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110TH CONGRESS
1ST SESSION

H. R. 4083

To amend the Federal Food, Drug, and Cosmetic Act to provide for the amendment or repeal of monographs, to expand the Food and Drug Administration's authority to regulate drug advertising, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 6, 2007

Mr. WAXMAN (for himself and Mr. ALLEN) 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 provide for the amendment or repeal of monographs, to expand the Food and Drug Administration's authority to regulate 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 ''Non-Prescription Drug Modernization Act of 2007''.

SEC. 2. AMENDING OR REPEALING MONOGRAPHS.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

"SEC. 568. AMENDING OR REPEALING MONOGRAPHS.

"(a) GOOD CAUSE.—In applying section 553 of title 5, United States Code, to any amendment to or repeal of a monograph established pursuant to section 330.10 of title 21, Code of Federal Regulations (or any successor regulation), good cause (as such term is used in subsections (b) and (d) of such section 553) is deemed to exist, and notice and public procedure are deemed to be unnecessary (as such term is used in subsection (b) of such section 553), for purposes of making such amendment or repeal if—

"(1) there is a finding—

"(A) by the Secretary that the category of drugs or the specific drug involved is associated with a significant risk; or

"(B) by the Secretary, after holding a meeting of an advisory committee of the Food and Drug Administration to evaluate the category of drugs or the specific drug involved, that such category of drugs or specific drug lacks evidence of effectiveness; and

''(2) such amendment or repeal is based, in whole or in part, on such finding.

''(b) SUBSEQUENT COMMENT PERIOD.—After the amendment or repeal of a monograph in accordance with subsection (a), the Secretary may provide a period for public comments on the amendment or repeal and may make additional changes with respect to the monograph to reflect comments received, if determined appropriate by the Secretary.''.

SEC. 3. EXPANSION OF FDA'S AUTHORITY TO REGULATE DRUG ADVERTISING.

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

(1) in section 303(g)(1), by striking ''With respect to'' and all that follows through ''section 351 of the Public Health Service Act,'' and inserting ''With respect to a person who is a holder of an approved application under section 505 or under section 351 of the Public Health Service Act, or a person who is the manufacturer of a drug marketed pursuant to a monograph established pursuant to section 330.10 of title 21, Code of Federal Regulations (or any successor regulation),''; and

(2) in section 502(n)—

(A) by striking the term ''prescription drug'' each place such term appears and inserting ''drug''; and

(B) by striking ''subject to section 503(b)(1)''.

(b) REGULATIONS.—The Commissioner of Food and Drugs shall promulgate such revisions to the regulations under section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) as may be necessary to carry out the amendments made by subsection (a).

(c) TRANSITIONAL PROVISIONS.—

(1) FALSE OR MISLEADING ADVERTISEMENTS.—During the period beginning on the date of the enactment of this Act and ending on the effective date of the regulations required by subsection (b), a drug other than a prescription drug is deemed to be misbranded under section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) if any advertisement or other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributer with respect to that drug is false or misleading.

(2) DEFINITIONS.—The terms used in this subsection have the meanings applicable to those terms

in section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)).

SEC. 4. IDENTIFICATION AND REPORT ON MONOGRAPHS.

(a) IDENTIFICATION.—

(1) IN GENERAL.—The Commissioner of Food and Drugs (in this section referred to as the ''Commissioner'') shall identify each monograph established pursuant to section 330.10 of title 21, Code of Federal Regulations, that may require further review to determine whether the monograph is in need of amendment or repeal.

(2) PUBLIC COMMENTS.—To assist in the identification of such monographs, the Commissioner shall give interested persons, including medical societies and other entities with expertise on drugs, an opportunity to submit comments.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Commissioner shall submit a report to the Congress identifying any monographs that, as determined by the Commissioner, may require further review to determine whether such monographs are in need of amendment or repeal. Such report shall include—

(1) an assessment of the resources necessary to conduct such review and make such amendments or repeals;

(2) a summary of the comments received under subsection (a)(2); and

(3) a listing of the monographs that, as recommended in such comments, are in need of amendment or repeal and the basis for such recommendations.

SEC. 5. AUTHORIZATION OF APPROPRIATIONS.

To carry out this Act and the amendments made by this Act, there are authorized to be appropriated such sums as may be necessary.

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