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(Original Signature of Member)

115TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services to issue guidance with respect to the accelerated approval of certain drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services to issue guidance with respect to the accelerated approval of certain drugs, 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. EXPEDITED TREATMENT OF PAIN AND ADDICTION THERAPIES.

Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended by adding at the end the following:

''(i) PAIN AND ADDICTION THERAPIES.—

''(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this paragraph, the Secretary shall issue draft guidance, clarifying how and when the Food and Drug Administration will provide expedited treatment for drugs developed to treat pain or addiction. Such draft guidance shall specifically address—

''(A) with respect to such expedited treatment—

''(i) eligibility requirements for such drugs to receive such expedited treatment;

''(ii) opportunities for engagement with the Food and Drug Administration, with respect to such expedited treatment;

''(B) with respect to designation of such a drug as a breakthrough therapy under subsection (a)—

''(i) specific guidance on establishing an efficient drug development program for such drugs, beginning with phase 1;

''(ii) the organizational commitment of the Food and Drug Administration to facilitating breakthrough designation for such drugs, including the involvement of

senior managers of the Food and Drug Administration; and

''(C) with respect to accelerated approval of such a drug pursuant to subsection (c), the criteria to be used for developing novel surrogate or intermediate clinical endpoints or biomarkers.

''(2) FINAL GUIDANCE.—Not later than 6 months after the close of the period for public comment on the draft guidance under paragraph (1), the Secretary of Health and Human Services shall finalize such guidance.

''(3) REPORTS.—On or before April 1 of each calendar year (beginning with 2019), the Secretary shall submit to Congress a report on the covered division's use of accelerated approval under this subsection, with respect to drugs developed to treat pain or addiction, during the previous calendar year. Such report shall include—

''(A) the number of requests for such expedited treatment submitted to the covered division;

''(B) the number of such requests that the covered division granted and the number of such requests the covered division denied;

''(C) a description of the common reasons for the covered division granting or denying applications for expedited treatment;

''(D) timelines for the development and review of such drugs;

''(E) a comparison of the metrics described in subparagraphs (A) through (D), relative to other review divisions of the Food and Drug Administration;

''(F) a list of surrogate and intermediate endpoints approved by the covered division for use for accelerated approval pursuant to subsection (c);

''(G) a description of the common reasons for longer timelines for the development and review of such drugs, if appropriate; and

''(H) recommendations to better enable the utilization of expedited treatment under this subsection.

''(4) DEFINITIONS.—In this subsection:

''(A) The term 'covered division' means the Division of Anesthesia, Analgesia, and Addiction Products of the Food and Drug Administration or a successor to such review division.

"(B) the term 'expedited treatment' means, with respect to a drug—

"(i) the designation of the drug as a breakthrough therapy under subsection (a); or

"(ii) the accelerated approval of such drug pursuant to subsection (c).".