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(Original Signature of Member)

114TH CONGRESS  
2D SESSION

**H. R.**

To require the Commissioner of Food and Drugs to seek recommendations from an advisory committee of the Food and Drug Administration before approval of certain new drugs that are opioids without abuse-deterrent properties, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Mr. SEAN PATRICK MALONEY of New York (for himself and Mr. LANCE) introduced the following bill; which was referred to the Committee on

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**A BILL**

To require the Commissioner of Food and Drugs to seek recommendations from an advisory committee of the Food and Drug Administration before approval of certain new drugs that are opioids without abuse-deterrent properties, 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 “Opioid Review Mod-  
5 ernization Act of 2016”.

1 **SEC. 2. FDA OPIOID ACTION PLAN.**

2 Chapter V of the Federal Food, Drug, and Cosmetic  
3 Act is amended by inserting after section 569 of such Act  
4 (21 U.S.C. 350bbb–8) the following:

5 **“SEC. 569–1. OPIOID ACTION PLAN.**

6 “(a) NEW DRUG APPLICATION.—

7 “(1) IN GENERAL.—Subject to paragraph (2),  
8 prior to the approval pursuant to an application  
9 under section 505(b) of a new drug that is an opioid  
10 and does not have abuse-deterrent properties, the  
11 Secretary shall refer the application to an advisory  
12 committee of the Food and Drug Administration to  
13 seek recommendations from such advisory com-  
14 mittee.

15 “(2) PUBLIC HEALTH EXEMPTION.—A referral  
16 to an advisory committee under paragraph (1) is not  
17 required with respect to a new drug if the Sec-  
18 retary—

19 “(A) finds that such a referral is not in  
20 the interest of protecting and promoting public  
21 health;

22 “(B) finds that such a referral is not nec-  
23 essary based on a review of the relevant sci-  
24 entific information; and

25 “(C) submits a notice containing the ra-  
26 tionale for such findings to the Committee on

1 Health, Education, Labor, and Pensions of the  
2 Senate and the Committee on Energy and Com-  
3 merce of the House of Representatives.

4 “(b) PEDIATRIC OPIOID LABELING.—The Secretary  
5 shall convene the Pediatric Advisory Committee of the  
6 Food and Drug Administration to seek recommendations  
7 from such Committee regarding a framework for the inclu-  
8 sion of information in the labeling of drugs that are  
9 opioids relating to the use of such drugs in pediatric popu-  
10 lations before the Secretary approves any labeling or  
11 change to labeling for any drug that is an opioid intended  
12 for use in a pediatric population.

13 “(c) SUNSET.—The requirements of subsections (a)  
14 and (b) shall cease to be effective on October 1, 2022.”.

15 **SEC. 3. PRESCRIBER EDUCATION.**

16 Not later than 1 year after the date of the enactment  
17 of this Act, the Secretary of Health and Human Services,  
18 acting through the Commissioner of Food and Drugs, as  
19 part of the Food and Drug Administration’s evaluation  
20 of the Extended-Release/Long-Acting Opioid Analgesics  
21 Risk Evaluation and Mitigation Strategy, and in consulta-  
22 tion with relevant stakeholders, shall develop recommenda-  
23 tions regarding education programs for prescribers of  
24 opioids pursuant to section 505–1 of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355–1), including rec-  
2 ommendations on—

3 (1) which prescribers should participate in such  
4 programs; and

5 (2) how often participation in such programs is  
6 necessary.

7 **SEC. 4. GUIDANCE ON EVALUATING THE ABUSE DETER-**  
8 **RENCE OF GENERIC SOLID ORAL OPIOID**  
9 **DRUG PRODUCTS.**

10 Not later than 2 years after the end of the period  
11 for public comment on the draft guidance entitled “Gen-  
12 eral Principals for Evaluating the Abuse Deterrence of Ge-  
13 neric Solid Oral Opioid Drug Products” issued by the  
14 Center for Drug Evaluation and Research of the Food and  
15 Drug Administration in March 2016, the Commissioner  
16 of Food and Drugs shall publish in the Federal Register  
17 a final version of such guidance.