

118TH CONGRESS
1ST SESSION

S. _____

To authorize the President to enter into trade agreements for the reciprocal elimination of duties or other import restrictions with respect to medical goods to contribute to the national security and public health of the United States, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. CARPER (for himself and Mr. TILLIS) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To authorize the President to enter into trade agreements for the reciprocal elimination of duties or other import restrictions with respect to medical goods to contribute to the national security and public health of the United States, 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 “Medical Supply Chain
5 Resiliency Act”.

1 **SEC. 2. FINDINGS; SENSE OF CONGRESS.**

2 (a) FINDINGS.—Congress makes the following find-
3 ings:

4 (1) The COVID–19 pandemic created signifi-
5 cant demand pressures on the global medical supply
6 chain.

7 (2) According to a December 2020 report by
8 the United States International Trade Commission,
9 global demand significantly exceeded available sup-
10 ply of many goods critical for the response to the
11 COVID–19 pandemic (in this section referred to as
12 “COVID–19 critical goods”). Health care providers
13 in the United States faced difficulties in procuring
14 such goods in sufficient quantities. Foreign export
15 restrictions on finished drugs and active pharma-
16 ceutical ingredients may have contributed to stress
17 on the supply of some critical COVID–19 treatment
18 drugs (including anti-infective products), as well as
19 hormone medications and vitamins.

20 (3) According to the McKinsey Global Institute,
21 during the 20 years preceding the date of the enact-
22 ment of this Act, pharmaceutical supply chains have
23 become more globally dispersed and many generic
24 small-molecule products have shifted to lower-cost
25 production locations, some of which have been iden-

1 tified as posing a threat to the national security of
2 the United States.

3 (4) According to the Organisation for Economic
4 Co-operation and Development, while the United
5 States is one of the largest exporters of COVID–19
6 critical goods, it is also one of the largest importers
7 of those goods.

8 (5) The World Trade Organization has found
9 that, while the United States, Germany, and the
10 People’s Republic of China are all major producers
11 and importers of COVID–19 critical goods, United
12 States import partners are less diversified compared
13 to Germany and the People’s Republic of China. In
14 the United States, more than half of its imports of
15 COVID–19 critical goods came from only 3 part-
16 ners—the People’s Republic of China (30.6 percent),
17 Mexico (15.3 percent), and Malaysia (9.0 percent).

18 (6) While some of the countries in which med-
19 ical supply manufacturing occurs are reliable sup-
20 pliers and allies to the United States, others have
21 adopted or maintained policies that make United
22 States supply less secure.

23 (b) SENSE OF CONGRESS.—It is the sense of Con-
24 gress that, given the threat to national security and public
25 health that could arise if the United States is unable to

1 swiftly respond to significant demand surges for medical
2 products in a future pandemic, it is critical that the
3 United States diversify its trade relationships and
4 prioritize partners that adopt and maintain reliable supply
5 chain policies.

6 **SEC. 3. PURPOSES.**

7 The purposes of this Act are—

8 (1) to improve overall medical supply chain re-
9 silience for the United States by establishing a
10 framework to enhance medical supply chains with
11 trusted trade partners;

12 (2) to enhance supply chain security related to
13 technology transfer and intellectual property protec-
14 tion;

15 (3) to diversify and expand supplier networks to
16 ensure a reliable supply of medical goods, especially
17 in the event of emergency situations;

18 (4) to eliminate unnecessary trade barriers and
19 distortions that weaken or disrupt medical supply
20 chains;

21 (5) to expedite cross-border movement of crit-
22 ical medical goods;

23 (6) to foster international collaboration, encour-
24 age new investments, promote cooperation and part-
25 nership in public and private research and develop-

1 ment efforts, facilitate data flows for life science re-
2 search and development, and expand manufacturing
3 capacities for medical devices and pharmaceutical
4 goods;

5 (7) to promote regulatory cooperation with re-
6 spect to manufacturing of medical goods;

7 (8) to increase access to government procure-
8 ment markets for medical goods;

9 (9) to encourage adoption of and adherence to
10 good regulatory practices related to medical goods;

11 (10) to enable greater transparency, regulatory
12 harmonization, and reliance in authorization and li-
13 censing procedures for medical devices and pharma-
14 ceutical goods;

15 (11) to facilitate trade in medical goods to the
16 most efficient and practicable extent possible; and

17 (12) to identify current production capacities,
18 address potential weaknesses, and improve overall
19 resilience.

