

AMENDMENT TO H.R. 8038
OFFERED BY MR. SCHWEIKERT OF ARIZONA

At the end of the bill (before the short title), insert the following:

1 ENCOURAGING DEVELOPMENT OF VACCINES FOR OPIOID
2 USE DISORDER

3 SEC. ____.

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 USE DISORDER.—

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

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

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

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

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

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

15 (c) PRIORITY REVIEW.—

16 (1) IN GENERAL.—The Secretary of Health and
17 Human Services shall give priority review to any ap-
18 plication for a vaccine to prevent, treat, or mitigate
19 an opioid use disorder (including such a disorder re-
20 lated to fentanyl) 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.

