Presidential Documents

Executive Order 14293 of May 5, 2025

Regulatory Relief To Promote Domestic Production of Critical Medicines

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. *Purpose.* During my first term, my Administration took unprecedented action to improve the well-being of the American people by restoring capacity for domestic production of critical pharmaceutical products. Notably, in 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), I directed each executive department and agency involved in the procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs to take a variety of actions to increase their domestic procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs, as defined in section 7 of that order, and to identify vulnerabilities in our Nation's supply chains for these products. Unfortunately, the prior administration did too little to advance these goals. Critical barriers and information gaps persist in establishing a domestic, resilient, and affordable pharmaceutical supply chain for American patients.

One key area of concern is the length of time it takes to build pharmaceutical manufacturing facilities in the United States today. New construction must navigate myriad Federal, State, and local requirements ranging from building standards and zoning restrictions to environmental protocols that together diminish the certainty needed to generate investment for large manufacturing projects. For pharmaceutical manufacturing, these barriers are heightened by unannounced inspections of domestic manufacturers by the Food and Drug Administration (FDA), which are more frequent than such inspections at international facilities. Industry estimates suggest that building new manufacturing capacity for pharmaceuticals and critical inputs may take as long as 5 to 10 years, which is unacceptable from a national security standpoint. Even expanding existing capacity or modifying existing production lines to produce new or different products requires extensive permitting and regulatory approval, making it more difficult to repurpose existing underutilized pharmaceutical manufacturing capacity available domestically.

It is in the best interest of the Nation to eliminate regulatory barriers to the domestic production of the medicines Americans need. My Administration will work to make the United States the most competitive nation in the world for the manufacture of safe and effective pharmaceutical products.

Sec. 2. *Policy.* It is the policy of the United States that the regulation of manufacturing pharmaceutical products and inputs be streamlined to facilitate the restoration of a robust domestic pharmaceutical manufacturing base.

Sec. 3. *Streamlining Review of Domestic Pharmaceutical Manufacturing by the Food and Drug Administration.* Within 180 days of the date of this order, the Secretary of Health and Human Services, through the Commissioner of Food and Drugs (FDA Commissioner), shall review existing regulations and guidance that pertain to the development of domestic pharmaceutical manufacturing and shall take steps to eliminate any duplicative or unnecessary requirements in such regulations and guidance; maximize

the timeliness and predictability of agency review; and streamline and accelerate the development of domestic pharmaceutical manufacturing. The FDA Commissioner's review shall encompass all regulations and guidance that apply to the inspection and approval of new and expanded manufacturing capacity, emerging technologies that enable the manufacturing of pharmaceutical products, active pharmaceutical ingredients, key starting materials, and associated raw materials in the United States. The FDA Commissioner shall:

(a) evaluate the current risk-based approach to prior approval of licensure inspections, including when such inspections are necessary, and seek to improve upon this approach to ensure all required inspections are prompt, efficient, and limited to what is necessary to ensure compliance with the Federal Food, Drug, and Cosmetic Act and other Federal law;

(b) identify and undertake measures necessary to expand, as practicable, existing programs that provide early technical advice before a facility is operational;

(c) identify and undertake measures necessary to improve enforcement of data reporting under section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)(3)), including consideration of publicly displaying the list of facilities, including foreign facilities, that are not in compliance;

(d) provide clearer guidance regarding the requirements or recommendations for site changes, including moving production from a foreign to domestic facility, and validation of new or updated components necessary in manufacturing; and

(e) review and, as appropriate, seek to update any other relevant compliance policies, guidance documents, and regulations.

Sec. 4. *Enhancing Inspection of Foreign Manufacturing Facilities.* Within 90 days of the date of this order, the FDA Commissioner shall develop and advance improvements to the risk-based inspection regime that ensures routine reviews of overseas manufacturing facilities involved in the supply of United States medicines, which shall be funded by increased fees on foreign manufacturing facilities to the extent consistent with applicable law. Additionally, the FDA Commissioner shall publicly disclose the annual number of inspections that the FDA conducts on such foreign facilities, with specific detail by country and by manufacturer.

Sec. 5. *Streamlining Review of Domestic Pharmaceutical Manufacturing by the Environmental Protection Agency.* Within 180 days of the date of this order, the Administrator of the Environmental Protection Agency (EPA) shall take action to update regulations and guidance that apply to the inspection and approval of new and expanded manufacturing capacity of pharmaceutical products, active pharmaceutical ingredients, key starting materials, and associated raw materials in the United States to eliminate any duplicative or unnecessary requirements and maximize the timeliness and predictability of agency review.

Sec. 6. *Centralized Coordination of Environmental Permits to Expand Domestic Pharmaceutical Manufacturing Capacity.* For purposes of 42 U.S.C. 4336a, the EPA shall be the lead agency for the permitting of pharmaceutical manufacturing facilities that require preparation of an Environmental Impact Statement pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.,* unless that role is assumed by another agency. The lead agency shall designate a single point of contact within the agency to coordinate with permit applicants. The Office of Management and Budget shall coordinate with the lead agency and with other relevant agencies and the Federal Permitting Improvement Steering Committee, as needed, to expedite the review and approval of relevant permits.

Sec. 7. *Streamlining Review of Domestic Pharmaceutical Manufacturing by the United States Army Corps of Engineers.* Within 180 days of the date of this order, the Secretary of the Army, acting through the Assistant Secretary

of the Army for Civil Works, shall review the nationwide permits issued under section 404 of the Clean Water Act of 1972 (33 U.S.C. 1344) and section 10 of the Rivers and Harbors Appropriation Act of 1899 (33 U.S.C. 403) to determine whether an activity-specific nationwide permit is needed to facilitate the efficient permitting of pharmaceutical manufacturing facilities.

Sec. 8. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

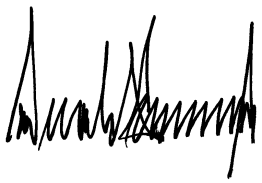
(i) the authority granted by law to an executive department or agency, or the head thereof; or

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

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

(c) This order 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) The Department of Health and Human Services shall provide funding for publication of this order in the *Federal Register*.



THE WHITE HOUSE,
May 5, 2025.

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