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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

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 HOUSE OF REPRESENTATIVES

Mrs. STEEL introduced the following bill; which was 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.

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 ''Medical Supply Chain Resiliency Act''.

SEC. 2. FINDINGS; SENSE OF CONGRESS.

(a) FINDINGS.—Congress makes the following findings:

(1) The COVID–19 pandemic created significant demand pressures on the global medical supply chain.

(2) According to a December 2020 report by the United States International Trade Commission, global demand significantly exceeded available supply of many goods critical for the response to the COVID–19 pandemic (in this section referred to as ''COVID–19 critical goods''). Health care providers in the United States faced difficulties in procuring such goods in sufficient quantities. Foreign export restrictions on finished drugs and active pharmaceutical ingredients may have contributed to stress on the supply of some critical COVID–19 treatment drugs (including anti-infective products), as well as hormone medications and vitamins.

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

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

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

(5) The World Trade Organization has found that, while the United States, Germany, and the People's Republic of China are all major producers and importers of COVID–19 critical goods, United States import partners are less diversified compared to Germany and the People's Republic of China. In the United States, more than half of its imports of COVID–19 critical goods came from only 3 partners—the People's Republic of China (30.6 percent), Mexico (15.3 percent), and Malaysia (9.0 percent).

(6) While some of the countries in which medical supply manufacturing occurs are reliable suppliers and allies to the United States, others have adopted or maintained policies that make United States supply less secure.

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

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

SEC. 3. PURPOSES.

The purposes of this Act are—

(1) to improve overall medical supply chain resilience for the United States by establishing a framework to enhance medical supply chains with trusted trade partners;

(2) to enhance supply chain security related to technology transfer and intellectual property protection;

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

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

(5) to expedite cross-border movement of critical medical goods;

(6) to foster international collaboration, encourage new investments, promote cooperation and partnership in public and private research and develop-

ment efforts, facilitate data flows for life science research and development, and expand manufacturing capacities for medical devices and pharmaceutical goods;

(7) to promote regulatory cooperation with respect to manufacturing of medical goods;

(8) to increase access to government procurement markets for medical goods;

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

(10) to enable greater transparency, regulatory harmonization, and reliance in authorization and licensing procedures for medical devices and pharmaceutical goods;

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

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

SEC. 4. DEFINITIONS.

In this Act:

(1) APPROPRIATE COMMITTEES OF CONGRESS.—The term ''appropriate committees of Congress'' means—

(A) the Committee on Finance of the Senate; and

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

(2) COUNTRY.—The term ''country'' means—

(A) any foreign country or territory, including any overseas dependent territory or possession of a foreign country; or

(B) the Trust Territory of the Pacific Islands.

(3) MEDICAL DEVICE.—The term ''medical device'' means a device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), that is intended for use in humans.

(4) MEDICAL GOOD.—The term ''medical good'' means any medical device, pharmaceutical good, or input for such a device or good.

(5) MEDICAL SUPPLY CHAIN.—The term ''medical supply chain'' means any activities involving design, procurement, manufacturing, production, distribution, operation, or management related to medical goods.

(6) PHARMACEUTICAL GOOD.—The term ''pharmaceutical good'' means a drug, as defined in section 201 of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 321), that is intended for use in humans.

(7) TRADE REPRESENTATIVE.—The term ''Trade Representative'' means the United States Trade Representative.

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

(9) TRUSTED TRADE PARTNER AGREEMENT.—The term ''trusted trade partner agreement'' means an agreement entered into under section 5.

SEC. 5. AUTHORITY TO ENTER INTO TRUSTED TRADE PARTNER AGREEMENTS.

(a) IN GENERAL.—Whenever the President determines, based on the considerations set forth in subsection (b), that the reciprocal elimination of existing duties or other import restrictions of a country or countries and the United States with respect to medical goods would contribute to the national security and public health of the United States, the President may, subject to the requirements under section 6—

(1) negotiate, enter into, and enforce a trusted trade partner agreement with the country or countries; and

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

(b) CONSIDERATIONS.—In determining whether to enter into negotiations for a trusted trade partner agreement with a country pursuant to subsection (a), the President shall take into account whether the government of the country has—

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

(2) demonstrated a commitment to contribute to global health security, including the national security of the United States and the health of United States citizens, by maintaining open trade in medical goods during a public health emergency, including to enable research, development, and manufacturing of those goods;

(3) adhered to and implemented the commitments and obligations under existing free trade agreements to which that country and the United States are parties;

(4) implemented measures to reduce or eliminate unnecessary trade barriers and distorting practices affecting medical goods;

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

(6) adopted and enforced laws that provide adequate and effective protection of intellectual property rights reflecting a standard of protection similar to that found under United States law; and

(7) agreed to recognize and promote good regulatory practices related to medical goods.

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

(1) reduction or elimination of duties, quotas, and other trade barriers that undermine the national security and public health of the United States by disincentivizing research, development, and manufacturing in the United States or in countries that are reliable suppliers of medical goods to the United States;

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

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

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

(5) adequate and effective protection of intellectual property rights for medical goods reflecting a standard of protection similar to that found under United States law;

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

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

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

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

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

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

SEC. 6. CONGRESSIONAL OVERSIGHT, NOTICE, CONSULTATIONS, ACCESS TO INFORMATION, AND REVIEW.

