Suspend the Rules and Pass the Bill, H.R. 5473, With an Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

115TH CONGRESS
2D SESSION

H. R. 5473

To direct the Secretary of Health and Human Services to update or issue one or more guidances 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

APRIL 11, 2018

Mrs. COMSTOCK (for herself and Mr. BEN RAY LUJÁN of New Mexico) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To direct the Secretary of Health and Human Services to update or issue one or more guidances 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 ''Better Pain Management Through Better Data Act of 2018''.

SEC. 2. 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 one or more guidances 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 one or more guidances addressing—

(A) alternative methods for data collection on opioid sparing;

(B) alternative methods for inclusion of such data in product labeling; and

(C) investigations other than clinical trials, including partially controlled studies and objective trials without matched controls such as historically controlled analyses, open-label studies,

and meta-analyses, on opioid sparing for inclusion in product labeling.

(2) CONTENTS.—The guidances 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 opioid use while maintaining adequate pain control;

(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 guidances required by paragraph (1), the Secretary shall consult with stakeholders, including representatives of regulated industry, academia, pa-

tients, 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 the one or more draft guidances required by paragraph (1); and

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

(c) DEFINITION.—In this section:

(1) The terms ''opioid sparing'' and ''opioid-sparing'' refer to the use of drugs or devices (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that reduce pain while enabling the reduction, replacement, or avoidance of oral opioids.

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