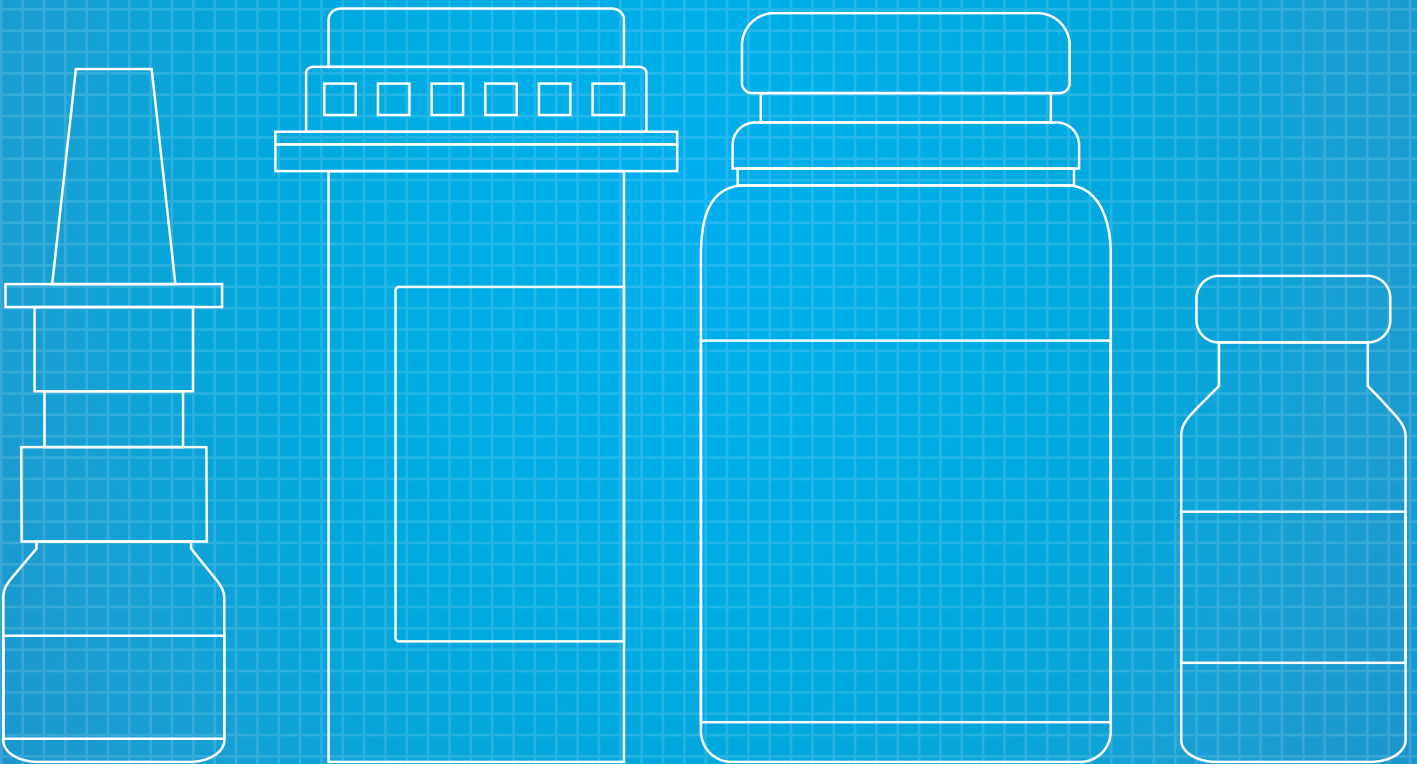




A Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain



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INTRODUCTION

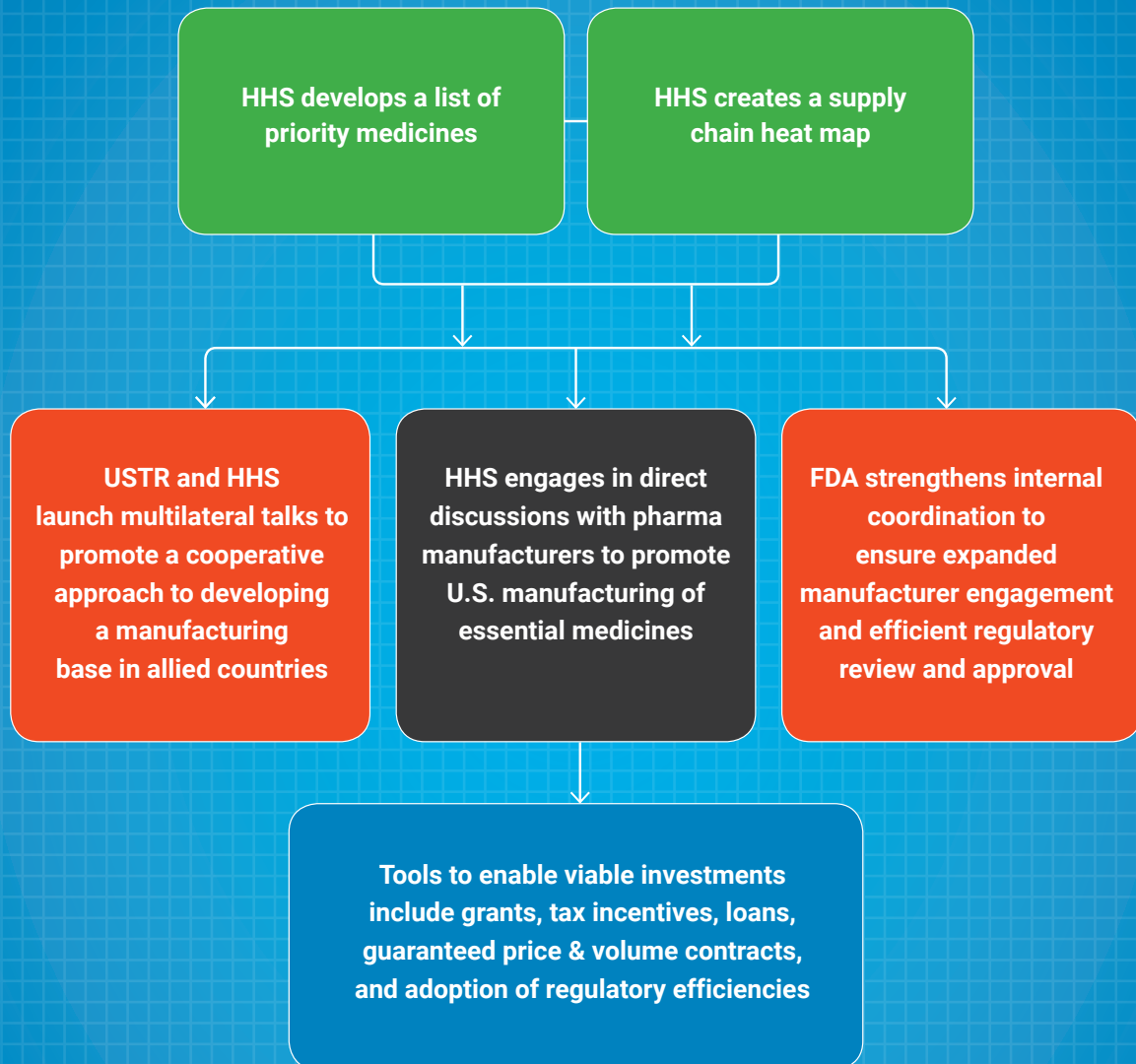
A closely connected, diverse, high-quality and resilient pharmaceutical supply chain based in the United States and in U.S. allied countries (such as Canada, Europe, India, Israel, Japan, Jordan and Mexico) is the best means to ensure that U.S. patients and the U.S. health care system have access to a secure and consistent supply of critical pharmaceuticals. The United States already plays an important role in this supply chain, with generic companies providing more than 36,000 jobs at nearly 150 facilities, and manufacturing more than 70 billion doses of prescription medicines annually.¹

With strategic support from the U.S. government, the economic footprint of the generic drug industry in the U.S. can expand even more, leading to increased national security, a stronger, more redundant supply chain for key pharmaceuticals or their components and an expanded employment base.

