

107TH CONGRESS
2^D SESSION

H. R. 4833

To amend the Federal Food, Drug, and Cosmetic Act to establish authority for the imposition of civil penalties for direct-to-consumer advertisements that violate such Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 23, 2002

Mr. ALLEN (for himself, Mr. BERRY, Mr. LANGEVIN, Mr. BROWN of Ohio, Mr. STARK, Mr. RANGEL, Ms. KAPTUR, Mr. BALDACCI, Ms. DELAURO, and Mr. WAXMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish authority for the imposition of civil penalties for direct-to-consumer advertisements that violate such Act, and for other purposes.

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 “Accuracy in Pharma-
5 ceutical Advertisements Act”.

1 **SEC. 2. CIVIL PENALTY FOR CERTAIN DIRECT-TO-CON-**
2 **SUMER ADVERTISEMENTS OF PRESCRIPTION**
3 **DRUGS.**

4 Section 303 of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 333) is amended by adding at the end the
6 following subsection:

7 “(h)(1) With respect to a violation of section 301 in-
8 volving the misbranding of a prescription drug within the
9 meaning of section 502(n), any person that engages in
10 such a violation shall be liable to the United States for
11 a civil penalty if—

12 “(A) the violation involves a direct-to-con-
13 sumer advertisement;

14 “(B) the Secretary provides written notice
15 of the violation to the person; and

16 “(C) the person fails to correct or cease
17 the advertisement so as to eliminate such viola-
18 tion not later than 180 days after the date of
19 the notice.

20 “(2) The amount of a civil penalty for a violation de-
21 scribed in paragraph (1) shall not exceed \$500,000 in the
22 case of an individual and \$5,000,000 in the case of any
23 other person, not to exceed \$10,000,000 for all such viola-
24 tions adjudicated in a single proceeding.

25 “(3) Paragraphs (3) through (5) of subsection (g)
26 apply with respect to a civil penalty under paragraph (1)

1 of this subsection to the same extent and in the same man-
2 ner as such paragraphs (3) through (5) apply with respect
3 to a civil penalty under paragraph (1) or (2) of subsection
4 (g).”.

5 **SEC. 3. REPORTS; PUBLIC NOTICE OF VIOLATIONS.**

6 With respect to direct-to-consumer advertisements
7 for prescription drugs, the Secretary of Health and
8 Human Services (referred to in this section as the “Sec-
9 retary”), acting through the Commissioner of Food and
10 Drugs, shall annually submit to the Committee on Energy
11 and Commerce of the House of Representatives, the Com-
12 mittee on Health, Education, Labor, and Pensions of the
13 Senate, and any other appropriate committee of the Con-
14 gress a report that, for the most recent 1-year period for
15 which data are available—

16 (1) provides the total number of such advertise-
17 ments made by television, radio, Internet, written
18 publication, or other media;

19 (2) identifies, for each such advertisement—

20 (A) the dates on which, the times at which,
21 and the markets in which the advertisement
22 was made; and

23 (B) the type of advertisement (reminder,
24 help-seeking, or product-claim); and

