

Mike Braun
Amendment #6

AMENDMENT NO. _____ Calendar No. _____

Purpose: To amend the Countermeasure Injury Compensation Program with respect to COVID-19 vaccines.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 3799

To prepare for, and respond to, existing viruses, emerging new threats, and pandemics.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. BRAUN

Viz:

1 At the appropriate place in subtitle A of title I, insert
 2 the following:

3 **SEC. 1 ____ . AMENDMENT TO THE COUNTERMEASURE IN-**
 4 **JURY COMPENSATION PROGRAM.**

5 Section 319F-4 of the Public Health Service Act (42
 6 U.S.C. 247d-6e) is amended—

7 (1) in subsection (b)—

8 (A) in paragraph (1), by striking “under
 9 319F-3(b)” and inserting “under section
 10 319F-3(b)”;

11 (B) in paragraph (2)—

1 (i) by striking “and be in the same
2 amount” and all that follows through
3 “shall not apply” and inserting “be in the
4 same amount, and be subject to the same
5 conditions as is prescribed by section
6 2115”;

7 (C) by striking paragraphs (3) and (4) and
8 inserting the following:

9 “(3) DETERMINATION OF ELIGIBILITY AND
10 COMPENSATION.—Compensation shall be awarded
11 under this section to eligible individuals in accord-
12 ance with the procedure set forth in sections 2111,
13 2112, 2113, and 2121 for purposes of the National
14 Vaccine Injury Compensation Program, subject to
15 the other provisions of this section.”;

16 (D) by inserting before paragraph (5) the
17 following:

18 “(4) TIME FOR FILING PETITIONS.—

19 “(A) PREVIOUSLY SUBMITTED RE-
20 QUESTS.—

21 “(i) PENDING CLAIMS.—In the case of
22 a request for compensation submitted
23 under this section before the date of enact-
24 ment of the PREVENT Pandemics Act for
25 which no compensation has been provided

1 prior to such date of enactment, in order
2 to be eligible for compensation under this
3 section, not later than 28 months after
4 such date of enactment, the individual
5 shall submit a new petition under this sec-
6 tion, consistent with the amendments made
7 by the PREVENT Pandemics Act.

8 “(ii) PREVIOUSLY PAID CLAIMS.—In
9 the case of a request for compensation sub-
10 mitted under this section and paid under
11 this section before the date of enactment of
12 the PREVENT Pandemics Act that relates
13 to a COVID-19 countermeasure, the indi-
14 vidual receiving such compensation may
15 submit a subsequent petition under this
16 section for additional compensation in the
17 amount the individual would have received
18 for such claim under this section after
19 such date of enactment, less the amount
20 already received by the individual.

21 “(B) SUBSEQUENT PETITIONS.—In the
22 case of a an injury or death resulting from the
23 administration or use of a covered counter-
24 measure to which subparagraph (A) does not

1 apply, a petition for benefits or compensation
2 under this section shall be filed not later than—

3 “(i) subject to clause (ii)—

4 “(I) in the case of serious phys-
5 ical injury, 3 years after the first
6 symptom or manifestation of onset of
7 a significant aggravation of a covered
8 injury; or

9 “(II) in the case of death—

10 “(aa) 2 years after death
11 from the administration or use of
12 the covered countermeasure; and

13 “(bb) 4 years after the oc-
14 currence of the first symptom or
15 manifestation of onset or of the
16 significant aggravation of the in-
17 jury from which the death re-
18 sulted; and

19 “(ii) in the case that a covered coun-
20 termeasure is added to the table under
21 paragraph (5)(A) and the effect is to per-
22 mit an individual who was not, before such
23 addition, eligible to seek compensation
24 under this section, such individual may file
25 a petition for such compensation not later

1 than 2 years after the effective date of the
2 addition of such countermeasure.”;

3 (E) in paragraph (5), by striking subpara-
4 graphs (B) and (C) and inserting the following:

5 “(B) AMENDMENT WITH RESPECT TO
6 COVID-19 VACCINES.—

7 “(i) IN GENERAL.—Not later than 60
8 days after receipt of the report under sub-
9 paragraph (C)(iii), the Secretary, taking
10 into consideration such report, shall amend
11 the covered countermeasure injury table
12 established under subparagraph (A) to in-
13 clude all injuries related to COVID-19
14 vaccines that meet the standard described
15 in subparagraph (A). In amending such
16 table, the Secretary shall consider injuries
17 caused by use of any vaccine that is, or
18 was, the subject of an emergency use au-
19 thorization under section 564 of the Fed-
20 eral Food, Drug, and Cosmetic Act.

21 “(ii) EXPLANATION OF CERTAIN DE-
22 TERMINATIONS.—With respect to any rec-
23 ommendation of the COVID-19 Vaccine
24 Commission included in the report under
25 subparagraph (C)(iii) that the Secretary

1 does not adopt pursuant to this subpara-
2 graph, the Secretary, not later than 7 days
3 after the covered countermeasure injury
4 table has been amended pursuant to clause
5 (i), shall publish a written explanation of
6 the determination not to adopt such rec-
7 ommendation.

