

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Better Pain Manage-
5 ment Through Better Data Act of 2018”.

1 **SEC. 2. GUIDANCE ADDRESSING ALTERNATIVE AP-**
2 **PROACHES TO DATA COLLECTION AND LA-**
3 **BELING CLAIMS FOR OPIOID SPARING.**

4 (a) **IN GENERAL.**—For purposes of assisting spon-
5 sors in collecting and incorporating opioid-sparing data in
6 product labeling, the Secretary of Health and Human
7 Services (referred to in this section as the “Secretary”)
8 shall conduct a public meeting and update or issue one
9 or more guidances in accordance with subsection (b).

10 (b) **GUIDANCE.**—

11 (1) **IN GENERAL.**—The Secretary of Health and
12 Human Services, acting through the Commissioner
13 of Food and Drugs, shall update or issue one or
14 more guidances addressing—

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

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

19 (C) investigations other than clinical trials,
20 including partially controlled studies and objec-
21 tive trials without matched controls such as his-
22 torically controlled analyses, open-label studies,
23 and meta-analyses, on opioid sparing for inclu-
24 sion in product labeling.

25 (2) **CONTENTS.**—The guidances under para-
26 graph (1) shall address—

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

4 (B) primary and secondary endpoints for
5 the reduction of opioid use while maintaining
6 adequate pain control;

7 (C) use of real world evidence, including
8 patient registries, and patient reported out-
9 comes to support inclusion of opioid-sparing
10 data in product labeling; and

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

14 (i) commencement of such data collec-
15 tion; or

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

18 (3) PUBLIC MEETING.—Prior to updating or
19 issuing the guidances required by paragraph (1), the
20 Secretary shall consult with stakeholders, including
21 representatives of regulated industry, academia, pa-
22 tients, and provider organizations, through a public
23 meeting to be held not later than 12 months after
24 the date of enactment of this Act.

25 (4) TIMING.—The Secretary shall—

1 (A) not later than 12 months after the
2 date of the public meeting required by para-
3 graph (3), update or issue the one or more
4 draft guidances required by paragraph (1); and

5 (B) not later than 12 months after the
6 date on which the public comment period for
7 such draft guidances closes, finalize such guid-
8 ances.

9 (c) DEFINITION.—In this section:

10 (1) The terms “opioid sparing” and “opioid-
11 sparing” refer to the use of drugs or devices (as de-
12 fined in section 201 of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 321)) that reduce pain
14 while enabling the reduction, replacement, or avoid-
15 ance of oral opioids.

16 (2) The term “Secretary” means the Secretary
17 of Health and Human Services.

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