

115TH CONGRESS
2D SESSION

H. R. 5473

IN THE SENATE OF THE UNITED STATES

JUNE 13, 2018

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

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

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

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

13 (b) GUIDANCE.—

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

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

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

22 (C) investigations other than clinical trials,
23 including partially controlled studies and objec-
24 tive trials without matched controls such as his-
25 torically controlled analyses, open-label studies,

1 and meta-analyses, on opioid sparing for inclu-
2 sion in product labeling.

3 (2) CONTENTS.—The guidances under para-
4 graph (1) shall address—

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

8 (B) primary and secondary endpoints for
9 the reduction of opioid use while maintaining
10 adequate pain control;

11 (C) use of real world evidence, including
12 patient registries, and patient reported out-
13 comes to support inclusion of opioid-sparing
14 data in product labeling; and

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

18 (i) commencement of such data collec-
19 tion; or

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

22 (3) PUBLIC MEETING.—Prior to updating or
23 issuing the guidances required by paragraph (1), the
24 Secretary shall consult with stakeholders, including
25 representatives of regulated industry, academia, pa-

1 tients, and provider organizations, through a public
2 meeting to be held not later than 12 months after
3 the date of enactment of this Act.

4 (4) TIMING.—The Secretary shall—

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

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

13 (c) DEFINITION.—In this section:

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

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

Passed the House of Representatives June 12, 2018.

Attest: KAREN L. HAAS,
Clerk.