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(Original Signature of Member)

114TH CONGRESS
2D SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Ms. DELAURO introduced the following bill; which was referred to the Committee on _____

A BILL

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

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 ''Responsibility in Drug Advertising Act of 2016''.

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

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

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

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

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

''SEC. 506G. DIRECT-TO-CONSUMER DRUG ADVERTISING.

''(a) PROHIBITIONS.—

''(1) FIRST THREE YEARS.—

''(A) IN GENERAL.—Subject to subparagraph (B), no person shall conduct direct-to-consumer advertising of a drug for which an application is submitted under section 505(b) before the end of the 3-year period beginning on the date of the approval of such application.

''(B) WAIVER.—The Secretary may waive the application of subparagraph (A) to a drug during the third year of the 3-year period described in such subparagraph if—

''(i) the sponsor of the drug submits an application to the Secretary pursuant to subparagraph (C); and

''(ii) the Secretary, after considering the application and any accompanying materials, determines that direct-to-consumer

advertising of the drug would have an affirmative value to public health.

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

''(2) SUBSEQUENT YEARS.—The Secretary may prohibit direct-to-consumer advertising of a drug during the period beginning at the end of the 3-year period described in paragraph (1)(A) if the Secretary determines that the drug has significant adverse health effects based on post-approval studies, risk-benefit analyses, adverse event reports, the scientific literature, any clinical or observational studies, or any other appropriate resource.

''(b) REGULATIONS.—Not later than 1 year after the date of the enactment of this section, the Secretary shall revise the regulations promulgated under this Act governing drug advertisements to the extent necessary to implement this section.

''(c) RULE OF CONSTRUCTION.—This section shall not be construed to diminish the authority of the Secretary

to prohibit or regulate direct-to-consumer advertising of drugs under other provisions of law.

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