

110TH CONGRESS
1ST SESSION

H. R. 2823

To amend the Internal Revenue Code of 1986 to deny any deduction for direct-to-consumer advertisements of prescription drugs that fail to provide certain information or to present information in a balanced manner, to amend the Federal Food, Drug, and Cosmetic Act to require reports regarding such advertisements, and to amend such Code to deny any deduction for direct-to-consumer advertisements of qualified prescription drugs for a two-year period.

IN THE HOUSE OF REPRESENTATIVES

JUNE 21, 2007

Mr. STARK introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and 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 amend the Internal Revenue Code of 1986 to deny any deduction for direct-to-consumer advertisements of prescription drugs that fail to provide certain information or to present information in a balanced manner, to amend the Federal Food, Drug, and Cosmetic Act to require reports regarding such advertisements, and to amend such Code to deny any deduction for direct-to-consumer advertisements of qualified prescription drugs for a two-year period.

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 “Fair Balance Prescrip-
5 tion Drug Advertisement Act of 2007”.

6 **SEC. 2. DISALLOWANCE OF DEDUCTION FOR DIRECT-TO-**
7 **CONSUMER ADVERTISEMENT OF PRESCRIP-**
8 **TION DRUG THAT FAILS TO PROVIDE CER-**
9 **TAIN INFORMATION OR TO PRESENT BAL-**
10 **ANCED INFORMATION.**

11 (a) GENERAL RULE.—Part IX of subchapter B of
12 chapter 1 of the Internal Revenue Code of 1986 (relating
13 to items not deductible) is amended by adding at the end
14 the following new section:

15 **“SEC. 280I. DIRECT-TO-CONSUMER ADVERTISEMENT OF**
16 **PRESCRIPTION DRUG THAT FAILS TO PRO-**
17 **VIDE CERTAIN INFORMATION OR TO**
18 **PRESENT BALANCED INFORMATION.**

19 “No deduction shall be allowed under this chapter for
20 any expense of an advertisement for a prescription drug
21 if, with respect to such advertisement, the Secretary of
22 Health and Human Services has submitted to the Sec-
23 retary of the Treasury a report under section 311 of the
24 Federal Food, Drug, and Cosmetic Act.”.

1 (b) CLERICAL AMENDMENT.—The table of sections
 2 for part IX of subchapter B of chapter 1 of such Code
 3 is amended by adding at the end the following new item:

“Sec. 280I. Direct-to-consumer advertisement of prescription drug that fails to
 provide certain information or to present balanced informa-
 tion.”.

4 (c) EFFECTIVE DATE.—The amendments made by
 5 this section shall apply to amounts paid or incurred after
 6 December 31, 2007.

7 **SEC. 3. PROHIBITIONS REGARDING DIRECT-TO-CONSUMER**
 8 **PRESCRIPTION DRUG ADVERTISING; RE-**
 9 **PORTING OF VIOLATIONS TO INTERNAL REV-**
 10 **ENUE SERVICE.**

11 Chapter III of the Federal Food, Drug, and Cosmetic
 12 Act (21 U.S.C. 331 et seq.) is amended by adding at the
 13 end the following section:

14 “PROHIBITIONS REGARDING DIRECT-TO-CONSUMER PRE-
 15 SCRIPTION DRUG ADVERTISING; REPORTING OF VIO-
 16 LATIONS TO INTERNAL REVENUE SERVICE

17 “SEC. 311. With respect to a direct-to-consumer ad-
 18 vertisement of a prescription drug, the Secretary shall re-
 19 port to the Secretary of the Treasury—

20 “(1) any violation of section 301 involving the
 21 misbranding of the prescription drug by reason of
 22 failure to comply with the requirements of section
 23 502(n) that relate to the provision in the advertise-

1 ment of true statements relating to side effects, con-
2 traindications, and effectiveness; or

3 “(2) any determination by the Secretary, made
4 upon a petition of an interested person or the Sec-
5 retary’s own initiative, that under criteria estab-
6 lished by the Secretary by regulation, the portion of
7 the advertisement devoted to describing side effects,
8 contraindications, or any lack of effectiveness is less
9 than the portion of the advertisement devoted to de-
10 scribing the benefits of the drug, taking into account
11 the amount and type size of any printed informa-
12 tion, whether all printed material is printed together
13 or on facing or consecutive pages, the duration of
14 the advertisement (in the case of an advertisement
15 through media such as television or radio), and such
16 other factors as the Secretary determines to be ap-
17 propriate.”.

18 **SEC. 4. DISALLOWANCE OF DEDUCTION FOR DIRECT-TO-**
19 **CONSUMER ADVERTISEMENT OF QUALIFIED**
20 **PRESCRIPTION DRUG FOR TWO-YEAR PE-**
21 **RIOD.**

22 (a) GENERAL RULE.—Part IX of subchapter B of
23 chapter 1 of the Internal Revenue Code of 1986 (as
24 amended by section 2) is amended by adding at the end
25 the following new section:

1 **“SEC. 280J. DIRECT-TO-CONSUMER ADVERTISEMENT OF**
2 **QUALIFIED PRESCRIPTION DRUG.**

3 “(a) IN GENERAL.—No deduction shall be allowed
4 under this chapter for any expense of an advertisement
5 for a qualified prescription drug paid or incurred during
6 the two-year period beginning on the date that the quali-
7 fied prescription drug is first introduced into interstate
8 commerce.

9 “(b) QUALIFIED PRESCRIPTION DRUG.—For pur-
10 poses of this section, the term ‘qualified prescription drug’
11 means a new drug, a new combination of active sub-
12 stances, or a new delivery system for an existing drug.

13 “(c) DISCRETIONARY AUTHORITY.—At the discretion
14 of the Secretary, and in consultation with the Commis-
15 sioner of Food and Drugs, the Secretary may exempt a
16 qualified prescription drug from the disallowance of a de-
17 duction under subsection (a).”.

18 (b) CLERICAL AMENDMENT.—The table of sections
19 for part IX of subchapter B of chapter 1 of such Code
20 is amended by adding at the end the following new item:

“Sec. 280J. Direct-to-consumer advertisement of qualified prescription drug.”.

21 (c) EFFECTIVE DATE.—The amendments made by
22 this section shall apply to amounts paid or incurred after
23 December 31, 2007.

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