

Administration of Joseph R. Biden, Jr., 2023

Presidential Determination and Waiver Pursuant to Section 303 of the Defense Production Act of 1950, as Amended, on Essential Medicines, Medical Countermeasures, and Critical Inputs

December 27, 2023

Presidential Determination No. 2024–03

Memorandum for the Secretary of Health and Human Services

Subject: Presidential Determination and Waiver Pursuant to Section 303 of the Defense Production Act of 1950, as amended, on Essential Medicines, Medical Countermeasures, and Critical Inputs

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 303 of the Defense Production Act of 1950, as amended (the "Act") (50 U.S.C. 4533), it is hereby ordered as follows:

Section 1. Determination. (a) I hereby determine, pursuant to section 303(a)(5) of the Act, that:

- (i) the essential medicines, medical countermeasures, and critical inputs referenced in subsection (b) of this section are industrial resources, materials, or critical technology items essential to the national defense;
- (ii) without Presidential action under section 303 of the Act, United States industry cannot reasonably be expected to provide the capability for the needed industrial resources, materials, or critical technology items in a timely manner; and
- (iii) purchases, purchase commitments, or other action pursuant to section 303 of the Act are the most cost-effective, expedient, and practical alternative method for meeting the need.

(b) The scope of projects implemented pursuant to section 303 of the Act under the determination in this section is limited to drug and biologic essential medicines, medical countermeasures, and critical inputs identified, as of the date of this determination, pursuant to section 3(c) of Executive Order 13944 of August 6, 2020 (Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States).

Sec. 2. Waiver of Statutory Requirements. Pursuant to section 303(a)(7)(B) of the Act, I find that action to expand the domestic production capabilities for essential medicines, medical countermeasures, and critical inputs is necessary to avert an industrial resource or critical technology item shortfall that would severely impair national defense capability. Therefore, I waive the requirements of section 303(a)(5)–(a)(6) of the Act for the purpose of expanding the domestic production capabilities for essential medicines, medical countermeasures, and critical inputs needed for national defense.

Sec. 3. General Provisions. (a) Nothing in this determination shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This determination shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This determination is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) You are authorized and directed to publish this determination in the *Federal Register*

JOSEPH R. BIDEN, JR.

[Filed with the Office of the Federal Register, 8:45 a.m., December 29, 2023]

NOTE: This memorandum was published in the *Federal Register* on January 2, 2024.

Categories: Communications to Federal Agencies : Essential medicines, medical countermeasures, and critical inputs, Defense Production Act of 1950 determination and waiver, memorandum.

Subjects: Defense Production Act of 1950, Presidential authorities; Medical equipment and supplies; Pharmaceutical industry, domestic production of critical inputs, promotion efforts.

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