

115TH CONGRESS  
2D SESSION

# S. 2665

To require guidance on how the Food and Drug Administration will consider claims of opioid sparing and on the conditions under which the Food and Drug Administration will consider misuse and abuse of drugs in making certain determinations of safety.

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## IN THE SENATE OF THE UNITED STATES

APRIL 12, 2018

Mr. YOUNG (for himself and Mr. DONNELLY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To require guidance on how the Food and Drug Administration will consider claims of opioid sparing and on the conditions under which the Food and Drug Administration will consider misuse and abuse of drugs in making certain determinations of safety.

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. OPIOID SPARING CLAIMS AND INDICATIONS.**

4       (a) OPIOID SPARING.—

5           (1) DRAFT GUIDANCE.—Not later than 1 year  
6 after the date of enactment of this Act, the Sec-  
7 retary, acting through the Commissioner of Food

1 and Drugs, shall issue draft guidance to clarify how  
2 the Food and Drug Administration will assess evi-  
3 dence to support claims of opioid sparing for non-  
4 opioid or other non-addictive medical products in-  
5 tended to treat pain. Such guidance shall include—

6 (A) data collection methodologies, includ-  
7 ing the use of innovative clinical trial designs  
8 (consistent with section 3021 of the 21st Cen-  
9 tury Cures Act (Public Law 114–255)), and  
10 real world evidence (as defined in section  
11 505F(b) of the Federal Food, Drug, and Cos-  
12 metic Act (21 U.S.C. 355g(b))), as appropriate,  
13 to support product labeling;

14 (B) ethical implications of exposure to con-  
15 trolled substances in clinical trials to support  
16 opioid sparing claims and considerations on  
17 methods to reduce harm;

18 (C) endpoints, including primary, sec-  
19 ondary, and surrogate endpoints, to evaluate  
20 the reduction in opioid use;

21 (D) best practices for communication be-  
22 tween sponsors and the agency on the develop-  
23 ment of such data collection methods, including  
24 the initiation of data collection; and

1           (E) the appropriate format to submit such  
2           data results to the Secretary.

3           (2) FINAL GUIDANCE.—Not later than 6  
4           months after the close of the period for public com-  
5           ment on the draft guidance under paragraph (1),  
6           the Secretary shall finalize such guidance.

7           (b) RISK OF ABUSE AND MISUSE.—

8           (1) DRAFT GUIDANCE.—Not later than 1 year  
9           after the date of enactment of this Act, the Sec-  
10          retary, acting through the Commissioner of Food  
11          and Drugs, shall issue draft guidance to clarify the  
12          circumstances under which the Food and Drug Ad-  
13          ministration considers misuse and abuse of drugs in  
14          making determinations of safety under paragraphs  
15          (2) and (4) of subsection (d) of section 505 of the  
16          Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
17          355) and in finding that a drug is unsafe under  
18          paragraph (1) or (2) of subsection (e) of such sec-  
19          tion.

20          (2) FINAL GUIDANCE.—Not later than 6  
21          months after the close of the period for public com-  
22          ment on the draft guidance under paragraph (1),  
23          the Secretary shall finalize such guidance.

24          (c) DEFINITIONS.—In this section—

1           (1) the term “medical product” means a drug  
2           (as that term is defined by section 201(g)(1) of the  
3           Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
4           321(g)(1))), biological product (as that term is de-  
5           fined by section 351(i) of this Act (42 U.S.C.  
6           262(i))), or device (as that term is defined by sec-  
7           tion 201(h) of the Federal Food, Drug, and Cos-  
8           metic Act (21 U.S.C. 321(h)); and  
9           (2) the term “opioid sparing” means reducing  
10          the use of opioids or other controlled substances.

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