(a) NOTICE.—Not later than 60 days before initiating negotiations with a trusted trade partner under section 5(a) for a trusted trade partner agreement, the President shall submit to Congress written notice of the intention of the President to enter into the negotiations, which shall include the date negotiations will begin and the trust-

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

(b) CONSULTATION WITH MEMBERS OF CONGRESS.—

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

(A) meet upon request with the appropriate committees of Congress regarding negotiating objectives, the status of negotiations in progress, and potential effects to the laws of the United States with respect to the agreement;

(B) upon request by the appropriate committees of Congress, provide access to pertinent documents relating to the negotiations; and

(C) consult closely and on a timely basis with, and keep fully apprised of the negotiations, the appropriate committees of Congress.

(2) CONSULTATION BEFORE ENTRY INTO AGREEMENT.—Before entering into a trusted trade partner agreement under section 5, the Trade Representative shall consult with—

(A) the appropriate committees of Congress; and

(B) each other committee of the Senate and the House of Representatives, and each joint committee of Congress, that has jurisdiction over legislation involving a subject matter that would be affected by the agreement.

(c) CONSULTATION WITH FEDERAL AGENCIES.—In the course of negotiations under section 5(a) for a trusted trade partner agreement, the Trade Representative shall inform and consult with any Federal agency having expertise in the matters being negotiated, including the Department of Health and Human Services.

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

(1) has obtained advice regarding the proposed action from the appropriate advisory committees established under section 135 of the Trade Act of 1974 (19 U.S.C. 2155) and the International Trade Commission;

(2) has submitted to the appropriate committees of Congress a report that sets forth—

(A) the action proposed to be proclaimed;

(B) the reasons for such action; and

(C) the advice obtained under paragraph (1); and

(3) has consulted with the appropriate committees of Congress regarding the proposed action during the 60-day period on the date on which the President has met the requirements under paragraphs (1) and (2).

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

(1) the nature and scope of the agreement;

(2) the proposed duration of the agreement;

(3) how and to what extent the agreement will achieve the applicable purposes, policies, priorities, and objectives of this Act;

(4) whether sufficient evidence exists demonstrating that—

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

(B) the reciprocal elimination of existing duties or other import restrictions of the trusted trade partner or the United States with respect to medical goods would contribute to the

national security and public health of the United States; and

(5) the proposed implementation of the agreement, including the general effect of the agreement on existing laws.

(f) CONGRESSIONAL RIGHT TO REVIEW AND DISAPPROVE.—

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

(A) the proposed agreement has been submitted to Congress, together with the report required under subsection (e) with respect to that agreement; and

(B) the review period required under paragraph (2) following the date on which the proposed agreement has been submitted to Congress under subparagraph (A) has been exhausted, during which period a joint resolution is not enacted under paragraph (4).

(2) REVIEW.—

(A) INITIAL REVIEW.—Unless extended under subparagraph (B) or (C), the review period under this paragraph with respect to a trusted trade partner agreement is 30 days,

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

(i) the President failed or refused to provide notice with respect to the agreement in accordance with subsection (a);

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

(iii) the President failed or refused to submit to Congress a report with respect to the agreement in accordance with subsection (e); or

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

(B) FURTHER REVIEW.—If, during the 30-day period under subparagraph (A) with respect to a trusted trade partner agreement, one House of Congress adopts a resolution stating that the House of Congress wishes to further review the proposed agreement, the review period under this paragraph with respect to the

proposed agreement shall be extended by a period of 60 days, during which time the appropriate committees of Congress shall engage the President with respect to the proposed agreement and the failures or refusals of the President specified under subparagraph (A).

(C) ADDITIONAL PERIOD.—If, during the 60-day period under subparagraph (B) with respect to a trusted trade partner agreement, one House of Congress adopts a resolution stating that the House of Congress wishes to further review the proposed agreement, the review period under this paragraph with respect to the proposed agreement shall be further extended by a period of 30 days.

(3) PROCEDURES FOR CONSIDERING RESOLUTIONS.—A resolution under subparagraph (B) or (C) of paragraph (2)—

(A) in the Senate—

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

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

(iii) may not be amended; and

(B) in the House of Representatives—

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

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

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

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

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

SEC. 7. MONITORING AND ENFORCEMENT OF CONTINUED COMPLIANCE WITH TRUSTED TRADE PARTNER AGREEMENTS.

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

(b) ACTIONS IN RESPONSE TO FAILURE TO COMPLY.—

(1) DETERMINATION AND REPORT OF TRADE REPRESENTATIVE.—If the Trade Representative determines that a trusted trade partner has failed to satisfactorily implement, maintain, and enforce the commitments and obligations of the partner under a trusted trade partner agreement, the Trade Representative shall submit to the President a report setting forth—

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

(B) based on such findings, the recommendations of the Trade Representative for action or inaction under this subsection.

(2) DETERMINATION OF PRESIDENT.—Not later than 30 days after receiving a report under paragraph (1) with respect to a trusted trade partner, the President shall—

(A) determine whether the President concurs with the determination of the Trade Representative set forth in the report; and

(B) if the President concurs, determine whether—

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

(ii) to enter into a binding agreement with the partner that commits the partner—

(I) to eliminate any burden or restriction on the United States resulting from the failure of the partner to comply with the commitments and obligations of the partner under a trusted trade partner agreement; and

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

(iii) to take such other actions as the Trade Representative considers necessary to encourage the partner to adhere to the commitments and obligations of the partner under a trusted trade partner agreement, including suspending the exemption of the partner from trade-restrictive measures imposed with respect to medical goods during a public health emergency.

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