(A) HEARING.—If, after providing notice
23 and an opportunity for a hearing, the Secretary
24 determines that a manufacturer has failed to
25 maintain substantial compliance with the agree-

1 ment under subsection (a), the Secretary shall
2 order the manufacturer—

3 “(i) to pay to the United States an
4 amount as a penalty for such failure,
5 which amount does not exceed the amount
6 specified under paragraph (1)(A) as a liq-
7 uidated penalty; and

8 “(ii) to take appropriate action to
9 bring the manufacturer into compliance
10 with the agreement.

11 “(B) LOSS OF EFFECTIVE STATUS.—If a
12 manufacturer fails to comply with an order
13 under subparagraph (A), the Secretary may
14 transmit to the Secretary of the Treasury a no-
15 tice in writing that an agreement under this
16 section is not in effect with respect to the
17 brand-name prescription drug involved.

18 “(e) GENERAL PROVISIONS.—

19 “(1) INDIVIDUAL DRUG AGREEMENTS.—The
20 Secretary shall ensure that each agreement under
21 subsection (a) concerns only one brand-name pre-
22 scription drug.

23 “(2) MONITORING OF COMPLIANCE.—With re-
24 spect to brand-name prescription drugs for which
25 agreements under subsection (a) are in effect, the

1 Secretary shall monitor the prices at which such
2 drugs are being sold and determine whether the
3 manufacturers involved are in compliance with the
4 agreements. The Secretary may require, as a condi-
5 tion of a entering into an agreement under sub-
6 section (a) with a manufacturer, that the agreement
7 include provisions regarding the cooperation of the
8 manufacturer with such monitoring of prices.

9 “(3) ACCESS TO RECORDS.—The Secretary may
10 require, as a condition of a entering into an agree-
11 ment under subsection (a) with a manufacturer, that
12 the manufacturer provide the Secretary, during ne-
13 gotiations and after the agreement is made, with ac-
14 cess to financial records of the manufacturer that
15 relate to the brand-name prescription drug involved.

16 “(4) CONSIDERATION OF COMPLIANCE
17 RECORD.—In determining to what extent to estab-
18 lish requirements under paragraphs (2) and (3) with
19 respect to an agreement under subsection (a) with a
20 manufacturer, the Secretary shall take into account
21 whether the manufacturer has maintained substan-
22 tial compliance with any other agreements under
23 such subsection that have been made by the manu-
24 facturer.

1 “(f) ADVISORY PANEL ON DRUG-PRICE NEGOTIA-
2 TIONS.—

3 “(1) IN GENERAL.—The Secretary shall estab-
4 lish an advisory panel to be known as the Advisory
5 Panel on Drug-Price Negotiations (in this subsection
6 referred to as the ‘Advisory Panel’).

7 “(2) DUTIES.—The Advisory Panel shall pro-
8 vide advice to the Secretary on establishing prices
9 for the sale of brand-name prescription drugs at
10 wholesale under agreements under subsection (a).
11 Not later than one year after the date on which the
12 initial appointments to the Advisory Panel under
13 paragraph (3) are completed, the Panel shall—

14 “(A) select, from brand-name prescription
15 drugs in commercial distribution as of the date
16 of the enactment of the Sustainable Drug Pric-
17 ing Act—

18 “(i) a list of 25 drugs that the Panel
19 considers important to the public health;
20 and

21 “(ii) a list of the 25 most commonly
22 prescribed drugs in the United States, ex-
23 clusive of drugs included on the list under
24 clause (i); and

1 “(B) submit to the Secretary the rec-
2 ommendations of the Panel with respect to such
3 prices for drugs on the lists.

4 “(3) COMPOSITION.—The Advisory Panel shall
5 be composed of five members appointed by the Sec-
6 retary from among individuals who are not officers
7 or employees of the Federal Government. Of such
8 members—

9 “(A) one shall be a representative of the
10 pharmaceutical industry;

11 “(B) one shall be a representative of retail
12 consumers generally;

13 “(C) one shall be a representative of retail
14 consumers who are members of racial or ethnic
15 minority groups;

16 “(D) one shall be an academic with exper-
17 tise in health care economics; and

18 “(E) one shall be an academic with exper-
19 tise in public health.

