115TH CONGRESS
2D SESSION

H. R. _____

To direct the Secretary of Health and Human Services to update or issue guidance addressing alternative methods for data collection on opioid sparing and inclusion of such data in product labeling, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To direct the Secretary of Health and Human Services to update or issue guidance addressing alternative methods for data collection on opioid sparing and inclusion of such data in product labeling, 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 "_____ Act of 2018".

SEC. 2. FINDINGS.

The Congress finds the following:

(1) The United States is undergoing an epidemic of addiction and deaths caused by prescription drug overdoses. One major contributing factor is the increased use of opioid analgesics.

(2) Education designed to address prescribing concerns and the abuse potential for opioids to treat moderate to severe chronic pain has not had a measurable impact on the existing public health emergency.

(3) Practitioners must prioritize the utilization of non-opioid alternatives for treating pain associated with underlying chronic conditions and diseases.

(4) A renewed emphasis on the development of novel, non-addictive analgesics and utilization of currently available non-addictive analgesics that may replace, delay, or reduce use of opioids (e.g., ''opioid-sparing'' products or alternatives), specifically models and mechanisms for data collection that would enable product manufacturers to communicate with health care professionals and patients, would have a measurable impact on the existing public health emergency.

(5) Current regulatory models for appropriate data collection and endpoints commonly accepted by

the Food and Drug Administration (FDA) to measure clinical effectiveness are not ideally suited to accelerate development of opioid-sparing products or alternatives and may be untenable when considering the abuse potential involved in maintaining a control arm of a clinical trial on opioids for a prolonged period.

(6) An alternative, flexible model for data collection must—

(A) be designed in such a way that multiple sponsors can successfully replicate the model;

(B) follow a process whereby a sponsor and the FDA can agree to a framework and appropriate measures within a reasonable timeframe; and

(C) allow for such data to be placed in the appropriate section of the product labeling to enable ethical scientific engagement with health care professionals.

SEC. 3. GUIDANCE ADDRESSING ALTERNATIVE APPROACHES TO DATA COLLECTION AND LABELING CLAIMS FOR OPIOID SPARING.

(a) IN GENERAL.—For purposes of assisting sponsors in collecting and incorporating opioid-sparing data in

product labeling, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall conduct a public meeting and update or issue guidance in accordance with subsection (b).

(b) GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall update or issue guidance addressing alternative methods for—

(A) data collection on opioid sparing; and

(B) inclusion of such data in product labeling.

(2) CONTENTS.—The guidance under paragraph (1) shall address—

(A) innovative clinical trial designs for ethically and efficiently collecting data on opioid sparing for inclusion in product labeling;

(B) primary and secondary endpoints for the reduction of both chronic pain intensity and opioid use;

(C) use of real world evidence, including patient registries, and patient reported outcomes to support inclusion of opioid-sparing data in product labeling; and

(D) how sponsors may obtain feedback from the Secretary relating to such issues prior to—

(i) commencement of such data collection; or

(ii) the submission of resulting data to the Secretary.

(3) PUBLIC MEETING.—Prior to updating or issuing the guidance required by paragraph (1), the Secretary shall consult with stakeholders, including representatives of regulated industry, academia, patients, and provider organizations, through a public meeting to be held not later than 12 months after the date of enactment of this Act.

(4) TIMING.—The Secretary shall—

(A) not later than 12 months after the date of the public meeting required by paragraph (3), update or issue a draft version of the guidance required by paragraph (1); and

(B) not later than 12 months after the date on which the public comment period for the draft guidance closes, finalize such guidance.

(c) DEFINITION.—In this section:

(1) **[***add?*:**]**The terms ''opioid sparing'' and ''opioid-sparing'' refer to the use of one or more non-addictive analgesic drugs in place of an opioid.

(2) The term ''Secretary'' means the Secretary of Health and Human Services.