

114TH CONGRESS
2D SESSION

H. R. 4565

To amend the Federal Food, Drug, and Cosmetic Act to restrict direct-to-consumer drug advertising.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 12, 2016

Ms. DELAURO 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 restrict direct-to-consumer drug advertising.

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 “Responsibility in Drug
5 Advertising Act of 2016”.

6 **SEC. 2. DIRECT-TO-CONSUMER DRUG ADVERTISING.**

7 The Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 301 et seq.) is amended—

9 (1) in section 301 (21 U.S.C. 331), by adding
10 at the end the following:

1 “(eee) The conduct of direct-to-consumer advertising
2 of a drug in violation of section 506G.”; and

3 (2) in chapter V, by inserting after section
4 506F (21 U.S.C. 356f) the following:

5 **“SEC. 506G. DIRECT-TO-CONSUMER DRUG ADVERTISING.**

6 “(a) PROHIBITIONS.—

7 “(1) FIRST THREE YEARS.—

8 “(A) IN GENERAL.—Subject to subpara-
9 graph (B), no person shall conduct direct-to-
10 consumer advertising of a drug for which an
11 application is submitted under section 505(b)
12 before the end of the 3-year period beginning
13 on the date of the approval of such application.

14 “(B) WAIVER.—The Secretary may waive
15 the application of subparagraph (A) to a drug
16 during the third year of the 3-year period de-
17 scribed in such subparagraph if—

18 “(i) the sponsor of the drug submits
19 an application to the Secretary pursuant to
20 subparagraph (C); and

21 “(ii) the Secretary, after considering
22 the application and any accompanying ma-
23 terials, determines that direct-to-consumer
24 advertising of the drug would have an af-
25 firmative value to public health.

1 “(C) APPLICATION FOR WAIVER.—To seek
2 a waiver under subparagraph (B), the sponsor
3 of a drug shall submit an application to the
4 Secretary at such time, in such manner, and
5 containing such information as the Secretary
6 may require.

7 “(2) SUBSEQUENT YEARS.—The Secretary may
8 prohibit direct-to-consumer advertising of a drug
9 during the period beginning at the end of the 3-year
10 period described in paragraph (1)(A) if the Sec-
11 retary determines that the drug has significant ad-
12 verse health effects based on post-approval studies,
13 risk-benefit analyses, adverse event reports, the sci-
14 entific literature, any clinical or observational stud-
15 ies, or any other appropriate resource.

16 “(b) REGULATIONS.—Not later than 1 year after the
17 date of the enactment of this section, the Secretary shall
18 revise the regulations promulgated under this Act gov-
19 erning drug advertisements to the extent necessary to im-
20 plement this section.

21 “(c) RULE OF CONSTRUCTION.—This section shall
22 not be construed to diminish the authority of the Secretary
23 to prohibit or regulate direct-to-consumer advertising of
24 drugs under other provisions of law.

1 “(d) EFFECTIVE DATE.—This section applies only
2 with respect to a drug for which an application submitted
3 under section 505(b) is approved on or after the date that
4 is 1 year before the date of the enactment of this section.”.

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