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(Original Signature of Member)

118TH CONGRESS
2D SESSION

H. R. _____

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

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''End the Vaccine Carveout Act''.

SEC. 2. ENDING LIABILITY SHIELD FOR VACCINE MANUFACTURERS.

(a) NATIONAL VACCINE INJURY COMPENSATION PROGRAM.—

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

(A) in subsection (a)—

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

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

''(2) Beginning on the date of enactment of the End the Vaccine Carveout Act, and subject to paragraph (4)(B), irrespective of whether a person has filed a petition for compensation under the Program in relation to a vaccine-related injury or death, such person may bring a civil action against a vaccine administrator or manufacturer in a State or Federal court for damages arising from such injury or death.'';

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

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

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

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

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

(B) in subsection (c)(1)(B)(i)(III), by striking ''not later than 6 months''.

(2) LIMITATIONS OF ACTIONS.—

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

(i) in subsection (a)—

(I) in paragraph (2), by striking ''no petition may be filed for compensation under the Program for such

injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury'' and inserting ''unless prohibited by section 2111(a)(4)(A), a petition may be filed for compensation under the Program for such injury at any time''; and

(II) in paragraph (3), by striking ''no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted'' and inserting ''unless prohibited by section 2111(a)(4)(A), a petition may be filed for compensation under the Program for such death at any time''; and

(ii) in subsection (b)—

(I) by striking ''notwithstanding section 2111(b)(2)'' and inserting ''notwithstanding section 2111(b)(2), and unless prohibited by section 2111(a)(4)(A)'';

(II) by striking ''not later than 2 years after the effective date of the revision'' and inserting ''at any time'';

(III) by striking ''table if—'' and inserting ''table if such vaccine-related injury or death occurred before the effective date of this part.''; and

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

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

(3) REPEALS.—

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

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

(C) TRIAL.—Section 2123 of the Public Health Service Act (42 U.S.C. 300aa–23) is repealed.

(4) CONFORMING AMENDMENTS.—

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

(i) by striking paragraph (2); and

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

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

(i) by striking paragraph (1);

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

(iii) in paragraph (1) (as so redesignated), by striking ''Such compensation may not be paid after an election under section 2121(a) to file a civil action for damages for the vaccine-related injury or

death for which such compensation was awarded.''; and

(iv) in paragraph (3)(B) (as so redesignated), by striking ''If the appropriations under subsection (j) are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 2121(a) shall not apply to a civil action for damages brought by the petitioner entitled to the payment.''.

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

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

(i) by striking ''and accepted under section 2121(a)''; and

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

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

''(1) COVERED COUNTERMEASURE.—The term 'covered countermeasure'—

''(A) means—

''(i) a qualified pandemic or epidemic product (as defined in paragraph (7));

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

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

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

''(iv) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency declared under section 319; and

''(B) does not include any vaccine used to mitigate, prevent, or treat COVID–19.''.