

118TH CONGRESS  
2D SESSION

# H. R. 7827

To amend the Federal Food, Drug, and Cosmetic Act to encourage the development of vaccines to prevent, treat, or mitigate opioid, cocaine, methamphetamine, or alcohol use disorder, to establish an x-prize for the development of such a vaccine, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 26, 2024

Mr. SCHWEIKERT introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to encourage the development of vaccines to prevent, treat, or mitigate opioid, cocaine, methamphetamine, or alcohol use disorder, to establish an x-prize for the development of such a vaccine, 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. ENCOURAGING DEVELOPMENT OF VACCINES**  
2 **FOR OPIOID, COCAINE, METHAMPHETAMINE,**  
3 **OR ALCOHOL USE DISORDER.**

4 (a) **BREAKTHROUGH THERAPIES.**—Section 506(a) of  
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
6 356(a)) is amended by adding at the end the following:

7 “(4) **VACCINES FOR OPIOID, COCAINE, METH-**  
8 **AMPHETAMINE, OR ALCOHOL USE DISORDER.**—

9 “(A) **IN GENERAL.**—If a request is sub-  
10 mitted under paragraph (1) for a vaccine to  
11 prevent, treat, or mitigate an opioid use dis-  
12 order (including such a disorder related to  
13 fentanyl), a cocaine use disorder, a meth-  
14 amphetamine use disorder, or an alcohol use  
15 disorder, such vaccine is deemed to be a break-  
16 through therapy.

17 “(B) **SUNSET.**—Subparagraph (A) shall  
18 cease to be effective on the date that is 10  
19 years after the date of enactment of this para-  
20 graph.”.

21 (b) **FAST TRACK PRODUCTS.**—Section 506(b) of the  
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(b))  
23 is amended by adding at the end the following:

24 “(4) **VACCINES FOR OPIOID, COCAINE, METH-**  
25 **AMPHETAMINE, OR ALCOHOL USE DISORDER.**—

1           “(A) IN GENERAL.—If a request is sub-  
2           mitted under paragraph (1) for a vaccine to  
3           prevent, treat, or mitigate an opioid use dis-  
4           order (including such a disorder related to  
5           fentanyl), a cocaine use disorder, a meth-  
6           amphetamine use disorder, or an alcohol use  
7           disorder, such vaccine is deemed to be a fast  
8           track product.

9           “(B) SUNSET.—Subparagraph (A) shall  
10          cease to be effective on the date that is 10  
11          years after the date of enactment of this para-  
12          graph.”.

13          (c) PRIORITY REVIEW.—

14                 (1) IN GENERAL.—The Secretary of Health and  
15                 Human Services shall give priority review to any ap-  
16                 plication for a vaccine to prevent, treat, or mitigate  
17                 an opioid use disorder (including such a disorder re-  
18                 lated to fentanyl), a cocaine use disorder, a meth-  
19                 amphetamine use disorder, or an alcohol use dis-  
20                 order that is submitted under—

21                         (A) section 505 of the Federal Food,  
22                         Drug, and Cosmetic Act (21 U.S.C. 355); or

23                         (B) section 351 of the Public Health Serv-  
24                         ice Act (42 U.S.C. 262).



1 availability of appropriations, pay the eligible new drug  
2 sponsor \$1,000,000,000.

3 (d) SINGLE AWARD.—The Secretary of Health and  
4 Human Services may not award more than 1 Vaccine X-  
5 Prize.

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