.....

(Original Signature of Member)

115TH CONGRESS
2D SESSION

H. R. _____

To require the Secretary of Health and Human Services to issue guidance with respect to the expedited 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 require the Secretary of Health and Human Services to issue guidance with respect to the expedited 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. SHORT TITLE.

This Act may be cited as the ''21st Century Tools for Pain and Addiction Treatment Act''.

SEC. 2. CLARIFYING FDA REGULATION OF NON-ADDICTIVE PAIN AND ADDICTION THERAPIES.

(a) PUBLIC MEETINGS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall hold not less than one public meeting to address the challenges and barriers of developing nonaddictive medical products intended to treat pain or addiction, which may include—

(1) the application of novel clinical trial designs (consistent with section 3021 of the 21st Century Cures Act (Public Law 114–255)), use of real world evidence (consistent with section 505F of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355g)), and use of patient experience data (consistent with section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c)) for the development of non-addictive medical products intended to treat pain or addiction; and

(2) the application of eligibility criteria under sections 506 and 515B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356, 360e–3) for non-addictive medical products intended to treat pain or addiction.

(b) GUIDANCE.—Not later than one year after the public meetings are conducted under subsection (a) the

Secretary shall issue one or more final guidance documents, or update existing guidance documents, to help address challenges to developing non-addictive medical products to treat pain or addiction. Such guidance documents shall include information regarding—

(1) how the Food and Drug Administration may apply sections 506 and 515B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356, 360e–3) to non-addictive medical products intended to treat pain or addiction, including the circumstances under which the Secretary—

(A) may apply the eligibility criteria under such sections 506 and 515B to non-opioid or non-addictive medical products intended to treat pain or addiction;

(B) considers the risk of addiction of controlled substances approved to treat pain when establishing unmet medical need; and

(C) considers pain, pain control, or pain management in assessing whether a disease or condition is a serious or life-threatening disease or condition; and

(2) the methods by which sponsors may evaluate acute and chronic pain, endpoints for non-addictive medical products intended to treat pain, the

manner in which endpoints and evaluations of efficacy will be applied across and within review divisions, taking into consideration the etiology of the underlying disease, and the manner in which sponsors may use surrogate endpoints, intermediate endpoints, and real world evidence.

(c) MEDICAL PRODUCT DEFINED.—In this section, the term ''medical product'' means a drug (as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i))), or device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))).

SEC. 3. REPORTS.

(a) IN GENERAL.—Beginning on the date that is one year after the date of the enactment of this Act and each year thereafter for the next five years, the Secretary shall submit to Congress a report on the covered division's use of expedited treatment under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), with respect to drugs developed to treat pain or addiction, during the previous calendar year. Such report shall include—

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

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

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

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

(5) a comparison of the metrics described in paragraphs (1) through (4), relative to other review divisions of the Food and Drug Administration;

(6) a list of surrogate and intermediate endpoints approved by the covered division for use for expedited treatment;

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

(8) recommendations to better enable the utilization of expedited treatment under such section 506.

(b) DEFINITIONS.—In this subsection:

(1) 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.

(2) The term ''expedited treatment'' means, with respect to a drug—

(A) the designation of the drug as a breakthrough therapy under subsection (a) of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356); or

(B) the accelerated approval of such drug pursuant to subsection (c) of such section.