

# The U.S. Should Focus on Targeted and Temporary Tools to Ensure Access to Medical Supply Chains

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## KEY TAKEAWAYS

The coronavirus outbreak has caused many Americans to ask if the U.S. is over-reliant on foreign suppliers of key medical and pharmaceutical goods.

While the U.S. has taken pragmatic steps to address possible shortages, it should refrain from increasing regulatory barriers that ultimately decrease access.

The Administration and Congress should use targeted and temporary emergency measures to ensure supply of critical pharmaceuticals and medical equipment.

The U.S. government is working to remove regulatory barriers that could prevent medical professionals from being fully equipped to address the COVID-19 crisis in the United States. The Trump Administration has also invoked the Defense Production Act to direct production of specific products and waived tariffs for imports of products from China.<sup>1</sup> These are both pragmatic approaches to the supply challenges being faced by the health industry.

In response to additional concerns about supply, and actions of other governments to impose export controls, Congress and the Administration are proposing policies that would reduce imports of pharmaceuticals and medical equipment. However, if policymakers rush to implement such policies before fully evaluating their potential effect on manufacturing and supply chains, they risk inadvertently creating new disruptions and shortages that could further jeopardize Americans' access to life-saving products.

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Prior to the current crisis, Congress and the Food and Drug Administration (FDA) were already working to address drug shortages, a process that requires careful deliberation. In the midst of this crisis, it is important that U.S. government policies do not introduce new regulatory obstacles to companies bringing Americans the medical products they need, when they need them. It is also crucial that any policy changes do not undermine the ability of companies to innovate and continue bringing Americans the best treatments and cures. While existing public policies should be constantly reviewed and improved where needed, it is important to recognize that U.S. patients currently enjoy one of the world's best environments for access both to innovative new drugs and to low-cost generic versions of older drugs. In short, when addressing these issues, policymakers should keep in mind one of the oldest adages in medicine: First, do no harm.

Any drug or device shortages, or other medical supply chain issues, arising during the COVID-19 crisis should be met with the proper emergency policy responses: (1) the FDA exercising its statutory emergency authorities to expedite the availability of needed medical products, and (2) the targeted and temporary use of the Strategic National Stockpile or (3) the Defense Production Act. The Trump Administration is already implementing all three of these responses.

## **Responses to Medical Equipment Supply Challenges During the Pandemic**

As policymakers are working to ensure that medical professionals have the materials they need to combat the COVID-19 pandemic, concerns have been raised about the availability of items such as ventilators and N95 face masks. The Department of Health and Human Services (HHS) estimates that 3.5 billion N95 masks are needed as medical professionals fight COVID-19 in the U.S., but as of early March 2020, the government had stockpiled only around 12 million. Additionally, the World Health Organization estimates that manufacturing of this kind of medical equipment would need to increase by 40 percent to meet the spike in demand.<sup>2</sup>

In response to this possible future shortage, as well as to the already existing shortage, the Trump Administration approved exclusion requests for dozens of medical product imports from China, shielding these products from costly tariffs.<sup>3</sup> The President also signed an executive order that allows the government to use authorities delegated by the Defense Production Act to financially support industries that produce the medical equipment that is in high demand and shore up supply.<sup>4</sup> In addition, the FDA has provided manufacturers and suppliers with a series of Emergency Use Authorizations

to help speed the production and distribution of needed drugs, devices, and tests.<sup>5</sup> Longer term, Congress included a provision in the Coronavirus Aid, Relief, and Economic Security (CARES) Act requiring the HHS to commission a study with the National Academies of Sciences, Engineering, and Medicine “to examine, and, in a manner that does not compromise national security, report on, the security of the United States medical product supply chain.”<sup>6</sup> These actions represent pragmatic approaches to addressing supply concerns and ensuring public safety during the pandemic.

At the same time, broader concerns about the origin of pharmaceuticals and medical equipment consumed in the U.S. and their relevant supply chains are fueling efforts in Congress and the Administration to impose new restrictions on these industries. While it is important to question drug safety and supply for Americans, the solutions currently being considered by Congress and the Administration could actually worsen the supply challenges that exist today.

**Buy American Executive Order.** *The New York Times* reported that the White House is considering an executive order that would require all federal agencies to purchase only American-made pharmaceuticals and medical equipment.<sup>7</sup> Supply chains in these industries are highly diverse, and developing new production comes with costly and time-consuming regulatory barriers, as well as inspections needed to ensure that the resulting products meet standards for safety and effectiveness. This means that supply would not meet demand for some time, and the costs for these products could rise substantially in the meantime, consequences that are unhelpful to Americans in the midst of a pandemic.

**Legislative Efforts.** Similarly, Senator Tom Cotton (R-AK) and Representative Mike Gallagher (R-WI) introduced legislation that aims to “end U.S. dependence on China for pharmaceutical manufacturing.” The legislation would do so by preventing federal agencies from purchasing drugs from China or drugs with active ingredients from China. It would also impose additional regulations on drug manufacturers requiring country of origin labeling.<sup>8</sup> While this policy would be phased in over two years, it would likely still have a negative impact on the supply of the products for Americans. It is more important to focus on policies that increase patient safety and access to medical supplies.

