A RESOLUTION TO BE SUBMITTED BY
LEGISLATORS TODARO, LORIGO, RATH & MILLS

Re: Support for Proposed Federal Legislation to Identify and Curtail the Volume of Chinese Active Pharmaceutical Ingredients from the U.S. Medical Drug Supply, and Support for Buy American Initiatives

WHEREAS, China has exported pharmaceutical products to the U.S. since the 1990s, becoming the United States' second-largest exporter of medications and medical supplies; and

WHEREAS, information from the Food and Drug Administration in October 2019 showed that China's manufacturing capacity for active pharmaceutical ingredients (API) was increasing; and

WHEREAS, a pneumonia with an unknown cause was detected in Wuhan, Hubei Province, China and reported to the World Health Organization (WHO) Office in China on December 31, 2019, which led to an outbreak being declared a "public health emergency of international concern" by the WHO on January 30, 2020; and

WHEREAS, Covid-19 is caused by a new coronavirus, where coronaviruses are a large family of viruses that are common in people and many different species of animals, including camels, cattle, cats, and bats. Rarely, animal coronaviruses can infect people and then spread between people such as with MERS-CoV, SARS-CoV, and now with this new virus SARS-CoV-2 (Covid-19); and

WHEREAS, New York State Governor Andrew Cuomo on April 2, 2020 lamented "It is the cruelest irony that this nation is now dependent on China" for many medical supplies, as states deal with an outbreak originating in China; and

WHEREAS, U.S. President Donald Trump has emphasized the importance of U.S. manufacturing in keeping supply chains secure during the pandemic, saying "This pandemic has reaffirmed the importance of keeping vital supply chains at home", while the administration works to incentivize American production of pharmaceuticals; and

WHEREAS, U.S. Trade Representative Robert Lighthizer noted "we are learning in this crisis that over-dependence on other countries as a source of cheap medical products and supplies has created a strategic vulnerability to our economy;" and

WHEREAS, the coronavirus pandemic has made it clear how dependent the U.S. is on China for consumer goods, medical products and pharmaceuticals; and

WHEREAS, in 2018, the U.S. imported more than $12.7 billion worth of pharmaceuticals and antibiotics, medical devices, and food products from China, and 30 percent of U.S. imports of medical personal protective equipment; and

WHEREAS, the Food and Drug Administration (FDA) currently requires drugmakers to include the sources of a drug's API, but doesn't require them to provide the volume of API deriving from each of its sources, proposed federal legislation would require additional reporting so the volume of API is disclosed; and

WHEREAS, this additional reporting would allow the federal agencies to identify the extent of U.S. dependence on foreign entities for drugs, API and pharmaceutical components; and

WHEREAS, the proposed legislation would also allow the Department of Defense to determine whether a dependency creates a national security risk and make recommendations to mitigate this issue; and

WHEREAS, it is estimated that China supplies about 80 percent of API to the U.S.; and

WHEREAS, the proposed bicameral and bipartisan federal legislation, S.3538 (2020) and H.R.6393 (2020), is sponsored by Senators Marco Rubio (R-FL), Elizabeth Warren (D-MA), Kevin Cramer (R-ND), Chris Murphy (D-CT), Tim Kaine (D-VA), and Rep. Michael Waltz (R-FL6); and

WHEREAS, it is the finding of this Honorable Body that the United States' dependence on foreign entities for pharmaceuticals, medical products, personal protective equipment and general consumer goods can put the county in great health and public safety peril.

NOW, THEREFORE, BE IT

RESOLVED, this Honorable Body supports proposed U.S. Senate legislation S.3538 (2020) and H.R.6393 (2020) to strengthen America's supply chain by determining and reporting the reliance on imports of certain pharmaceutical products, and requiring additional postmarket reporting requirements for pharmaceutical; and, be it further

RESOLVED, supports local, state and federal initiatives to Buy American, and stress the need for pharmaceuticals, medical products, personal protective equipment to be made domestically; and, be it further

RESOLVED, that certified copies of this resolution be sent to U.S. President Donald Trump, the WNY delegation of the U.S. House of Representatives, NY's U.S. Senate delegation, Governor Andrew Cuomo, WNY delegation of the State Senate and Assembly, and all other parties deemed necessary and proper.

Fiscal Impact: None

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116TH CONGRESS
2D SESSION

S. 3538

To require the Secretary of Defense to submit to Congress a report on the reliance by the Department of Defense on imports of certain pharmaceutical products made in part or in whole in certain countries, to establish postmarket reporting requirements for pharmaceuticals, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 19, 2020

Mr. RUBIO (for himself, Ms. WARREN, Mr. CRAMER, Mr. MURPHY, and Mr. KAINE) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To require the Secretary of Defense to submit to Congress a report on the reliance by the Department of Defense on imports of certain pharmaceutical products made in part or in whole in certain countries, to establish postmarket reporting requirements for pharmaceuticals, 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 "Strengthening America's Supply Chain and National Security Act".

SEC. 2. REPORT ON RELIANCE BY DEPARTMENT OF DEFENSE ON PHARMACEUTICAL PRODUCTS FROM CERTAIN COUNTRIES.

(a) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Defense, in coordination with the Secretary of Health and Human Services, shall submit to the appropriate congressional committees a classified report on the reliance by the Department of Defense on imports of certain pharmaceutical products made in part or in whole in a covered country.

