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(Original Signature of Member)

119TH CONGRESS  
1ST SESSION

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

To amend the Public Health Service Act to end the liability shield for  
vaccine manufacturers, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

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

\_\_\_\_\_  
**A BILL**

To amend the Public Health Service Act to end the liability  
shield for vaccine manufacturers, 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,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “End the Vaccine  
5       Carveout Act”.

6       **SEC. 2. ENDING LIABILITY SHIELD FOR VACCINE MANU-**  
7       **FACTURERS.**

8       (a) NATIONAL VACCINE INJURY COMPENSATION  
9       PROGRAM.—

1           (1) PETITIONS FOR COMPENSATION.—Section  
2       2111 of the Public Health Service Act (42 U.S.C.  
3       300aa–11) is amended—

4           (A) in subsection (a)—

5               (i) by striking paragraphs (2), (3),  
6               (5), and (6);

7               (ii) by inserting after paragraph (1)  
8               the following:

9           “(2) Beginning on the date of enactment of the  
10       End the Vaccine Carveout Act, and subject to para-  
11       graph (4)(B), irrespective of whether a person has  
12       filed a petition for compensation under the Program  
13       in relation to a vaccine-related injury or death, such  
14       person may bring a civil action against a vaccine ad-  
15       ministrator or manufacturer in a State or Federal  
16       court for damages arising from such injury or  
17       death.”;

18               (iii) by redesignating paragraph (4) as  
19       paragraph (3);

20               (iv) by redesignating paragraphs (7)  
21       through (10) as paragraphs (4) through  
22       (7), respectively; and

23               (v) by amending paragraph (4) (as so  
24       redesignated) to read as follows:

1           “(4)(A) If in a civil action brought against a  
2 vaccine administrator or manufacturer for a vaccine-  
3 related injury or death damages are awarded under  
4 a judgment of a court or a settlement of such action,  
5 the person who brought such action may not file a  
6 petition under subsection (b) for such injury or  
7 death, and any pending petition for such injury or  
8 death shall be dismissed.

9           “(B) If compensation is awarded for a petition  
10 filed under the Program for a vaccine-related injury  
11 or death, the person who filed such petition may not  
12 bring a civil action against a vaccine administrator  
13 or manufacturer for such injury or death, and any  
14 pending civil action for such injury or death shall be  
15 dismissed.”; and

16           (B) in subsection (c)(1)(B)(i)(III), by  
17 striking “not later than 6 months”.

18           (2) LIMITATIONS OF ACTIONS.—

19           (A) IN GENERAL.—Section 2116 of the  
20 Public Health Service Act (42 U.S.C. 300aa–  
21 16) is amended—

22           (i) in subsection (a)—

23                   (I) in paragraph (2), by striking  
24 “no petition may be filed for com-  
25 pensation under the Program for such

1 injury after the expiration of 36  
2 months after the date of the occur-  
3 rence of the first symptom or mani-  
4 festation of onset or of the significant  
5 aggravation of such injury” and in-  
6 serting “unless prohibited by section  
7 2111(a)(4)(A), a petition may be filed  
8 for compensation under the Program  
9 for such injury at any time”; and

10 (II) in paragraph (3), by striking  
11 “no petition may be filed for com-  
12 pensation under the Program for such  
13 death after the expiration of 24  
14 months from the date of the death  
15 and no such petition may be filed  
16 more than 48 months after the date  
17 of the occurrence of the first symptom  
18 or manifestation of onset or of the  
19 significant aggravation of the injury  
20 from which the death resulted” and  
21 inserting “unless prohibited by section  
22 2111(a)(4)(A), a petition may be filed  
23 for compensation under the Program  
24 for such death at any time”; and  
25 (ii) in subsection (b)—

1 (I) by striking “notwithstanding  
2 section 2111(b)(2)” and inserting  
3 “notwithstanding section 2111(b)(2),  
4 and unless prohibited by section  
5 2111(a)(4)(A)”;

6 (II) by striking “not later than 2  
7 years after the effective date of the re-  
8 vision” and inserting “at any time”;

9 (III) by striking “table if—” and  
10 inserting “table if such vaccine-related  
11 injury or death occurred before the ef-  
12 fective date of this part.”; and

13 (IV) by striking paragraphs (1)  
14 and (2).

15 (B) RETROACTIVITY.—The amendments  
16 made by subparagraph (A) shall apply as if in-  
17 cluded in the enactment of section 2116 of the  
18 Public Health Service Act (42 U.S.C. 300aa–  
19 16).

