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(Original Signature of Member)

115TH CONGRESS
2D SESSION

H. R. 5811

To amend the Federal Food, Drug, and Cosmetic Act with respect to post-approval study requirements for certain controlled substances, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. MCNERNEY introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, 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. POSTAPPROVAL STUDY REQUIREMENTS.

(a) PURPOSES OF STUDY.—Section 505(o)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)(B)) is amended by adding at the end the following:

"(iv) To assess a potential reduction in effectiveness or an increase in serious risk of the drug for the conditions of use prescribed, recommended, or suggested in the labeling thereof if—

"(I) the drug involved—

"(aa) is or contains a substance for which a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled Substances Act; or

"(bb) is a drug that has not been approved under this section or licensed under section 351 of the Public Health Service Act, for which an application for such approval or licensure is pending or anticipated, and for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act; and

"(II) the potential reduction in effectiveness or the increase in serious risk could result in the benefits of the drug no longer outweighing the risks.".

(b) ESTABLISHMENT OF REQUIREMENT.—Section 505(o)(3)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)(C)) is amended by striking "such requirement" and all that follows through "safety information." and inserting the following: "such requirement—

"(i) in the case of a purpose described in clause (i), (ii), or (iii) of subparagraph (B), only if the Secretary becomes aware of new safety information; and

"(ii) in the case of a purpose described in clause (iv) of such subparagraph, if the Secretary determines that new effectiveness information exists.".

(c) APPLICABILITY.—Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)) is amended by adding at the end the following new subparagraph:

"(E) APPLICABILITY.—The conduct of a study or clinical trial required pursuant to this

paragraph for the purpose specified in subparagraph (B)(iv) shall not be considered a new clinical investigation for the purpose of a period of exclusivity under clause (iii) or (iv) of subsection (c)(3)(E) or clause (iii) or (iv) of subsection (j)(5)(F).''.

(d) NEW EFFECTIVENESS INFORMATION DEFINED.—Section 505(o)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(2)) is amended by adding at the end the following new subparagraph:

''(D) NEW EFFECTIVENESS INFORMATION.—The term 'new effectiveness information', with respect to a drug that is or contains a controlled substance for which a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled Substances Act, means new information about the effectiveness of the drug, including a new analysis of existing information, derived from—

''(i) a clinical trial; an adverse event report; a postapproval study or clinical trial (including a study or clinical trial under paragraph (3));

''(ii) peer-reviewed biomedical literature;

''(iii) data derived from the postmarket risk identification and analysis system under subsection (k); or

''(iv) other scientific data determined to be appropriate by the Secretary.''.

(e) CONFORMING AMENDMENTS WITH RESPECT TO LABELING CHANGES.—Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(4)) is amended—

(1) in subparagraph (A)—

(A) in the heading, by inserting ''OR NEW EFFECTIVENESS'' after ''SAFETY'';

(B) by striking ''safety information'' and inserting ''new safety information or new effectiveness information such''; and

(C) by striking ''believes should be'' and inserting ''believes changes should be made to'';

(2) in subparagraph (B)(i)—

(A) by striking ''new safety information'' and by inserting ''new safety information or new effectiveness information''; and

(B) by inserting ''indications,'' after ''boxed warnings,'';

(3) in subparagraph (C), by inserting ''or new effectiveness information'' after ''safety information''; and

(4) in subparagraph (E), by inserting ''or new effectiveness information'' after ''safety information''.

(f) RULE OF CONSTRUCTION.—Nothing in the amendments made by this section shall be construed to alter, in any manner, the meaning or application of the provisions of paragraph (3) of section 505(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)) with respect to the authority of the Secretary of Health and Human Services to require a postapproval study or clinical trial for a purpose specified in clauses (i) through (iii) of subparagraph (B) of such paragraph (3) or paragraph (4) of such section 505(o) with respect to the Secretary's authority to require safety labeling changes.