

119TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mr. PAUL introduced the following bill; which was read twice and 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.—Section
19 2116(b) of the Public Health Service Act (42 U.S.C.
20 300aa–16(b)) is amended by striking “notwith-
21 standing section 2111(b)(2)” and inserting “not-
22 withstanding section 2111(b)(2), and unless prohib-
23 ited by section 2111(a)(4)(A)”.

24 (3) REPEALS.—

1 (A) ELECTION.—Section 2121(a) of the
2 Public Health Service Act (42 U.S.C. 300aa–
3 21(a)) is repealed.

4 (B) STANDARDS OF RESPONSIBILITY.—
5 Section 2122 of the Public Health Service Act
6 (42 U.S.C. 300aa–22) is repealed.

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

10 (4) CONFORMING AMENDMENTS.—

11 (A) ATTORNEYS’ FEES.—Section 2115(e)
12 of the Public Health Service Act (42 U.S.C.
13 300aa–15(e)) is amended—

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

15 (ii) by redesignating paragraph (3) as
16 paragraph (2).

17 (B) PAYMENT OF COMPENSATION.—Sec-
18 tion 2115(f) of the Public Health Service Act
19 (42 U.S.C. 300aa–15(f)) is amended—

20 (i) by striking paragraph (1);

21 (ii) by redesignating paragraphs (2)
22 through (4) as paragraphs (1) through (3),
23 respectively;

24 (iii) in paragraph (1) (as so redesign-
25 nated), by striking “Such compensation

1 may not be paid after an election under
2 section 2121(a) to file a civil action for
3 damages for the vaccine-related injury or
4 death for which such compensation was
5 awarded.”; and

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

14 (C) STATE LIMITATIONS OF ACTIONS.—

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

1 (D) TERMINATION OF PROGRAM.—Section
2 2134(b)(1) of the Public Health Service Act
3 (42 U.S.C. 300aa–34(b)(1)) is amended—

4 (i) by striking “and accepted under
5 section 2121(a)”;

6 (ii) by striking “Section 2111(a) and
7 part B shall not apply to civil actions for
8 damages for a vaccine-related injury or
9 death for which a petition may not be filed
10 because of subparagraph (B).”.

11 (b) EXCLUDING COVID–19 VACCINES FROM DEFINI-
12 TION OF COVERED COUNTERMEASURE.—Section 319F–
13 3(i)(1) of the Public Health Service Act (42 U.S.C. 247d–
14 6d(i)(1)) is amended to read as follows:

15 “(1) COVERED COUNTERMEASURE.—The term
16 ‘covered countermeasure’—

17 “(A) means—

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

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

22 “(iii) a drug (as such term is defined
23 in section 201(g)(1)) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C.
25 321(g)(1)), biological product (as such

1 term is defined by section 351(i) of this
2 Act), or device (as such term is defined by
3 section 201(h) of the Federal Food, Drug
4 and Cosmetic Act (21 U.S.C. 321(h))) that
5 is authorized for emergency use in accord-
6 ance with section 564, 564A, or 564B of
7 the Federal Food, Drug, and Cosmetic
8 Act; or

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

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