20 (3) REPEALS.—

21 (A) ELECTION.—Section 2121(a) of the  
22 Public Health Service Act (42 U.S.C. 300aa–  
23 21(a)) is repealed.

1 (B) STANDARDS OF RESPONSIBILITY.—  
2 Section 2122 of the Public Health Service Act  
3 (42 U.S.C. 300aa–22) is repealed.

4 (C) TRIAL.—Section 2123 of the Public  
5 Health Service Act (42 U.S.C. 300aa–23) is re-  
6 pealed.

7 (4) CONFORMING AMENDMENTS.—

8 (A) ATTORNEYS’ FEES.—Section 2115(e)  
9 of the Public Health Service Act (42 U.S.C.  
10 300aa–15(e)) is amended—

11 (i) by striking paragraph (2); and

12 (ii) by redesignating paragraph (3) as  
13 paragraph (2).

14 (B) PAYMENT OF COMPENSATION.—Sec-  
15 tion 2115(f) of the Public Health Service Act  
16 (42 U.S.C. 300aa–15(f)) is amended—

17 (i) by striking paragraph (1);

18 (ii) by redesignating paragraphs (2)  
19 through (4) as paragraphs (1) through (3),  
20 respectively;

21 (iii) in paragraph (1) (as so redesign-  
22 ated), by striking “Such compensation  
23 may not be paid after an election under  
24 section 2121(a) to file a civil action for  
25 damages for the vaccine-related injury or

1 death for which such compensation was  
2 awarded.”; and

3 (iv) in paragraph (3)(B) (as so reded-  
4 icated), by striking “If the appropriations  
5 under subsection (j) are insufficient to  
6 make a payment of an annual installment,  
7 the limitation on civil actions prescribed by  
8 section 2121(a) shall not apply to a civil  
9 action for damages brought by the peti-  
10 tioner entitled to the payment.”.

11 (C) STATE LIMITATIONS OF ACTIONS.—  
12 Section 2116(c) of the Public Health Service  
13 Act (42 U.S.C. 300aa–16(c)) is amended by  
14 striking “an election is made under section  
15 2121(a) to file the civil action” and inserting  
16 “judgment is entered by the United States  
17 Court of Federal Claims (or, if an appeal is  
18 taken under section 2112(f), the appellate  
19 court’s mandate is issued) with respect to the  
20 petition”.

21 (D) TERMINATION OF PROGRAM.—Section  
22 2134(b)(1) of the Public Health Service Act  
23 (42 U.S.C. 300aa–34(b)(1)) is amended—

24 (i) by striking “and accepted under  
25 section 2121(a)”;

1 (ii) by striking “Section 2111(a) and  
2 part B shall not apply to civil actions for  
3 damages for a vaccine-related injury or  
4 death for which a petition may not be filed  
5 because of subparagraph (B).”.

6 (b) EXCLUDING COVID–19 VACCINES FROM DEFINITION OF COVERED COUNTERMEASURE.—Section 319F–  
7 3(i)(1) of the Public Health Service Act (42 U.S.C. 247d–  
8 6d(i)(1)) is amended to read as follows:

10 “(1) COVERED COUNTERMEASURE.—The term  
11 ‘covered countermeasure’—

12 “(A) means—

13 “(i) a qualified pandemic or epidemic  
14 product (as defined in paragraph (7));

15 “(ii) a security countermeasure (as  
16 defined in section 319F–2(c)(1)(B));

17 “(iii) a drug (as such term is defined  
18 in section 201(g)(1) of the Federal Food,  
19 Drug, and Cosmetic Act (21 U.S.C.  
20 321(g)(1)), biological product (as such  
21 term is defined by section 351(i) of this  
22 Act), or device (as such term is defined by  
23 section 201(h) of the Federal Food, Drug  
24 and Cosmetic Act (21 U.S.C. 321(h)) that  
25 is authorized for emergency use in accord-



1           ance with section 564, 564A, or 564B of  
2           the Federal Food, Drug, and Cosmetic  
3           Act; or

4                 “(iv) a respiratory protective device  
5           that is approved by the National Institute  
6           for Occupational Safety and Health under  
7           part 84 of title 42, Code of Federal Regu-  
8           lations (or any successor regulations), and  
9           that the Secretary determines to be a pri-  
10          ority for use during a public health emer-  
11          gency declared under section 319; and

12                 “(B) does not include any vaccine used to  
13          mitigate, prevent, or treat COVID–19.”.