20 **SEC. 4. DEFINITIONS.**

21 In this Act:

22 (1) **APPROPRIATE COMMITTEES OF CON-**
23 **GRESS.**—The term “appropriate committees of Con-
24 gress” means—

1 (A) the Committee on Finance of the Sen-
2 ate; and

3 (B) the Committee on Ways and Means of
4 the House of Representatives.

5 (2) COUNTRY.—The term “country” means—

6 (A) any foreign country or territory, in-
7 cluding any overseas dependent territory or pos-
8 session of a foreign country; or

9 (B) the Trust Territory of the Pacific Is-
10 lands.

11 (3) MEDICAL DEVICE.—The term “medical de-
12 vice” means a device, as defined in section 201 of
13 the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 321), that is intended for use in humans.

15 (4) MEDICAL GOOD.—The term “medical good”
16 means any medical device, pharmaceutical good, or
17 input for such a device or good.

18 (5) MEDICAL SUPPLY CHAIN.—The term “med-
19 ical supply chain” means any activities involving de-
20 sign, procurement, manufacturing, production, dis-
21 tribution, operation, or management related to med-
22 ical goods.

23 (6) PHARMACEUTICAL GOOD.—The term “phar-
24 maceutical good” means a drug, as defined in sec-
25 tion 201 of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 321), that is intended for use in hu-
2 mans.

3 (7) TRADE REPRESENTATIVE.—The term
4 “Trade Representative” means the United States
5 Trade Representative.

6 (8) TRUSTED TRADE PARTNER.—The term
7 “trusted trade partner” means any country that has
8 entered into an agreement with the United States
9 under section 5.

10 (9) TRUSTED TRADE PARTNER AGREEMENT.—
11 The term “trusted trade partner agreement” means
12 an agreement entered into under section 5.

13 **SEC. 5. AUTHORITY TO ENTER INTO TRUSTED TRADE PART-**
14 **NER AGREEMENTS.**

15 (a) IN GENERAL.—Whenever the President deter-
16 mines, based on the considerations set forth in subsection
17 (b), that the reciprocal elimination of existing duties or
18 other import restrictions of a country or countries and the
19 United States with respect to medical goods would con-
20 tribute to the national security and public health of the
21 United States, the President may, subject to the require-
22 ments under section 6—

23 (1) negotiate, enter into, and enforce a trusted
24 trade partner agreement with the country or coun-
25 tries; and

1 (2) proclaim such modification of any existing
2 duty, such continuance of existing duty-free or excise
3 treatment, or such additional duties, as the Presi-
4 dent determines to be required or appropriate to
5 carry out any such trade agreement.

6 (b) CONSIDERATIONS.—In determining whether to
7 enter into negotiations for a trusted trade partner agree-
8 ment with a country pursuant to subsection (a), the Presi-
9 dent shall take into account whether the government of
10 the country has—

11 (1) expressed a desire to be enter into such an
12 agreement;

13 (2) demonstrated a commitment to contribute
14 to global health security, including the national secu-
15 rity of the United States and the health of United
16 States citizens, by maintaining open trade in medical
17 goods during a public health emergency, including to
18 enable research, development, and manufacturing of
19 those goods;

20 (3) adhered to and implemented the commit-
21 ments and obligations under existing free trade
22 agreements to which that country and the United
23 States are parties;

1 (4) implemented measures to reduce or elimi-
2 nate unnecessary trade barriers and distorting prac-
3 tices affecting medical goods;

4 (5) maintained the rule of law by enacting and
5 enforcing laws and regulations in a clear, publicized,
6 transparent, and nondiscriminatory manner;

7 (6) adopted and enforced laws that provide ade-
8 quate and effective protection of intellectual property
9 rights reflecting a standard of protection similar to
10 that found under United States law; and

11 (7) agreed to recognize and promote good regu-
12 latory practices related to medical goods.

