



(Original Signature of Member)

118TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

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

Mr. SCHWEIKERT introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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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           (2) SUNSET.—Paragraph (1) shall cease to be  
2           effective on the date that is 10 years after the date  
3           of enactment of this subsection.

4 **SEC. 2. X-PRIZE FOR VACCINE FOR OPIOID, COCAINE,**  
5                           **METHAMPHETAMINE, OR ALCOHOL USE DIS-**  
6                           **ORDER.**

7           (a) ELIGIBLE NEW DRUG SPONSOR.—In this section,  
8           the term “eligible new drug sponsor” means the sponsor  
9           of a vaccine to prevent, treat, or mitigate an opioid use  
10          disorder (including such a disorder related to fentanyl),  
11          a cocaine use disorder, a methamphetamine use disorder,  
12          or an alcohol use disorder that—

13                   (1) is approved under section 505 of the Fed-  
14          eral Food, Drug, and Cosmetic Act (21 U.S.C. 355)  
15          or is licensed under section 351 of the Public Health  
16          Service Act (42 U.S.C. 262); and

17                   (2) is mass-produced.

18          (b) APPLICATION.—An eligible new drug sponsor  
19          may submit to the Secretary of Health and Human Serv-  
20          ices an application for an award, to be known as the “Vac-  
21          cine X-Prize.

22          (c) AWARD.—Subject to subsection (d), if the Sec-  
23          retary of Health and Human Services determines that an  
24          eligible new drug sponsor has submitted an application  
25          under subsection (b), the Secretary shall, subject to the

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.