8 “(C) COVID-19 VACCINE COMMISSION.—

9 “(i) IN GENERAL.—There is estab-
10 lished a commission to be known as the
11 COVID-19 Vaccine Commission (referred
12 to in this subparagraph as the ‘Commis-
13 sion’) that is tasked with identifying cov-
14 ered injuries related to COVID-19 vac-
15 cines, for purposes of recommending to the
16 Secretary injuries for inclusion on the cov-
17 ered countermeasure injury table, as de-
18 scribed in subparagraph (B).

19 “(ii) MEMBERSHIP.—

20 “(I) IN GENERAL.—The Commis-
21 sion shall be composed of the fol-
22 lowing:

23 “(aa) The Secretary, or a
24 designee of the Secretary, to
25 serve as an ex officio member.

1 “(bb) The following mem-
2 bers, selected, not later than 30
3 days after the date of enactment
4 of the PREVENT Pandemics
5 Act, in accordance with subclause
6 (II):

7 “(AA) 3 members ap-
8 pointed by the Chair of the
9 Committee on Health, Edu-
10 cation, Labor, and Pensions
11 of the Senate.

12 “(BB) 3 members ap-
13 pointed by the Ranking
14 Member of the Committee
15 on Health, Education,
16 Labor, and Pensions of the
17 Senate.

18 “(CC) 3 members ap-
19 pointed by the Chair of the
20 Committee on Energy and
21 Commerce of the House of
22 Representatives.

23 “(DD) 3 members ap-
24 pointed by the Ranking
25 Member of the Committee

1 on Energy and Commerce of
2 the House of Representa-
3 tives.

4 “(II) ELIGIBILITY.—Members se-
5 lected to serve on the Commission
6 pursuant to subclause (I)(bb) shall—

7 “(aa) be chosen on the basis
8 of their experience, integrity, im-
9 partiality, and good judgement;

10 “(bb) at the time of appoint-
11 ment, not be elected or appointed
12 officers or employees in the exec-
13 utive, legislative, or judicial
14 branch of the Federal Govern-
15 ment; and

16 “(cc) at the time of appoint-
17 ment, not be a member of the
18 board or an employee of an entity
19 whose product is under review, or
20 expected to be under review, by
21 the Commission.

22 “(III) NO COMPENSATION.—
23 Members of the Commission shall not
24 be compensated.

1 “(IV) CONFLICT OF INTEREST.—

2 Each member of the Commission shall
3 recuse themselves from advising on a
4 covered countermeasure for which the
5 member has a conflict of interest as
6 described in section 208 of title 18,
7 United States Code.

8 “(iii) REPORT.—No later than one
9 year after the date of enactment of the
10 PREVENT Pandemics Act, the Commis-
11 sion shall submit to the Secretary and
12 make publicly available a report identifying
13 covered injuries considered for purposes of
14 inclusion on the covered countermeasure
15 injury table pursuant to subparagraph (B),
16 and the vote counts and outcomes for each
17 such injury.

18 “(iv) SUNSET.—The Commission es-
19 tablished under this subparagraph shall be
20 terminated upon publication of the report
21 under clause (iii).”;

22 (F) by redesignating paragraph (6) as
23 paragraph (7);

24 (G) by inserting after paragraph (5) the
25 following:

1 “(6) ELECTRONIC FILING OF PETITIONS.—The
2 clerk of the United States Court of Federal Claims
3 shall provide an option for the electronic filing of a
4 petition to initiate a proceeding for compensation
5 under this section.”; and

6 (H) in paragraph (7), as so redesignated—

7 (i) by striking “sections 262, 263,
8 264, 265, and 266” and inserting “sec-
9 tions 2111, 2112, 2113, 2115, and 2121”;

10 (ii) in subparagraph (A), by striking
11 “terms ‘vaccine’ and ‘smallpox vaccine’”
12 and inserting “term ‘vaccine’”;

13 (iii) by amending subparagraph (B) to
14 read as follows:

15 “(B) the term ‘Vaccine Injury Table’ shall
16 be deemed to mean the table established under
17 paragraph (5)(A);”;

18 (iv) by redesignating subparagraph
19 (C) as subparagraph (F); and

20 (v) by inserting after subparagraph
21 (B) the following:

22 “(C) the term ‘factors unrelated to the ad-
23 ministration of the vaccine’ shall be deemed to
24 mean factors unrelated to the administration or
25 use of a covered countermeasure;

1 “(D)(i) the terms ‘petition’, ‘petition under
2 section 2111’, and ‘petition filed under section
3 2111’ shall be deemed to mean a request for
4 compensation under this section; and

5 “(ii) the term ‘petitioner’ shall be deemed
6 to mean a covered individual, as defined in sub-
7 section (e), who makes a request for benefits or
8 compensation under this section;

9 “(E) the term ‘vaccine-related injury or
10 death’ shall be deemed to mean a covered in-
11 jury, as defined in subsection (e); and”;

12 (2) in subsection (d)—

13 (A) in paragraph (1), by striking “, or if
14 the Secretary fails” and all that follows through
15 “319F-3(d)” and inserting a period; and

16 (B) in paragraph (5), by striking “under
17 subsection (a) the Secretary determines that a
18 covered individual qualifies for compensation”
19 and inserting “a covered individual is deter-
20 mined under subsection (a) to be eligible for
21 compensation under this section”.