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(Original Signature of Member)

118TH CONGRESS
2D SESSION

H. R. _____

To criminalize fraudulent statements made with respect to clinical vaccine trials.

IN THE HOUSE OF REPRESENTATIVES

Mr. GREEN of Tennessee introduced the following bill; which was referred to the Committee on _____

A BILL

To criminalize fraudulent statements made with respect to clinical vaccine trials.

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 ''Vaccines In Trial And Liability Act of 2024'' or the ''VITAL Act of 2024''.

SEC. 2. MEDICAL RESEARCH COMPANY OR SPONSOR.

(a) IN GENERAL.—Chapter 47 of title 18, United States Code, is amended by adding at the end the following:

"§ 1041. Clinical vaccine trial fraud

''Whoever, being a medical research company or sponsor, makes a fraudulent statement to, or conceals from, any department or agency of the United States, any material data collected from a clinical vaccine trial, shall be fined under this title, imprisoned not more than 5 years, or both.''.

(b) CLERICAL AMENDMENT.—The table of sections for chapter 47 of title 18, United States Code, is amended by adding at the end the following:

''1041. Clinical vaccine trial fraud.''.

SEC. 3. SCOPE OF AUTHORIZATION.

Section 564(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3(c)) is amended—

(1) in paragraph (4), by striking ''and''

(2) by redesignating paragraph (5) as paragraph (6); and

(3) by inserting after paragraph (4) the following:

''(5) the authorization is based on a certification by a medical research company or sponsor that no fraudulent material statements were made, and no material information was concealed, with respect to the circumstances described under subsection (b)(1) or the criteria under this subsection; and''.

SEC. 4. REVISION AND REVOCATION.

Section 564(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3(g)(2)) is amended—

(1) in subparagraph (B), by striking ''or'' at the end;

(2) by redesignating subparagraph (C) as subparagraph (D); and

(3) by inserting after subparagraph (B) the following:

''(C) the Secretary determines that fraudulent material statements were made, or material information was concealed, with respect to the circumstances described under subsection (b)(1) or the criteria under subsection (c); or''.

SEC. 5. EXCEPTION TO LIMITATION ON LIABILITY.

Section 2(b)(1) of the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (21 U.S.C. 360bbb–0a note) is amended—

(1) in subparagraph (A), by inserting '', unless a fraudulent material statement was made, or material information was concealed, with respect to data collected from a clinical trial of the investigational drug'' before the semicolon; and

(2) in subparagraph (B), by inserting '', including a fraudulent material statement made, or mate-

rial information concealed, with respect to data collected from a clinical trial of the investigational drug'' before the period.

SEC. 6. EXCEPTION TO TARGETED LIABILITY PROTECTIONS FOR PANDEMIC AND EPIDEMIC PRODUCTS.

Section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d(c)) is amended—

(1) in subsection (c)—

(A) in paragraph (1)(A)—

(i) by redesignating clauses (i), (ii), and (iii) as subclauses (I), (II), and (III), respectively;

(ii) by moving subclauses (I), (II), and (III), as redesignated, 2 ems to the right;

(iii) by striking the period at the end of subclause (III), as redesignated;

(iv) by striking ''subsection (d), denote'' and inserting the following: ''subsection (d)—

''(i) denote''; and

(v) by adding at the end the following:

''(ii) includes—

''(I) making a fraudulent material statement with respect to data collected from a clinical trial; or

''(II) concealing material information with respect to data collected from a clinical trial.''; and

(B) in paragraph (5)(A)—

(i) in the matter preceding clause (i), by striking ''subsection (d) if—'' and inserting ''subsection (d)—'';

(ii) in clause (i)—

(I) by inserting ''if'' before ''neither''; and

(II) by striking ''or'' at the end;

(iii) in clause (ii)—

(I) by inserting ''if'' before ''such an enforcement''; and

(II) by striking the period at the end and inserting ''; and''; and

(iv) by adding at the end the following:

''(iii) unless the Secretary determines, after notice and opportunity for a hearing, that a fraudulent material statement was made, or material information was con-

cealed, by a covered person with respect to data collected from a clinical trial of a covered countermeasure.'';

(2) in subsection (d) by adding at the end the following:

''(11) AWARD OF DAMAGES.—Notwithstanding any other provision of law, the amount of an award of damages made to a plaintiff may not be reduced because of any other award for damages the plaintiff may receive as a result of such claim.''; and

(3) subsection (e), by striking paragraph (7).

SEC. 7. NATIONAL VACCINE INJURY COMPENSATION PROGRAM.

Section 2122 of the Public Health Service Act (42 U.S.C. 300aa–22) is amended by adding at the end the following:

''(f) LIABILITY.—

''(1) FRAUDULENT MATERIAL STATEMENT.—No civil action against a vaccine manufacturer or vaccine sponsor shall be barred under this part if the Secretary determines, after notice and opportunity for a hearing, that a fraudulent material statement was made, or material information was concealed, by a vaccine manufacturer with respect to data collected from a clinical trial of a vaccine.

''(2) AWARD OF DAMAGES.—

''(A) IN GENERAL.—Notwithstanding any other provision of law, an plaintiff bringing a claim pursuant to paragraph (1) may—

''(i) seek compensation under the program established under this part; and

''(ii) concurrently bring an action with respect to such claim in any appropriate United States district court.

''(B) AWARD OF DAMAGES.—Notwithstanding any other provision of law, the amount of an award of damages made to a plaintiff for a claim pursuant to paragraph (1) may not be reduced on the basis of any other damages the plaintiff may receive as a result of such claim.

''(3) APPLICABILITY WITH RESPECT TO COVID–19 VACCINE.—Notwithstanding any other provision of law, a civil action against a vaccine manufacturer pursuant to paragraph (1) with respect to a vaccine related to COVID–19 may be made at any time.

''(4) COVID–19 DEFINITION.—In this section, the term 'COVID–19' means the coronavirus disease caused by the severe acute respiratory syndrome coronavirus 2 or the SARS–CoV–2. This term also

relates to any and all variations of that virus of which there is no termination date for this term.''

SEC. 8. LIABILITY HEARING.

(a) FRAUDULENT MATERIAL OR STATEMENTS.—In the case that the Secretary of Health and Human Services determines that a vaccine manufacturer or vaccine sponsor has made fraudulent material or statements or concealed material information with respect to a situation described in this Act, or an amendment made by this Act, the Secretary shall and provide such manufacturer or sponsor 30 days to refute a determination made in a hearing described in subsection (b).

(b) HEARING.—

(1) IN GENERAL.—The Secretary shall determine a date, time, and format for a hearing under this subsection, including a requirement that the vaccine manufacturer or vaccine sponsor provide any requested document to the Secretary not more than five days before the hearing.

(2) FORMAT.—The format of a hearing under paragraph (1) shall be determined by the Secretary.

(3) PUBLICATION.—Any written or verbal testimony submitted by the vaccine manufacturer or vaccine sponsor at the hearing under paragraph (1)

shall be published on the internet website of the Secretary of Health and Human Services.

(c) DOES NOT PROVIDE INFORMATION.—In the case that the vaccine manufacturer or vaccine sponsor does not respond to the Secretary in accordance with this section, an initial determination of fraud shall be maintained and shall have the full force and effect of this Act.