20 The Secretary shall appoint the initial members of
21 the Advisory Panel not later than 180 days after the
22 date of the enactment of the Sustainable Drug Pric-
23 ing Act.

1 “(4) CHAIR.—The Advisory Panel shall select,
2 by recorded vote, a member of the Panel to serve as
3 the chair of the Panel.

4 “(5) TERMS.—

5 “(A) IN GENERAL.—Each member of the
6 Advisory Panel shall be appointed for a term of
7 four years, except that the term of each of the
8 initial members expires December 31, 2007.

9 “(B) SERVICE AFTER EXPIRATION OF
10 TERM.—A member of the Advisory Panel may
11 continue to serve after the expiration of the
12 term of the member until a successor is ap-
13 pointed.

14 “(6) VACANCIES.—

15 “(A) AUTHORITY OF ADVISORY PANEL.—A
16 vacancy in the membership of the Advisory
17 Panel does not affect the power of the remain-
18 ing members to carry out the duties of the
19 Panel.

20 “(B) APPOINTMENT OF SUCCESSORS.—A
21 vacancy in the membership of the Advisory
22 Panel shall be filled in the manner in which the
23 original appointment was made.

24 “(C) INCOMPLETE TERM.—If a member of
25 the Advisory Panel does not serve the full term

1 under paragraph (5)(A), the Secretary, not
2 later than 30 days after the date on which the
3 vacancy occurs, shall appoint an individual to
4 serve as a member of the Advisory Panel for
5 the remainder of such term.

6 “(g) DEFINITIONS.—For purposes of this section:

7 “(1) The term ‘brand-name prescription drug’
8 means a drug meeting each of the following criteria:

9 “(A) An approved application under sec-
10 tion 505(b)(1) of the Federal Food, Drug, and
11 Cosmetic Act is in effect for the drug, or in the
12 case of a drug that is a biological product, a
13 biologics license is in effect for the drug under
14 section 351 of this Act.

15 “(B) The drug is subject to section
16 503(b)(1) of the Federal Food, Drug, and Cos-
17 metic Act.

18 “(C) A period of market exclusivity is in
19 effect with respect to the drug pursuant to a
20 patent or pursuant to section 505(j) or 505A of
21 such Act.

22 “(2) The term ‘drug’ has the meaning given
23 such term in section 201(g)(1) of such Act.”.

1 **SEC. 3. DENIAL OF CERTAIN TAX BENEFITS UNLESS UN-**
2 **LESS PRICING AGREEMENT FOR BRAND-**
3 **NAME PRESCRIPTION DRUGS IS IN EFFECT.**

4 (a) DEDUCTIONS FOR ADVERTISING.—

5 (1) IN GENERAL.—Part IX of subchapter B of
6 chapter 1 of subtitle A of the Internal Revenue Code
7 of 1986 (relating to items not deductible) is amend-
8 ed by adding at the end the following:

9 **“SEC. 280I. DENIAL OF DEDUCTIONS FOR ADVERTISING**
10 **FOR BRAND-NAME PRESCRIPTION DRUGS UN-**
11 **LESS PRICING AGREEMENT IS IN EFFECT.**

12 “(a) IN GENERAL.—No deduction shall be allowed
13 under this chapter for any taxable year for any expendi-
14 ture relating to the advertising, promoting, or marketing
15 (in any medium) of any brand-name prescription drug
16 manufactured by the taxpayer.

17 “(b) EXCEPTION FOR QUALIFIED PRICING AGREE-
18 MENT.—

19 “(1) IN GENERAL.—Subsection (a) shall not
20 apply with respect to any brand-name prescription
21 drug for a taxable year if there is in effect for the
22 entire taxable year a qualified pricing agreement
23 with respect to such drug.