13 (c) TRUSTED TRADE PARTNER AGREEMENTS.—A
14 trusted trade partner agreement may, with respect to
15 medical goods, provide for—

16 (1) reduction or elimination of duties, quotas,
17 and other trade barriers that undermine the national
18 security and public health of the United States by
19 disincentivizing research, development, and manufac-
20 turing in the United States or in countries that are
21 reliable suppliers of medical goods to the United
22 States;

23 (2) diversification and expansion of supplier
24 networks to secure a reliable supply of medical
25 goods;

1 (3) harmonization or convergence of regulatory
2 procedures, regulatory reliance, inspection coopera-
3 tion, and adoption of international standards (such
4 as to streamline post-approval changes) to expedite
5 cross-border movement of medical goods;

6 (4) increased access to government procurement
7 markets for medical goods and, in the case of a mul-
8 tilateral agreement entered into under the auspices
9 of the World Trade Organization, membership in the
10 Agreement on Government Procurement of the
11 World Trade Organization referred to in section
12 101(d)(17) of the Uruguay Round Agreements Act
13 (19 U.S.C. 3511(d)(17));

14 (5) adequate and effective protection of intellec-
15 tual property rights for medical goods reflecting a
16 standard of protection similar to that found under
17 United States law;

18 (6) regulatory cooperation on manufacturing
19 standards for medical goods;

20 (7) a collaboration framework to promote public
21 and private research and development efforts related
22 to medical goods, including facilitation of data flows
23 for life science research and development;

1 (8) adherence to good regulatory practices for
2 sound, affordable, and efficient regulation of medical
3 goods;

4 (9) promotion of regulatory compatibility and
5 cooperation to facilitate trade and investment related
6 to medical goods and accelerate manufacturing of
7 such goods during a public health emergency; and

8 (10) exemption of parties to the agreement
9 from trade-restrictive measures imposed with respect
10 to medical goods during a public health emergency.

11 (d) **REPORT REQUIRED.**—Not later than 180 days
12 after the date of the enactment of this Act, and every 180
13 days thereafter, the President shall submit to Congress
14 a report on the status of negotiations conducted under
15 subsection (a) for trusted trade partner agreements.

16 **SEC. 6. CONGRESSIONAL OVERSIGHT, NOTICE, CONSULTA-**
17 **TIONS, ACCESS TO INFORMATION, AND RE-**
18 **VIEW.**

19 (a) **NOTICE.**—Not later than 60 days before initi-
20 ating negotiations with a trusted trade partner under sec-
21 tion 5(a) for a trusted trade partner agreement, the Presi-
22 dent shall submit to Congress written notice of the inten-
23 tion of the President to enter into the negotiations, which
24 shall include the date negotiations will begin and the trust-

1 ed trade partner with whom the President seeks to enter
2 into the agreement.

3 (b) CONSULTATION WITH MEMBERS OF CON-
4 GRESS.—

5 (1) CONSULTATION DURING NEGOTIATIONS AND
6 ACCESS TO INFORMATION.—In the course of negotia-
7 tions under section 5(a) for a trusted trade partner
8 agreement, the Trade Representative shall—

9 (A) meet upon request with the appro-
10 priate committees of Congress regarding negoti-
11 ating objectives, the status of negotiations in
12 progress, and potential effects to the laws of
13 the United States with respect to the agree-
14 ment;

15 (B) upon request by the appropriate com-
16 mittees of Congress, provide access to pertinent
17 documents relating to the negotiations; and

18 (C) consult closely and on a timely basis
19 with, and keep fully apprised of the negotia-
20 tions, the appropriate committees of Congress.

21 (2) CONSULTATION BEFORE ENTRY INTO
22 AGREEMENT.—Before entering into a trusted trade
23 partner agreement under section 5, the Trade Rep-
24 resentative shall consult with—

1 (A) the appropriate committees of Con-
2 gress; and

3 (B) each other committee of the Senate
4 and the House of Representatives, and each
5 joint committee of Congress, that has jurisdic-
6 tion over legislation involving a subject matter
7 that would be affected by the agreement.

