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109TH CONGRESS
1ST SESSION

H. R. 3696

To amend the Federal Food, Drug, and Cosmetic Act to require prior approval by the Food and Drug Administration of advertisements for prescription drugs and restricted medical devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 8, 2005

Mr. BROWN of Ohio introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require prior approval by the Food and Drug Administration of advertisements for prescription drugs and restricted medical devices, 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 ''Medical Advertising Reform Act''.

TITLE I—LABELING AND ADVERTISING FOR PRESCRIPTION DRUGS

SEC. 101. ADVERTISING FOR PRESCRIPTION DRUGS.

(a) ADVERTISEMENTS INTENDED FOR CONSUMERS; PRIOR APPROVAL.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by striking ''except that (A)'' and all that follows through ''and (B)'' and inserting the following: ''provided that (A)(i) in the case of an advertisement intended for consumers of a prescription drug, such regulations shall require prior approval by the Secretary of the content of the advertisement, which approval or denial shall be issued not later than 30 days after the content is submitted to the Secretary, and (ii) in the case of an advertisement not so intended, such regulations may not, except in extraordinary circumstances, require prior approval by the Secretary of the content of the advertisement, and (B)''.

(b) TWO-YEAR PROHIBITION AFTER APPROVAL OF DRUG.—

(1) IN GENERAL.—Section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) is amended by adding at the end the following paragraph:

''(5)(A) In the case of a prescription drug, the Secretary shall require as a condition of the approval of an application under subsection (b) that the applicant ensure that no advertisement for the drug is issued or caused to be issued during the two-year period beginning on the date on which the application is approved.

''(B) The Secretary, after notice and opportunity for a hearing, may extend the two-year period under subparagraph (A) if the Secretary determines that such extension is necessary to protect the public health.''.

(2) ENFORCEMENT.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(x) If it is a prescription drug with respect to which there is a failure to comply with a requirement under section 505(c)(5).''.

(c) RULE OF CONSTRUCTION.—The amendments made by subsections (a) and (b) may not be construed as affecting the authority of the Secretary of Health and Human Services under section 319 of the Public Health Service Act (relating to actions to respond to public health emergencies).

SEC. 102. LABELING AND ADVERTISING FOR PRESCRIPTION DRUGS; REPORT TO CONGRESS REGARDING COMPARATIVE EFFECTIVENESS AND COST-EFFECTIVENESS.

Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit to the Committee on Energy and Commerce in the House of Representatives, and the Committee on Health, Education, Labor, and Pensions in the Senate, a report providing a proposal for the inclusion in the labeling and advertisements for each prescription drug of information concerning the comparative effectiveness and comparative cost-effectiveness of the drug in relation to other prescription drugs that are in the same class of drugs. Such report shall include a description of the amendments to the Federal Food, Drug, and Cosmetic Act that would be necessary to enact such proposal.

SEC. 103. FUNDING FOR DIVISION OF DRUG MARKETING, ADVERTISING, AND COMMUNICATIONS.

For carrying out the responsibilities of the Division of Drug Marketing, Advertising, and Communications (within the Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration), there are authorized to be appropriated $25,000,000

for fiscal year 2007, and such sums as may be necessary for each subsequent fiscal year.

TITLE II—ADVERTISING FOR RESTRICTED MEDICAL DEVICES

SEC. 201. ADVERTISING FOR RESTRICTED DEVICES.

(a) ADVERTISEMENTS INTENDED FOR CONSUMERS; PRIOR APPROVAL.—Section 502(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(r)) is amended—

(1) by inserting after the first period the following: ''In the case of an advertisement intended for consumers of a restricted device, regulations under this paragraph shall require prior approval by the Secretary of the content of the advertisement, which approval or denial shall be issued not later than 30 days after the content is submitted to the Secretary.''; and

(2) by striking ''Except in extraordinary circumstances'' and all that follows through ''prior approval'' and inserting the following: ''In the case of an advertisement not so intended, such regulations may not, except in extraordinary circumstances, require prior approval''.

(b) STUDY BY GOVERNMENT ACCOUNTABILITY OFFICE; REPORT TO CONGRESSIONAL COMMITTEES.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the impact of consumer-directed advertising on restricted device utilization and spending. Such study shall consider, for the period January 1, 2001, through December 31, 2005—

(A) the growth in retail sales of the 25 restricted devices most heavily advertised (as measured by the volume of advertisements aired or published) relative to the sales of other restricted devices;

(B) annual retail price increases of the 25 most heavily advertised devices compared to those of other devices; and

(C) such other information as the Comptroller General determines is useful in assessing the impact of advertising on the national health care consumption and spending.

(2) EVALUATION OF REGULATORY CONTROLS AND SUFFICIENCY OF RESOURCES.—

(A) IN GENERAL.—In conducting the study under paragraph (1), the Comptroller General shall, in addition to considerations under such paragraph, evaluate whether—

(i) current regulatory controls are designed and implemented so as to effectively ensure that consumer-directed device advertising provides complete and accurate information concerning the safety and effectiveness considerations associated with advertised devices; and

(ii) the Food and Drug Administration devotes sufficient resources to the tasks of monitoring and enforcing such controls.

(B) RECOMMENDATIONS FOR CONGRESS.—If the Comptroller General concludes that the design or implementation of current regulatory controls is ineffective within the meaning of subparagraph (A)(i), or that the resources allocated for their implementation are insufficient within the meaning of subparagraph (A)(ii), the Comptroller General shall develop recommendations for the Congress for remediation of the deficiencies.

(3) DEFINITIONS.—For purposes of this subsection, the terms ''device'' and ''restricted device'' have the meanings that apply for purposes of the Federal Food, Drug, and Cosmetic Act.

(4) REPORT.—Not later than July 1, 2006, the Comptroller General shall submit to the Committee on Energy and Commerce in the House of Representatives, and the Committee on Finance in the Senate, a report providing the findings of the study under paragraph (1), including (as applicable) recommendations under paragraph (2)(B).

SEC. 202. FUNDING FOR OFFICE OF COMPLIANCE.

For carrying out the responsibilities of the Office of Compliance (within the Center for Devices and Radiological Health, Food and Drug Administration), there are authorized to be appropriated $5,000,000 for each of the fiscal years 2007 through 2009, and such sums as may be necessary for each subsequent fiscal year.

TITLE III—AVAILABILITY TO PUBLIC OF OBJECTIVE INFORMATION ON DRUGS

SEC. 301. AVAILABILITY OF INFORMATION.

(a) IN GENERAL.—The Secretary of Health and Human Services shall provide for the availability to the public of objective information on health conditions and treatments through—

(1) maintaining a toll-free telephone number to provide such information;

(2) carrying out a public information campaign to make the public aware that such information is available from the Department of Health and Human Services through such telephone number and through the Internet site www.healthfinder.gov (or successor site); and

(3) using the telephone number under paragraph (1), and the Internet site of the Food and Drug Administration, to make the public aware of the Internet site referred to in paragraph (2).

(b) AUTHORIZATION OF APPROPRIATIONS FOR PUBLIC INFORMATION CAMPAIGN.—For the purpose of carrying out subsection (a)(2), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2007 through 2009.

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