

107TH CONGRESS
1ST SESSION

H. R. 2352

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, and to amend the Federal Food, Drug, and Cosmetic Act to require reports regarding such advertisements.

IN THE HOUSE OF REPRESENTATIVES

JUNE 27, 2001

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, and to amend the Federal Food, Drug, and Cosmetic Act to require reports regarding such advertisements.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Fair Balance Prescrip-
3 tion Drug Advertisement Act of 2001”.

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

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

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

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

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

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

1 (c) EFFECTIVE DATE.—The amendments made by
2 this section shall apply to amounts paid or incurred after
3 December 31, 2001.

4 **SEC. 3. PROHIBITIONS REGARDING DIRECT-TO-CONSUMER**
5 **PRESCRIPTION DRUG ADVERTISING; RE-**
6 **PORTING OF VIOLATIONS TO INTERNAL REV-**
7 **ENUE SERVICE.**

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

11 “PROHIBITIONS REGARDING DIRECT-TO-CONSUMER PRE-
12 SCRIPTION DRUG ADVERTISING; REPORTING OF VIO-
13 LATIONS TO INTERNAL REVENUE SERVICE

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

17 “(1) any violation of section 301 involving the
18 misbranding of the prescription drug by reason of
19 failure to comply with the requirements of section
20 502(n) that relate to the provision in the advertise-
21 ment of true statements relating to side effects, con-
22 traindications, and effectiveness; or

23 “(2) any determination by the Secretary, made
24 upon a petition of an interested person or the Sec-

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

○