(b) ELEMENTS.—The report required by subsection (a) shall—

(1) analyze the percent of pharmaceutical products used by the Department of Defense that are made in part or in whole in a covered country, including—

(A) drugs;

(B) active ingredients;

(C) raw pharmaceutical components;

(D) nonprescription drugs intended for human use; and

(E) any other pharmaceutical product, or its components, as the Secretary considers appropriate;

(2) assess the products identified under paragraph (1) to determine—

(A) whether the Department of Defense can procure the product from other sources;

(B) whether reliance by the Department of Defense on the product is likely, or has significant potential, to be used for a military, geopolitical, or economic advantage against the United States;

(C) whether reliance on the product creates a risk for the United States; and

(D) what impact there would be if access to the product was terminated;

(3) set forth recommendations to ensure that by 2025 no pharmaceutical products purchased for beneficiaries of health care from the Department of Defense or any associated program are made in part or in whole in a covered country;

(4) assess the resilience and capacity of the current supply chain and industrial base to support national defense if no pharmaceutical products purchased for beneficiaries of health care from the Department of Defense or any associated program are made in part or in whole in a covered country, including with respect to—

(A) the manufacturing capacity of the United States;

(B) gaps in domestic manufacturing capabilities, including non-existent, extinct, threatened, and single-point-of-failure capabilities; and

(C) supply chains with single points of failure and limited resiliency;

(5) set forth recommendations—

(A) to diversify supply of pharmaceutical products away from complete dependency on sources of supply in countries that are competitors of the United States or politically unstable that may cut off supply in the United States;

(B) to address critical bottlenecks in the supply of pharmaceutical products in the United States; and

(C) to mitigate single points of failure and limited resilience of supply chains for pharmaceutical products in the United States; and

(6) set forth recommendations for legislative and administrative action necessary to avoid, or prepare for, contingencies identified in the report.

(c) PUBLICATION OF UNCLASSIFIED SUMMARY.—Concurrent with the submittal of the report required by

subsection (a), the Secretary of Defense shall publish on a publicly available internet website of the Department of Defense an unclassified summary of the report.

(d) DEFINITIONS.—In this section:

(1) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term "appropriate congressional committees" means—

(A) the Committee on Armed Services, the Select Committee on Intelligence, the Committee on Finance, the Committee on Banking, Housing, and Urban Affairs, and the Committee on Health, Education, Labor, and Pensions of the Senate; and

(B) the Committee on Armed Services, the Permanent Select Committee on Intelligence, the Committee on Ways and Means, the Committee on Financial Services, and the Committee on Energy and Commerce of the House of Representatives.

(2) COVERED COUNTRY.—The term "covered country" means—

(A) China; and

(B) any other country as determined by the Secretary of Defense for national security purposes.

(3) DRUG.—The term "drug" means a product subject to regulation under section 505 or section 802 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262).

(4) NONPRESCRIPTION DRUG.—The term "nonprescription drug" has the meaning given that term in section 760(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379aa(a)(2)).

SEC. 3. MODIFICATION OF RULES OF ORIGIN FOR PHARMACEUTICAL PRODUCTS.

(a) TRADE AGREEMENTS.—Section 308(4)(B) of the Trade Agreements Act of 1979 (19 U.S.C. 2518(4)(B)) is amended—

(1) in clause (i), by striking "instrumentality, or" and inserting "instrumentality,";

(2) in clause (ii)—

(A) by inserting ", other than an active pharmaceutical ingredient," after "part of materials"; and

(B) by striking the period at the end and inserting ", or"; and

(3) by inserting before the period at the end the following: "(iii) in the case of an article which consists of an active pharmaceutical ingredient, the

pharmaceutical ingredient is wholly the growth, product, or manufacture of that country or instrumentality".

(b) FEDERAL ACQUISITION REGULATION.—Not later than 180 days after the date of the enactment of this Act, the President shall prescribe regulations to update sections 52.225–5 and 25.003 of title 48, Code of Federal Regulations (or successor regulations) to be consistent with rules of origin determinations for active pharmaceutical ingredients made under section 308(4)(B) of the Trade Agreements Act of 1979 (19 U.S.C. 2518(4)(B)), as amended by subsection (a).

SEC. 4. POSTMARKET REPORTING REQUIREMENTS FOR PHARMACEUTICALS.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall ensure that each holder of an approved application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or under section 351 of the Public Health Service Act (42 U.S.C. 262) annually submit, as part of the postmarket annual report required by the Secretary under section 314.81(b)(2) of title 21, Code of Federal Regulations (or any successor regulation), the following information:

(1) The names and addresses of the sources of active and inactive ingredients of the drug.

(2) For each active and inactive ingredient of the drug, the percentage of the aggregate amount of such ingredient used in the manufacture of the drug during the reporting period that is from each of the sources identified under paragraph (1).

(b) DISCLOSURE OF INFORMATION.—The Secretary of Health and Human Services shall—

(1) annually provide the information reported in paragraphs (1) and (2) of subsection (a) to the Secretary of Defense for purposes of understanding the dependency on foreign manufacturers of drugs used by members of the Armed Forces; and

(2) publish the information reported under such paragraphs on a publicly available internet website of the Federal Government in a single, aggregate form, without disclosing proprietary information.

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