¹ Based on a 2016 survey of Association for Accessible Medicines' member companies.

Key Elements

Proposed Policy Framework



Expanding HHS Authority to Secure the U.S. Pharmaceutical Supply Chain:

Since the United States cannot produce all the medicines needed for its health care system and its patient population, the U.S. Department of Health and Human Services (HHS) must be given the authority to identify the most critical medicines for U.S. investment and to engage with the pharmaceutical industry to identify specific incentives necessary to maintain, utilize and attract investments that can cost as much as \$1 billion and take 5-7 years to build.

A. IDENTIFYING THE LIST OF MEDICINES MOST CRITICAL FOR U.S. MANUFACTURING

- **List of Essential Medicines.** Within 180 days of enactment, the Secretary of HHS shall establish a list of essential medicines for the United States. Essential medicines are defined as the active pharmaceutical ingredient (API) and finished dosage form (FD). The list of essential medicines shall include medicines deemed most critical to the U.S. health care system, vital during a secretary-designated public health emergency, and/or those that, if shortages occurred, could impact U.S. national security. In developing the list, the secretary shall consult with the U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH) and other public health agencies, as well as the Secretary of Defense and Secretary of State. The list shall be subject to a 60-day public comment period.
- **Assessment of Supply Chain.** Within one year of enactment, the Secretary of HHS shall prepare an assessment of the global supply chain's ability to source and manufacture the medicines on the list of essential medicines.² The assessment shall identify the location and number of facilities involved in the production of FD and API. The secretary shall consider several factors in preparing the assessment, including but not limited to the number of manufacturers of each FD and API; the number of manufacturers with approved Abbreviated New Drug Applications (ANDA); the market shares for manufacturers of each FD and API; the volume of FD and API manufactured at each facility; the extent of supply redundancy for each FD and API; and the geographic location of FD and API facilities. Information provided to HHS as part of the assessment shall be confidential and not subject to public disclosure due to its proprietary nature and potential to impact the market. The Secretary of HHS shall prepare and submit a report providing recommendations to Congress on how to strengthen the supply chain to ensure sustainable U.S. patient access to all essential medicines.
- **Designation of "High Priority" Essential Medicines.** From the list of essential medicines, and informed by the assessment of the supply chain, the Secretary of HHS shall publish a list of "high priority" essential medicines for the purpose of ensuring U.S. production and supply of those medicines. The secretary shall update the list annually and may designate additional medicines – including those not previously deemed essential – as "high priority" during a secretary-designated public health emergency. The list, and any updates, shall be subject to a 30-day public comment period.

2 The Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748) included several important steps intended to help strengthen the pharmaceutical supply chain. The CARES Act increases the transparency of the pharmaceutical supply chain by providing FDA with additional information on potential disruptions in the supply chain, on manufacturers' contingency plans to ensure continued supply and on the volume of medicines manufactured (Section 3112); stresses the importance of air transportation in maintaining well-functioning pharmaceutical supply chains (Section 4005); evaluates U.S. dependence on overseas manufacturing with a forthcoming report from the National Academies (Section 3101); and strengthens the national stockpile to ensure access to drugs, vaccines and other biological products (Section 3102). The policies outlined in this paper build on and enhance these provisions.

B. INCENTIVES TO SECURE THE U.S. PHARMACEUTICAL SUPPLY CHAIN

Within six months of the completion of the list of “high priority” medicines, HHS, acting through the Office of the Assistant Secretary for Preparedness and Response (ASPR), will seek new and specific proposals from pharmaceutical manufacturers to determine how individual companies can help secure the U.S. pharmaceutical manufacturing base for priority medicines. Proposals would include the list of specific FDs and APIs the company proposes manufacturing in the United States, and the specific type of incentives necessary to make the facilities economically viable. HHS would be authorized to make:

