AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

I

109TH CONGRESS
1ST SESSION

H. R. 3950

To amend the Federal Food, Drug, and Cosmetic Act with respect to drug advertising, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 29, 2005

Ms. DELAURO (for herself and Mrs. EMERSON) 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 with respect to drug advertising, and for other purposes.

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 2005".

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, by adding at the end the following:

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

(2) in chapter V, by inserting after section 506C the following:

''SEC. 506D. 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.''.

SEC. 3. PROMINENT DISPLAY OF INFORMATION IN ADVERTISING ON SIDE EFFECTS, CONTRAINDICATIONS, AND EFFECTIVENESS.

(a) REQUIREMENT.—Paragraph (3) of section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended—

(1) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii); and

(2) by striking ''such other information'' and all that follows through ''which shall be issued by'' and inserting ''such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which (A) shall require such information to be prominently displayed in terms of font size and location and (B) shall be issued by''.

(b) EFFECTIVE DATE.—The amendment made by this section applies with respect to any advertisement or other descriptive printed matter that is issued or caused to be issued on or after the date that is 90 days after the enactment of this Act. Not later than such date, the

Secretary shall revise any regulations promulgated pursuant to subsection (n) of section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) to the extent necessary to implement this section.

SEC. 4. CIVIL PENALTY.

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

''(g) DRUG ADVERTISING AND PROMOTION.—

''(1) CIVIL PENALTY.—

''(A) IN GENERAL.—Any manufacturer, packer, or distributor of a drug who violates section 505(n), section 506D, or any other requirement of this Act relating to the advertising or promotion of the drug shall be subject to a civil penalty in an amount not to exceed—

''(i) in the case of the first such violation by the manufacturer, packer, or distributor relating to the drug, $250,000; and

''(ii) in the case of each subsequent violation by the manufacturer, packer, or distributor relating to the drug, an amount that is twice the amount of the maximum

civil penalty applicable under this subparagraph to the previous violation.

"(B) PROCEDURE.—Paragraphs (3) through (5) of subsection (f) shall apply with respect to a civil penalty under subparagraph (A) to the same extent and in the same manner as those paragraphs apply with respect to a civil penalty under paragraph (1) or (2) of subsection (f).

"(2) DISTRIBUTION OF MATERIALS.—If the Secretary finds that a person committed a violation described in paragraph (1)(A), the Secretary may order the person to distribute materials in the same markets in which the violative advertisement or promotional material was distributed in a manner designed to notify the public and the medical community of the violation and to provide corrective information.

"(3) SEPARATE OFFENSE.—For purposes of imposing a civil penalty under this subsection, each violation described in paragraph (1)(A), including each distribution of a direct-to-consumer advertisement in violation of section 506A, shall constitute a separate offense.

''(4) RELATION TO OTHER PENALTIES.—A civil penalty under paragraph (1) and an order under paragraph (2) shall be in addition to any other penalty applicable under this Act or other law to the violation involved.''.

SEC. 5. ORDER REQUIRING POSTMARKET CHANGE IN LABELING.

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

(1) in section 502, by adding at the end the following:

''(x) If it is a drug and its labeling fails to comply with an order issued pursuant to section 506E, or the manufacturer of the drug fails to provide notification to physicians as required by the Secretary pursuant to such section.''; and

(2) by inserting after section 506D, as added by section 2, the following:

''SEC. 506E. POSTMARKET CHANGE IN LABELING.

''(a) IN GENERAL.—In the case of any drug for which an approval of an application submitted under section 505(b) or (j) is in effect, the Secretary may require by order that information, including specific wording, be included in the labeling of a drug on the basis that such

information is necessary to ensure the safe and effective use of the drug.

''(b) NOTIFICATION.—If the Secretary issues an order described in subsection (a), the Secretary may require the manufacturer of the drug involved to notify the public and the medical community of the labeling change.''.

SEC. 6. PUBLIC EDUCATION CAMPAIGN ON RISKS OF CERTAIN DRUGS.

The Secretary of Health and Human Services shall conduct an education campaign to increase public awareness of risks that, for some patients, may outweigh the benefits of using a particular drug, whether such risks are known at the time of the approval of the drug or become known after the approval of the drug.

SEC. 7. ADDITIONAL FUNDING FOR REGULATION OF DIRECT-TO-CONSUMER DRUG ADVERTISING.

There are authorized to be appropriated to the Food and Drug Administration $2,500,000 for each of fiscal years 2007 and 2008 for the purpose of regulating direct-to-consumer drug advertisements, including by carrying out the amendments made by section 2. The authorization of appropriations in the preceding sentence is in addition

to any other authorization of appropriations for such purpose.

○