24 “(2) SPECIAL RULE REGARDING INITIAL COM-
25 Mercial MARKETING.—In the case of the taxable
26 year during which a brand-name prescription drug

1 first enters the commercial market, subsection (a)
 2 shall not apply with respect to such drug for such
 3 taxable year if a qualified pricing agreement with re-
 4 spect to the drug is in effect on the date of such
 5 entry and remains in effect throughout the remain-
 6 der of such year.

7 “(c) DEFINITIONS.—For purposes of this section—

8 “(1) QUALIFIED PRICING AGREEMENT.—The
 9 term ‘qualified pricing agreement’ means an agree-
 10 ment entered into under section 340H of the Public
 11 Health Service Act.

12 “(2) BRAND-NAME PRESCRIPTION DRUG.—The
 13 term ‘brand-name prescription drug’ has the mean-
 14 ing given such term in section 340H of the Public
 15 Health Service Act.

16 “(d) AGGREGATION RULES.—For purposes of this
 17 section, all members of the same controlled group of cor-
 18 porations (within the meaning of section 52(a)) and all
 19 persons under common control (within the meaning of sec-
 20 tion 52(b)) shall be treated as 1 person.”.

21 (2) CLERICAL AMENDMENT.—The table of sec-
 22 tions for such part IX is amended by adding after
 23 the item relating to section 280H the following:

“280I. Denial of deductions for advertising for brand-name prescription drugs
 unless pricing agreement is in effect.”.

1 (b) FOREIGN TAX CREDIT.—Section 901 of such
 2 Code (relating to taxes of foreign countries and of posses-
 3 sions of United States) is amended by redesignating sub-
 4 section (l) as subsection (m) and by inserting after sub-
 5 section (k) the following new subsection:

6 “(l) DENIAL OF FOREIGN TAX CREDIT, ETC. WITH
 7 RESPECT TO BRAND-NAME PRESCRIPTION DRUGS UN-
 8 LESS PRICING AGREEMENT IS IN EFFECT.—

9 “(1) IN GENERAL.—Notwithstanding any other
 10 provision of this part, no credit shall be allowed
 11 under subsection (a) for any income, war profits, or
 12 excess profits taxes paid or accrued (or deemed paid
 13 under section 902 or 960) with respect to any
 14 brand-name prescription drug manufactured by the
 15 taxpayer.

16 “(2) EXCEPTION FOR QUALIFIED PRICING
 17 AGREEMENT.—

18 “(A) IN GENERAL.—Paragraph (1) shall
 19 not apply with respect to any brand-name pre-
 20 scription drug for a taxable year if there is in
 21 effect for the entire taxable year a qualified
 22 pricing agreement with respect to such drug.

23 “(B) SPECIAL RULE REGARDING INITIAL
 24 COMMERCIAL MARKETING.—In the case of the
 25 taxable year during which a brand-name pre-

1 scription drug first enters the commercial mar-
2 ket, paragraph (1) shall not apply with respect
3 to such drug for such taxable year if a qualified
4 pricing agreement with respect to the drug is in
5 effect on the date of such entry and remains in
6 effect throughout the remainder of such year.

7 “(3) DEFINITIONS.—For purposes of this sub-
8 section, the terms ‘qualified pricing agreement’ and
9 ‘brand-name prescription drug’ have the meanings
10 given such terms by section 280I.

11 “(4) AGGREGATION RULES.—For purposes of
12 this subsection, a rule similar to the rule of section
13 280I(d) shall apply. ”.

14 (c) EFFECTIVE DATE.—The amendments made by
15 this section shall apply to taxable years beginning after
16 December 31, 2005.

17 **SEC. 4. FEDERAL REGISTER NOTICE.**

18 Not later than 90 days after the date of the enact-
19 ment of this Act, the Secretary of Health and Human
20 Services shall publish in the Federal Register a notice that
21 informs manufacturers of brand-name prescription drugs
22 of the provisions of the amendments made by this Act,
23 and that invites the manufacturers to enter into negotia-
24 tions with the Secretary for purposes of entering into

- 1 agreements under section 340H of the Public Health Serv-
- 2 ice Act.

