

119TH CONGRESS
1ST SESSION

S. 483

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 6 (legislative day, FEBRUARY 5), 2025

Mr. KING (for himself, Mr. KAINE, and Mr. WELCH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 2025”.

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

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

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

6 “(a) PROHIBITIONS.—

7 “(1) FIRST 3 YEARS.—

8 “(A) IN GENERAL.—Subject to subpara-
9 graph (B), no person shall conduct direct-to-
10 consumer advertising, including on a social
11 media platform, of a drug approved under sec-
12 tion 505(c) before the end of the 3-year period
13 beginning on the date of such approval.

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, including on
9 social media platforms, of a drug during the period
10 beginning at the end of the 3-year period described
11 in paragraph (1)(A) if the Secretary determines that
12 the drug has significant adverse health effects based
13 on post-approval studies, risk-benefit analyses, ad-
14 verse event reports, the scientific literature, any clin-
15 ical or observational studies, or any other appro-
16 priate resource.

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

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

1 drugs, including on social media platforms, under any
2 other provision of law.

3 “(d) EFFECTIVE DATE.—This section applies only
4 with respect to a drug approved under section 505(c) on
5 or after the date that is 1 year before the date of enact-
6 ment of this section.”.

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