

AMENDMENT TO H.R. 27
OFFERED BY MR. SCHWEIKERT OF ARIZONA

At the end of the bill, add the following:

1 **SEC. ____.** **ENCOURAGING DEVELOPMENT OF VACCINES**
2 **FOR OPIOID USE DISORDER.**

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

6 “(4) **VACCINES FOR OPIOID USE DISORDER.**—

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

13 “(B) **SUNSET.**—Subparagraph (A) shall
14 cease to be effective on the date that is 10
15 years after the date of enactment of this para-
16 graph.”.

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

20 “(4) **VACCINES FOR OPIOID 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), such vaccine is deemed to be a fast
6 track product.

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

11 (c) PRIORITY REVIEW.—

12 (1) IN GENERAL.—The Secretary of Health and
13 Human Services shall give priority review to any ap-
14 plication for a vaccine to prevent, treat, or mitigate
15 an opioid use disorder (including such a disorder re-
16 lated to fentanyl) that is submitted under—

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

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

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

