

Title IX of FDAAA, Section 503B

SEC. 503B. PREREVIEW OF TELEVISION ADVERTISEMENTS.

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(5) REPORT ON DIRECT-TO-CONSUMER ADVERTISING- Not later than 24 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall report to the Congress on direct-to-consumer advertising and its ability to communicate to subsets of the general population, including elderly populations, children, and racial and ethnic minority communities. The Secretary shall utilize the Advisory Committee on Risk Communication established under this Act to advise the Secretary with respect to such report. The Advisory Committee shall study direct-to-consumer advertising as it relates to increased access to health information and decreased health disparities for these populations. The report required by this paragraph shall recommend effective ways to present and disseminate information to these populations. Such report shall also make recommendations regarding impediments to the participation of elderly populations, children, racially and ethnically diverse communities, and medically underserved populations in clinical drug trials and shall recommend best practice approaches for increasing the inclusion of such subsets of the general population. The Secretary of Health and Human Services shall submit the report under this paragraph to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

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Title IX of FDAAA, Section 906

SEC. 906. STATEMENT FOR INCLUSION IN DIRECT-TO-CONSUMER ADVERTISEMENTS OF DRUGS.

(a) Published Direct-to-Consumer Advertisements- Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), as amended by section 901(d)(6), is further amended by inserting `and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: `You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.' after `section 701(a),`.

(b) Study-

(1) IN GENERAL- In the case of direct-to-consumer television advertisements, the Secretary of Health and Human Services, in consultation with the Advisory Committee on Risk Communication under section 567 of the Federal Food, Drug, and Cosmetic Act (as added by section 917), shall, not later than 6 months after the date of the enactment of this Act, conduct a study to determine if the statement in section 502(n) of such Act (as added by subsection (a)) required with respect to published direct-to-consumer advertisements is appropriate for inclusion in such television advertisements.

*Excerpts from Title IX of the Food and Drug Administration Amendments Act of 2007
(FDAAA)*

Background for May 15-16, 2008 Risk Communication Advisory Committee Meeting

(2) CONTENT- As part of the study under paragraph (1), such Secretary shall consider whether the information in the statement described in paragraph (1) would detract from the presentation of risk information in a direct-to-consumer television advertisement. If such Secretary determines the inclusion of such statement is appropriate in direct-to-consumer television advertisements, such Secretary shall issue regulations requiring the implementation of such statement in direct-to-consumer television advertisements, including determining a reasonable length of time for displaying the statement in such advertisements. The Secretary shall report to the appropriate committees of Congress the findings of such study and any plans to issue regulations under this paragraph.