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117TH CONGRESS
1ST SESSION

H. R. 4711

To amend the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 to include principal negotiating objectives of the United States relating to trade in pharmaceutical products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 27, 2021

Mr. JOYCE of Pennsylvania (for himself and Mr. BANKS) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Rules, 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

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A BILL

To amend the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 to include principal negotiating objectives of the United States relating to trade in pharmaceutical products, 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 "International Pharmaceutical Supply Chain Security Agreement Act of 2021".

SEC. 2. PRINCIPAL NEGOTIATING OBJECTIVES OF THE UNITED STATES RELATING TO TRADE IN COVERED PHARMACEUTICAL PRODUCTS.

Section 102(b) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (19 U.S.C. 4201(b)) is amended by adding at the end the following:

''(23) TRADE IN COVERED PHARMACEUTICAL PRODUCTS.—

''(A) IN GENERAL.—With respect to an agreement relating to trade in covered pharmaceutical products that is proposed to be entered into with the United States and to which section 103(b) will apply, the principal negotiating objectives of the United States are the following:

''(i) To ensure that a party to the agreement adopts and maintains measures to eliminate the imposition or reimposition of tariffs on imports of such products, particularly in the event of a declared emergency.

''(ii) To ensure that a party to the agreement—

''(I) will reduce or eliminate regulatory and other technical barriers in the pharmaceutical sector;

''(II) will promote expedited approval of facilities for the production of such products being built by business enterprises that operate one or more such facilities in the territory of the party;

''(III) will promote the use of good regulatory practices and streamlined regulatory review and approval processes for the production of such products in the territory of the party;

''(IV) will eliminate duplicated actions and other barriers to reduce the time for approvals of both facilities and such products; and

''(V) will expand transparency and cooperation with other parties and their manufacturers, working collaboratively, to ensure regulatory processes are streamlined and harmonized among other parties to the maximum extent possible.

''(iii) To prohibit export restraints against parties to the agreement, particularly in the event of a declared emergency.

''(iv) With respect to use of subsidies—

''(I) to encourage the coordinated provision of those types of subsidies that are classified under World Trade Organization rules as 'non-prohibited', such as subsidies that are not contingent on exports or import-substitution, to incentivize manufacturing of such products, including the provision of grants, loans, tax incentives, and guaranteed price and volume contracts;

''(II) to explicitly permit, among parties to the agreement, the use of production subsidies to build pharmaceutical manufacturing capacity;

''(III) to affirm that subsidies provided by parties are not intended to be used primarily for export or to distort trade;

''(IV) to affirm parties' commitments under the Antidumping Agreement and the Agreement on Subsidies and Countervailing Measures, includ-

ing the recognition that 'dumping, by which products of one country are introduced into the commerce of another country at less than the normal value of the products, is to be condemned if it causes or threatens material injury to an established industry in the territory of a contracting party or materially retards the establishment of a domestic industry'; and

''(V) to encourage notification and consultation among parties as they are considering pharmaceutical manufacturing subsidies to increase coordination and avoid creating conditions such as oversupply or market inefficiencies among the parties.

''(v) With respect to government procurement—

''(I) to provide reciprocal access to government procurements for such products in parties to the agreement;

''(II) to increase coordination between participant countries and facilitate the involvement of participant

countries' companies in bids to supply such products; and

''(III) to ensure that any participant in the agreement that is not already so designated, becomes designated for purposes of section 301 of the Trade Agreements Act of 1979 (19 U.S.C. 2511).

''(vi) With respect to trade in services—

''(I) to obtain fair, open, and transparent access to supply chain services in the markets of parties to the agreement, such as distribution, logistics, and transportation services;

''(II) to ensure any restrictions or regulatory requirements maintained on such services are adopted and maintained in a transparent and efficient manner; and

''(III) to require parties to establish an internal process for identifying restrictions or regulatory requirements that could be waived in the event of a declared emergency.

''(vii) With respect to transparency and trade facilitation—

''(I) to obtain commitments among parties to the agreement to develop mechanisms for sharing information on pharmaceutical supply chain constraints and coordinate approaches with parties to minimize risks that could lead to supply chain failures; and

''(II) to the extent they have not done so yet, to obtain commitments from parties that they will fully implement the obligations under the World Trade Organization's Agreement on Trade Facilitation prior to the date the agreement enters into force.

''(viii) With respect to enforcement—

''(I) to ensure that benefits under the agreement can only be obtained by parties that are fully meeting their obligations under the agreement;

''(II) to ensure that parties will not bring a dispute under another

agreement for actions that are consistent with the agreement; and

''(III) to provide a dispute settlement mechanism comparable to the dispute settlement provisions of the Agreement between the United States of America, the United Mexican States, and Canada.

''(ix) To minimize the ability of parties to the agreement to undermine the effectiveness of the agreement by abusing exceptions in the agreement by including additional procedural requirements, such as notification of intent to rely on an exception at the time an inconsistent action is taken, and limiting the duration that participants may rely on an exception.

''(B) DEFINITIONS.—In this paragraph:

''(i) ACTIVE PHARMACEUTICAL INGREDIENT.—The term 'active pharmaceutical ingredient'—

''(I) means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment,

or prevention of a disease, or to affect the structure or any function of the body of a human or animal; and

"(II) does not include—

"(aa) intermediates used in the synthesis of a drug product; or

"(bb) components that may undergo chemical change in the manufacture of a drug product and be present in a drug product in a modified form that is intended to furnish such activity or effect.

"(ii) AGREEMENT ON SUBSIDIES AND COUNTERVAILING MEASURES.—The term 'Agreement on Subsidies and Countervailing Measures' means the agreement referred to in section 101(d)(12) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(12)).

"(iii) ANTIDUMPING AGREEMENT.—The term 'Antidumping Agreement' means the Agreement on Implementation of Article VI of the General Agreement on Tariffs

and Trade 1994 referred to in section 101(d)(7) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(7)).

''(iv) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given to such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

''(v) COVERED PHARMACEUTICAL PRODUCT.—The term 'covered pharmaceutical product' means—

''(I) a drug (including a biological product); or

''(II) an active pharmaceutical ingredient.''.

SEC. 3. REAUTHORIZATION OF TRADE AGREEMENTS AUTHORITY.

Section 103 of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (19 U.S.C. 4202) is amended—

(1) in subsection (a)—

(A) by striking ''July 1, 2018'' each place it appears and inserting ''July 1, 2023''; and

(B) by striking ''July 1, 2021'' each place it appears and inserting ''July 1, 2026'';

(2) in subsection (b)—

(A) by striking ''July 1, 2018'' each place it appears and inserting ''July 1, 2023''; and

(B) by striking ''July 1, 2021'' each place it appears and inserting ''July 1, 2026''; and

(3) in subsection (c)—

(A) by striking ''July 1, 2018'' each place it appears and inserting ''July 1, 2023'';

(B) by striking ''June 30, 2018'' and inserting ''June 30, 2023'';

(C) in paragraph (1)(B), by striking ''July 1, 2021'' and inserting ''July 1, 2026'';

(D) in paragraph (2), by striking ''April 1, 2018'' and inserting ''April 1, 2023''; and

(E) in paragraph (3), by striking ''June 1, 2018'' and inserting ''June 1, 2023''.

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