I

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

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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.

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 ''Fair Balance Prescription Drug Advertisement Act of 2007''.

SEC. 2. DISALLOWANCE OF DEDUCTION FOR DIRECT-TO-CONSUMER ADVERTISEMENT OF PRESCRIPTION DRUG THAT FAILS TO PROVIDE CERTAIN INFORMATION OR TO PRESENT BALANCED INFORMATION.

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

''SEC. 280I. DIRECT-TO-CONSUMER ADVERTISEMENT OF PRESCRIPTION DRUG THAT FAILS TO PROVIDE CERTAIN INFORMATION OR TO PRESENT BALANCED INFORMATION.

''No deduction shall be allowed under this chapter for any expense of an advertisement for a prescription drug if, with respect to such advertisement, the Secretary of Health and Human Services has submitted to the Secretary of the Treasury a report under section 311 of the Federal Food, Drug, and Cosmetic Act.''.

(b) CLERICAL AMENDMENT.—The table of sections for part IX of subchapter B of chapter 1 of such Code 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 information.".

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

SEC. 3. PROHIBITIONS REGARDING DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING; REPORTING OF VIOLATIONS TO INTERNAL REVENUE SERVICE.

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

"PROHIBITIONS REGARDING DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING; REPORTING OF VIOLATIONS TO INTERNAL REVENUE SERVICE

"SEC. 311. With respect to a direct-to-consumer advertisement of a prescription drug, the Secretary shall report to the Secretary of the Treasury—

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

ment of true statements relating to side effects, contraindications, and effectiveness; or

''(2) any determination by the Secretary, made upon a petition of an interested person or the Secretary's own initiative, that under criteria established by the Secretary by regulation, the portion of the advertisement devoted to describing side effects, contraindications, or any lack of effectiveness is less than the portion of the advertisement devoted to describing the benefits of the drug, taking into account the amount and type size of any printed information, whether all printed material is printed together or on facing or consecutive pages, the duration of the advertisement (in the case of an advertisement through media such as television or radio), and such other factors as the Secretary determines to be appropriate.''.

SEC. 4. DISALLOWANCE OF DEDUCTION FOR DIRECT-TO-CONSUMER ADVERTISEMENT OF QUALIFIED PRESCRIPTION DRUG FOR TWO-YEAR PERIOD.

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

"SEC. 280J. DIRECT-TO-CONSUMER ADVERTISEMENT OF QUALIFIED PRESCRIPTION DRUG.

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

''(b) QUALIFIED PRESCRIPTION DRUG.—For purposes of this section, the term 'qualified prescription drug' means a new drug, a new combination of active substances, or a new delivery system for an existing drug.

''(c) DISCRETIONARY AUTHORITY.—At the discretion of the Secretary, and in consultation with the Commissioner of Food and Drugs, the Secretary may exempt a qualified prescription drug from the disallowance of a deduction under subsection (a).''.

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

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

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

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