8 (c) CONSULTATION WITH FEDERAL AGENCIES.—In
9 the course of negotiations under section 5(a) for a trusted
10 trade partner agreement, the Trade Representative shall
11 inform and consult with any Federal agency having exper-
12 tise in the matters being negotiated, including the Depart-
13 ment of Health and Human Services.

14 (d) LIMITATION ON ACTION.—Any duty elimination
15 or staged rate reduction provided for under section 5 may
16 be proclaimed only if the President—

17 (1) has obtained advice regarding the proposed
18 action from the appropriate advisory committees es-
19 tablished under section 135 of the Trade Act of
20 1974 (19 U.S.C. 2155) and the International Trade
21 Commission;

22 (2) has submitted to the appropriate commit-
23 tees of Congress a report that sets forth—

24 (A) the action proposed to be proclaimed;

25 (B) the reasons for such action; and

1 (C) the advice obtained under paragraph
2 (1); and
3 (3) has consulted with the appropriate commit-
4 tees of Congress regarding the proposed action dur-
5 ing the 60-day period on the date on which the
6 President has met the requirements under para-
7 graphs (1) and (2).

8 (e) REPORT TO CONGRESS.—Not later than 60 days
9 before the date on which the President enters into a trust-
10 ed trade partner agreement with a trusted trade partner
11 under section 5, the President shall submit to Congress
12 a report describing—

13 (1) the nature and scope of the agreement;
14 (2) the proposed duration of the agreement;
15 (3) how and to what extent the agreement will
16 achieve the applicable purposes, policies, priorities,
17 and objectives of this Act;
18 (4) whether sufficient evidence exists dem-
19 onstrating that—

20 (A) the trusted trade partner satisfies the
21 conditions under section 5(b); and

22 (B) the reciprocal elimination of existing
23 duties or other import restrictions of the trust-
24 ed trade partner or the United States with re-
25 spect to medical goods would contribute to the

1 national security and public health of the
2 United States; and

3 (5) the proposed implementation of the agree-
4 ment, including the general effect of the agreement
5 on existing laws.

6 (f) CONGRESSIONAL RIGHT TO REVIEW AND DIS-
7 APPROVE.—

8 (1) IN GENERAL.—A trusted trade partner
9 agreement shall not take effect until—

10 (A) the proposed agreement has been sub-
11 mitted to Congress, together with the report re-
12 quired under subsection (e) with respect to that
13 agreement; and

14 (B) the review period required under para-
15 graph (2) following the date on which the pro-
16 posed agreement has been submitted to Con-
17 gress under subparagraph (A) has been ex-
18 hausted, during which period a joint resolution
19 is not enacted under paragraph (4).

20 (2) REVIEW.—

21 (A) INITIAL REVIEW.—Unless extended
22 under subparagraph (B) or (C), the review pe-
23 riod under this paragraph with respect to a
24 trusted trade partner agreement is 30 days,

1 during which time Congress shall review the
2 proposed agreement with respect to whether—

3 (i) the President failed or refused to
4 provide notice with respect to the agree-
5 ment in accordance with subsection (a);

6 (ii) the President failed or refused to
7 consult with respect to the agreement in
8 accordance with subsections (b) and (c);

9 (iii) the President failed or refused to
10 submit to Congress a report with respect
11 to the agreement in accordance with sub-
12 section (e); or

13 (iv) the President failed or refused to
14 demonstrate that the agreement would
15 achieve the applicable purposes, policies,
16 priorities, and objectives of this Act and
17 contribute to the national security and
18 public health of the United States.

19 (B) FURTHER REVIEW.—If, during the 30-
20 day period under subparagraph (A) with re-
21 spect to a trusted trade partner agreement, one
22 House of Congress adopts a resolution stating
23 that the House of Congress wishes to further
24 review the proposed agreement, the review pe-
25 riod under this paragraph with respect to the

1 proposed agreement shall be extended by a pe-
2 riod of 60 days, during which time the appro-
3 priate committees of Congress shall engage the
4 President with respect to the proposed agree-
5 ment and the failures or refusals of the Presi-
6 dent specified under subparagraph (A).

