Regulatory Relief to Promote Domestic Production of Critical Medicines

Administration Policy:

President Trump issued an Executive Order (EO) titled Regulatory Relief to Promote Domestic Production of Critical Medicines, to restore capacity for domestic production of critical pharmaceutical products by eliminating regulatory barriers to the domestic production of medicines.

This EO requires that:

- Within 180 days –
  - the Secretary of Health and Human Services (HHS), through the Commissioner of Food and Drugs (FDA Commissioner), review existing regulations and guidance that pertain to the development of domestic pharmaceutical manufacturing.
  - the Environmental Protection Agency (EPA) Administrator update regulations and guidance that apply to the inspection and approval of new and expanded manufacturing capacity of pharmaceutical products, active pharmaceutical ingredients (API), key starting materials, and associated raw materials in the U.S.
  - the Secretary of the Army, though the Assistant Secretary for the Army of Civil Works, must review nationwide permits issued under section 404 of the Clean Water Act and determine whether an activity-specific nationwide permit is needed to facilitate efficient permitting of pharmaceutical manufacturing facilities.
- Within 90 days, the FDA Commissioner develop and advance improvements to the risk-based inspection regime that ensures routine reviews of overseas manufacturing facilities involved in the supply of US medicines.

This EO also establishes that the EPA functions as the leading agency for the permitting of pharmaceutical manufacturing facilities when an Environmental Impact Statement is required.

Background:

- On August 6, 2020, in response to the COVID-19 Public Health Emergency (PHE), President Trump issued EO 13944 to direct each department and agency involved to take actions to increase their domestic procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs and identify vulnerabilities in our national supply chains of these products.
- Currently, India and China manufacture the API's needed to make 60-70% of generic drugs on the U.S. market.
- Over 80% of all API's for essential medicines used in the U.S. have no domestic manufacturing source.
- The high reliance on foreign drug production raises concerns regarding product safety, supply chain security, and drug shortage risk.
- 235 drugs are currently in shortage in the U.S. – this includes common drugs like chemotherapies, antibiotics, and saline.
- A fact sheet from the White House can be found here.