- **Long-Term Price and Volume Guaranteed Contracts.** Guaranteed volume and price agreements are essential to ensuring the viability of U.S.-based generic manufacturing for “high priority” medicines and to inoculate those investments against low-priced imports of the same medicine. When engaging with the industry, however, HHS must encourage multiple suppliers in the market and ensure, whenever possible, that no one company supplies the entire market (this protects against supply disruptions). The price and volume agreements would provide purchase guarantees that could be spread across the Strategic National Stockpile (SNS) and all federal agencies that procure medicines through the Federal Supply Schedule. For the SNS, HHS may take possession of such purchases or may pay manufacturers an inventory management fee to produce and maintain the specified quantity on behalf of the SNS. Specific volume and price levels would be negotiated on a company-by-company basis.
- **Grants.** HHS shall provide grants to support construction, alteration or renovation of facilities for the U.S.-based manufacture of medicines included on the high priority medicines list. Grants shall also be provided to pharmaceutical manufacturers to relocate production facilities from outside of the United States back to the United States to cover expenses in moving production and include funds to offset the cost of building new factories and research centers. Such grants shall be available only to manufacturers with an approved ANDA or authorized generic or to external/contract manufacturers of approved ANDAs or authorized generics. To support a diverse and reliable supply, such grants shall be available to multiple manufacturers of the same medicine. Grants will be administered by HHS/Biomedical Advanced Research and Development Authority (BARDA).

C. OTHER NECESSARY ELEMENTS TO SUPPORT AN EXPANDED U.S. PHARMACEUTICAL ECONOMIC FOOTPRINT

Certain additional measures will be necessary to support the economic viability of a U.S.-based pharmaceutical investment. The following elements will not be negotiated at an individual company level, like those listed above, but will instead be adopted for the entirety of the U.S. generics or biosimilars pharmaceutical manufacturing base:

- **Tax Incentives.** New tax incentives must be passed that promote U.S. pharmaceutical companies relocating foreign manufacturing back to the United States, build new greenfield sites, refurbish already existing manufacturing facilities and/or repurpose existing production lines to focus on pharmaceuticals that appear on HHS's list of "high priority" medicines.
 - » Manufacturers of medicines designated as "high priority" medicines shall be eligible for a tax deduction during whichever of the two periods is longer: throughout the period the medicine is deemed "high priority" or during the initial period that company has agreed with HHS to supply from its expanded investment. Specific tax incentives that will facilitate the onshoring of U.S. pharmaceutical manufacturing include:
 - » A dollar-for-dollar credit against federal taxes to pharmaceutical manufacturers for 50% of wages, investments and purchases made for manufacturing medications on the priority medicines list in the United States.
 - » A tax reduction modeled after the Section 199 Domestic Production Activities Deduction, which provided a tax deduction of as much as 9% of the company's income attributable to U.S. manufacturing operations.
 - » Increase the R&D credit rate to 20% for the alternative simplified credit.
 - » Provide full expensing for the construction of new factories built to move production from overseas to the United States.
- **Regulatory Efficiencies.** To expedite the approval of a facility and all the products to be produced in it the FDA will streamline its regulatory review and approval processes, removing duplicated actions and reducing the time for approvals across the board. The agency will expand cooperation with the manufacturer, working collaboratively to evaluate and approve the facility and the tech transfer processes concurrently, as opposed to waiting until after the facility is built and the equipment is installed/validated.



To accomplish these goals, the FDA will create an internal, intra-agency working group focused on helping to expedite reviews and approvals to onshore pharmaceutical manufacturing. This working group will consist of resources from the Office of Regulatory Affairs; the Office of Pharmaceutical Quality; the Office of Compliance; reviewers from both chemistry and microbiology disciplines; and the Office of Generic Drugs. This working group will focus on reviewing for approval the transfer of production back into either U.S.-approved facilities or newly constructed facilities at new or existing sites, including those utilizing advanced manufacturing technology. This working group will grant meetings with the company to discuss the overall transfer plans. For example:

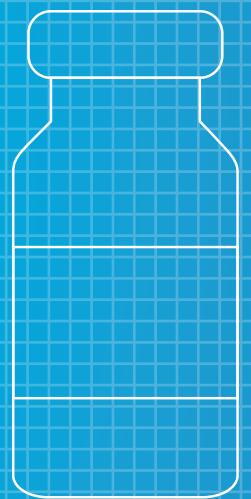
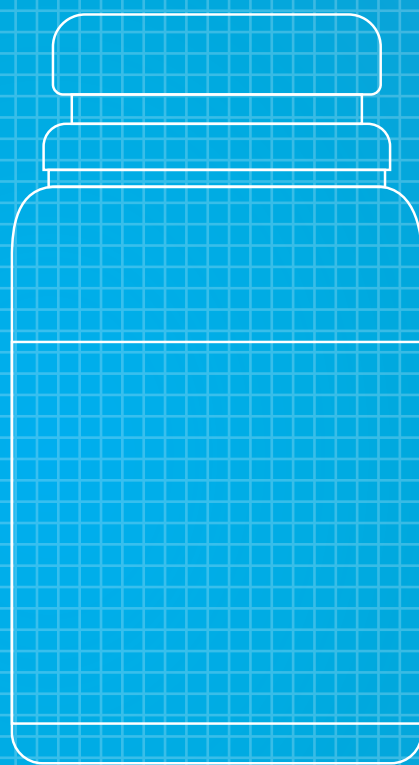
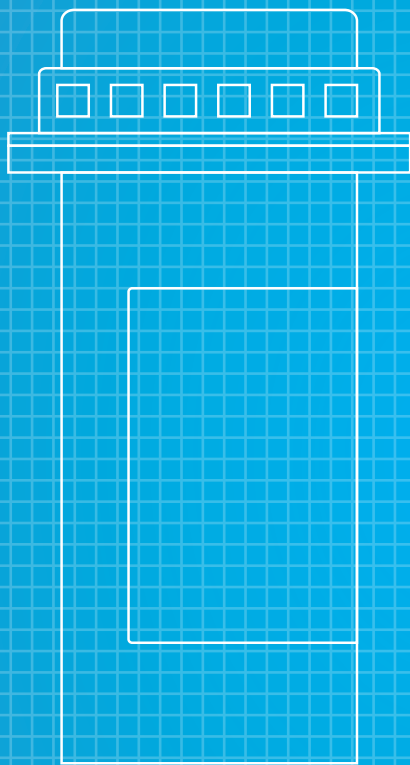
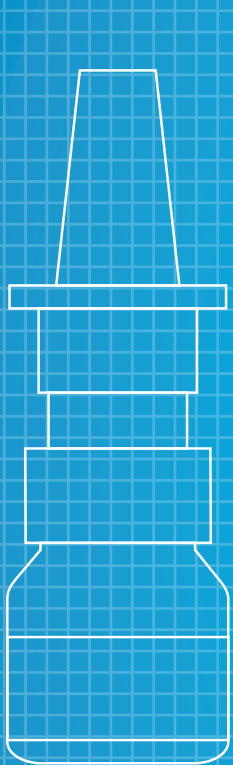
- » Inspector(s) and Office of Pharmaceutical Quality staff will make site visit(s) during the construction or validation phase.
- » The mechanism will be similar to a pre-ANDA meeting – that is, a developmental phase inspection and then a pre-submission inspection.
- » Microbiology reviewer(s) will conduct site visits.
- » Decouple submission and inspection. Inspections will be completed within 30 days of request for inspection, regardless of submission.

D. INCREASING U.S. PHARMACEUTICAL SUPPLY CHAIN SECURITY THROUGH GLOBAL COORDINATION

- **The International Pharmaceutical Supply Chain Agreement.** To promote the benefits of a globally diverse supply chain, the United States Trade Representative (USTR), working with HHS, should negotiate a plurilateral agreement with U.S. allies to promote a cooperative approach to securing the U.S. supply chain, ensuring diversity of supply and responding to global health care challenges and natural disasters, without resorting to export controls or other trade barriers. In addition, coordinating the expansion of pharmaceutical manufacturing with U.S. allies will allow for economies of scale and a coordinated approach to global pandemics. Possible signatories would include U.S. allies such as Canada, Europe, India, Israel, Japan, Jordan and Mexico.

Definitions

- “Generic drug” means “any drug that is marketed under an abbreviated new drug application (ANDA) as well as an ‘authorized generic drug.’”
- “Manufacture” has the meaning set forth in the Buy American Act, 41 U.S.C. §§ 8301-8305: “completion of an article in the form required for use by the government in the United States. For drugs this means readied for use as a medicine for human consumption.”





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