7 (C) ADDITIONAL PERIOD.—If, during the
8 60-day period under subparagraph (B) with re-
9 spect to a trusted trade partner agreement, one
10 House of Congress adopts a resolution stating
11 that the House of Congress wishes to further
12 review the proposed agreement, the review pe-
13 riod under this paragraph with respect to the
14 proposed agreement shall be further extended
15 by a period of 30 days.

16 (3) PROCEDURES FOR CONSIDERING RESOLU-
17 TIONS.—A resolution under subparagraph (B) or
18 (C) of paragraph (2)—

19 (A) in the Senate—

20 (i) may be introduced by any Member
21 of the Senate;

22 (ii) shall be referred to the Committee
23 on Finance; and

24 (iii) may not be amended; and

25 (B) in the House of Representatives—

1 (i) may be introduced by any Member
2 of the House;

3 (ii) shall be referred to the Committee
4 on Ways and Means or the Committee on
5 Rules; and

6 (iii) may not be amended by either
7 Committee; and

8 (C) the vote on passage of the resolution
9 shall occur immediately following the conclusion
10 of the debate on the trusted trade partner
11 agreement at issue and a single quorum call at
12 the conclusion of the debate.

13 (4) DISAPPROVAL.—If, during the review period
14 required under paragraph (2) with respect to a
15 trusted trade partner agreement, a joint resolution
16 is enacted stating that Congress does not favor the
17 agreement, the agreement shall not take effect.

18 **SEC. 7. MONITORING AND ENFORCEMENT OF CONTINUED**
19 **COMPLIANCE WITH TRUSTED TRADE PART-**
20 **NER AGREEMENTS.**

21 (a) MONITORING.—The Trade Representative shall
22 periodically monitor compliance by a trusted trade partner
23 with the commitments and obligations of the partner
24 under a trusted trade partner agreement.

1 (b) ACTIONS IN RESPONSE TO FAILURE TO COM-
2 PLY.—

3 (1) DETERMINATION AND REPORT OF TRADE
4 REPRESENTATIVE.—If the Trade Representative de-
5 termines that a trusted trade partner has failed to
6 satisfactorily implement, maintain, and enforce the
7 commitments and obligations of the partner under a
8 trusted trade partner agreement, the Trade Rep-
9 resentative shall submit to the President a report
10 setting forth—

11 (A) the determination and the findings
12 that support the determination; and

13 (B) based on such findings, the rec-
14 ommendations of the Trade Representative for
15 action or inaction under this subsection.

16 (2) DETERMINATION OF PRESIDENT.—Not
17 later than 30 days after receiving a report under
18 paragraph (1) with respect to a trusted trade part-
19 ner, the President shall—

20 (A) determine whether the President con-
21 curs with the determination of the Trade Rep-
22 resentative set forth in the report; and

23 (B) if the President concurs, determine
24 whether—

1 (i) to suspend, withdraw, or prevent
2 the application of the trusted trade partner
3 agreement with the trusted trade partner;

4 (ii) to enter into a binding agreement
5 with the partner that commits the part-
6 ner—

7 (I) to eliminate any burden or re-
8 striction on the United States result-
9 ing from the failure of the partner to
10 comply with the commitments and ob-
11 ligations of the partner under a trust-
12 ed trade partner agreement; and

13 (II) to provide the United States
14 with such compensatory trade benefits
15 as are negotiated between the Trade
16 Representative and the partner; or

17 (iii) to take such other actions as the
18 Trade Representative considers necessary
19 to encourage the partner to adhere to the
20 commitments and obligations of the part-
21 ner under a trusted trade partner agree-
22 ment, including suspending the exemption
23 of the partner from trade-restrictive meas-
24 ures imposed with respect to medical goods
25 during a public health emergency.

1 (3) TIMELINE FOR ACTION.—If the President
2 determines under paragraph (2)(B) to take action,
3 the President shall implement that action by not
4 later than the date that is 15 days after the day on
5 which the President determines to take action under
6 that paragraph.