

118TH CONGRESS
2D SESSION

H. R. 8380

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

IN THE HOUSE OF REPRESENTATIVES

MAY 14, 2024

Mr. GREEN of Tennessee introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

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

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 “Vaccines In Trial And
5 Liability Act of 2024” or the “VITAL Act of 2024”.

6 **SEC. 2. MEDICAL RESEARCH COMPANY OR SPONSOR.**

7 (a) IN GENERAL.—Chapter 47 of title 18, United
8 States Code, is amended by adding at the end the fol-
9 lowing:

1 **“§ 1041. Clinical vaccine trial fraud**

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

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

“1041. Clinical vaccine trial fraud.”.

11 **SEC. 3. SCOPE OF AUTHORIZATION.**

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

14 (1) in paragraph (4), by striking “and”

15 (2) by redesignating paragraph (5) as para-
16 graph (6); and

17 (3) by inserting after paragraph (4) the fol-
18 lowing:

19 “(5) the authorization is based on a certifi-
20 cation by a medical research company or sponsor
21 that no fraudulent material statements were made,
22 and no material information was concealed, with re-
23 spect to the circumstances described under sub-
24 section (b)(1) or the criteria under this subsection;
25 and”.

1 **SEC. 4. REVISION AND REVOCATION.**

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

4 (1) in subparagraph (B), by striking “or” at
5 the end;

6 (2) by redesignating subparagraph (C) as sub-
7 paragraph (D); and

8 (3) by inserting after subparagraph (B) the fol-
9 lowing:

10 “(C) the Secretary determines that fraudu-
11 lent material statements were made, or material
12 information was concealed, with respect to the
13 circumstances described under subsection (b)(1)
14 or the criteria under subsection (c); or”.

15 **SEC. 5. EXCEPTION TO LIMITATION ON LIABILITY.**

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

20 (1) in subparagraph (A), by inserting “, unless
21 a fraudulent material statement was made, or mate-
22 rial information was concealed, with respect to data
23 collected from a clinical trial of the investigational
24 drug” before the semicolon; and

25 (2) in subparagraph (B), by inserting “, includ-
26 ing a fraudulent material statement made, or mate-

1 rial information concealed, with respect to data col-
2 lected from a clinical trial of the investigational
3 drug” before the period.

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

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

8 (1) in subsection (c)—

9 (A) in paragraph (1)(A)—

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

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

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

18 (iv) by striking “subsection (d), de-
19 note” and inserting the following: “sub-
20 section (d)—

21 “(i) denote”; and

22 (v) by adding at the end the following:

23 “(ii) includes—

1 “(I) making a fraudulent mate-
2 rial statement with respect to data
3 collected from a clinical trial; or

4 “(II) concealing material infor-
5 mation with respect to data collected
6 from a clinical trial.”; and

7 (B) in paragraph (5)(A)—

8 (i) in the matter preceding clause (i),
9 by striking “subsection (d) if—” and in-
10 serting “subsection (d)—”;

11 (ii) in clause (i)—

12 (I) by inserting “if” before “nei-
13 ther”; and

14 (II) by striking “or” at the end;

15 (iii) in clause (ii)—

16 (I) by inserting “if” before “such
17 an enforcement”; and

18 (II) by striking the period at the
19 end and inserting “; and”; and

20 (iv) by adding at the end the fol-
21 lowing:

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

1 cealed, by a covered person with respect to
2 data collected from a clinical trial of a cov-
3 ered countermeasure.”;

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

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

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

12 **SEC. 7. NATIONAL VACCINE INJURY COMPENSATION PRO-**
13 **GRAM.**

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

17 “(f) LIABILITY.—

18 “(1) FRAUDULENT MATERIAL STATEMENT.—
19 No civil action against a vaccine manufacturer or
20 vaccine sponsor shall be barred under this part if the
21 Secretary determines, after notice and opportunity
22 for a hearing, that a fraudulent material statement
23 was made, or material information was concealed, by
24 a vaccine manufacturer with respect to data col-
25 lected from a clinical trial of a vaccine.

1 “(2) AWARD OF DAMAGES.—

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

5 “(i) seek compensation under the pro-
6 gram established under this part; and

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

10 “(B) AWARD OF DAMAGES.—Notwith-
11 standing any other provision of law, the amount
12 of an award of damages made to a plaintiff for
13 a claim pursuant to paragraph (1) may not be
14 reduced on the basis of any other damages the
15 plaintiff may receive as a result of such claim.

16 “(3) APPLICABILITY WITH RESPECT TO COVID-
17 19 VACCINE.—Notwithstanding any other provision
18 of law, a civil action against a vaccine manufacturer
19 pursuant to paragraph (1) with respect to a vaccine
20 related to COVID-19 may be made at any time.

21 “(4) COVID-19 DEFINITION.—In this section,
22 the term ‘COVID-19’ means the coronavirus disease
23 caused by the severe acute respiratory syndrome
24 coronavirus 2 or the SARS-CoV-2. This term also

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

3 **SEC. 8. LIABILITY HEARING.**

4 (a) **FRAUDULENT MATERIAL OR STATEMENTS.**—In
5 the case that the Secretary of Health and Human Services
6 determines that a vaccine manufacturer or vaccine sponsor
7 has made fraudulent material or statements or concealed
8 material information with respect to a situation described
9 in this Act, or an amendment made by this Act, the Sec-
10 retary shall and provide such manufacturer or sponsor 30
11 days to refute a determination made in a hearing de-
12 scribed in subsection (b).

13 (b) **HEARING.**—

14 (1) **IN GENERAL.**—The Secretary shall deter-
15 mine a date, time, and format for a hearing under
16 this subsection, including a requirement that the
17 vaccine manufacturer or vaccine sponsor provide any
18 requested document to the Secretary not more than
19 five days before the hearing.

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

22 (3) **PUBLICATION.**—Any written or verbal testi-
23 mony submitted by the vaccine manufacturer or vac-
24 cine sponsor at the hearing under paragraph (1)

1 shall be published on the internet website of the Sec-
2 retary of Health and Human Services.

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

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