

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.

IN THE HOUSE OF REPRESENTATIVES

MARCH 26, 2024

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

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.

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