## Understanding Supply Chain Challenges

The broader issue of ensuring an adequate and consistent supply of drugs has been of concern to policymakers for some time. Specifically, there is

apprehension about the extent to which pharmaceutical supply chains have expanded abroad over the past several decades. According to the FDA “about 40 percent of finished drugs and 80 percent of active drug ingredients are manufactured overseas.”<sup>9</sup>

Despite this diversification in production locations, manufacturers are working to maintain patient safety in cooperation with the FDA. In testimony before the Energy and Commerce Subcommittee on Oversight and Investigations Janet Woodcock, director of the Center for Drug Evaluation and Research at the FDA, explained that while facility inspections used to be primarily conducted in the U.S., as a result of more foreign production sites being added to the supply chain, “since 2015, [the FDA] has conducted more foreign than domestic drug inspections.”<sup>10</sup>

Currently, of the manufacturing facilities that produce FDA-regulated active pharmaceutical ingredients, 28 percent are located in the U.S., 26 percent are in EU countries, 18 percent are in India, 13 percent are in China, and 2 percent are in Canada.<sup>11</sup> With regard to facilities that manufacture FDA-regulated finished dosage forms, 47 percent are located in the U.S., 18 percent are in EU countries, 11 percent are in India, 7 percent are in China, and 4 percent are in Canada.<sup>12</sup>

In the broader context of supply concerns, the economics of generic drug production presents a unique set of challenges for producers.<sup>13</sup> The key challenge is that because prices are so competitive, facilities utilize nearly 100 percent of their capacity. That means there is very little ability for them to increase production on existing lines to quickly meet new demand, especially when that demand increases exponentially in a matter of days or weeks. Rather, investment in building new capacity must be made, which takes time and capital.

Regulatory approvals are also required when either an existing manufacturer adds a new production line to increase the volume of the drug it makes, or an additional manufacturer starts to produce the drug. These considerations are in play regardless of the physical location of the factories producing the drugs. Indeed, they would all still be important and relevant issues even if 100 percent of generic drugs were manufactured domestically.

Once the crisis is resolved, policymakers need to address those issues thoughtfully, deliberately, and consistently over a sustained period of time. Given that policymakers must balance ensuring reliable production with ensuring that the resulting products are safe and affordable for consumers, possible changes to laws or regulations are unlikely to be either simple or immediately executable.

## Using Emergency Measures to Secure Critical Materials

The economic realities explained above do not mean that production changes are impossible. In the case of an emergency shortage, the government could assist in a targeted and temporary manner to help offset the challenges faced by producers. In recent weeks, the FDA has been using its emergency authorities to do just that, particularly with respect to meeting the most pressing needs for COVID-19 tests, personal protective equipment, and ventilators. Also, Congress already took steps in the CARES Act to enhance the FDA's ability to more quickly identify potential shortages, and thus address them before they become major problems. Moving forward, it is wise for the government to have a plan in the event of a critical pharmaceutical shortage. The government should only intervene in a true emergency, and it should do so in a way that is limited in scope and duration. The following are policy tools that could potentially be used or adapted for this situation.

**Strategic National Stockpile.** The Strategic National Stockpile is the country's largest reserve of medicines and medical supplies for use in emergencies. Managed by the HHS, it was created in 1999 to ensure readiness in the event of bioterrorism and has been used to address a variety of public health emergencies, from hurricanes to influenza outbreaks.<sup>14</sup> The Strategic National Stockpile has already shipped more than 539 tons of cargo in response to the COVID-19 emergency, specifically to support U.S. citizen repatriation and to provide states with much-needed personal protective equipment.

The stockpile has been used to supply specific regions with critical pharmaceuticals during national disasters: It provided 30,000 vials of insulin and other critical medications to Louisiana and Mississippi in the wake of Hurricane Katrina, for instance.<sup>15</sup> However, it is unclear whether the Strategic National Stockpile could provide enough drugs in the case of a country-wide shortage. Policymakers should explore the feasibility of using the stockpile to address potential critical pharmaceutical shortages.

**The Defense Production Act.** The Defense Production Act gives the President the power to influence domestic industry in the interests of national defense. President Trump invoked the act on March 18 in order to prioritize and allocate medical supplies in response to the spread of COVID-19. It gives the President (and, per the March 27 Executive Order, the HHS Secretary and the Secretary of Homeland Security) the power to reallocate raw materials and finished goods, prioritize government contracts at private firms, and increase companies' production of key goods as needed to treat or slow the spread of the coronavirus.<sup>16</sup>

Currently, the Administration has used the act to compel General Motors to produce ventilators, to direct 3M to produce more masks, and to increase the availability of components for ventilators.<sup>17</sup> The larger use of the act thus far has been to provide leverage to persuade businesses' voluntary efforts to ramp up production of these items.<sup>18</sup> Similarly, use of the act could be justified in the case of pharmaceutical shortages if they are set to become an emergency of similar magnitude to COVID-19 itself, and the shortages of drugs are as dire as the current shortages of ventilators and N95 masks.

If the act were invoked to address an emergency pharmaceutical shortage, the President and the HHS Secretary would have a variety of tools at their disposal, including the power to allocate materials among pharmaceutical companies (under Title I of the act) and to award grants to these companies for facilities expansions (under Title III).<sup>19</sup> These measures could boost domestic production without further interrupting global supply chains. Any action, however, should be aimed at specific drug shortages, rather than a general response across the pharmaceutical industry.

## Recommendations

When addressing pharmaceutical supply issues, it is important that U.S. government policies not add regulatory barriers that impair the ability of the industry to bring Americans what they need when they need it. It is also crucial that any policy changes continue to encourage innovation and competition.

To ensure these principles, Congress and the Administration should:

- **Evaluate concerns over drug sourcing and quality control independently of the COVID-19 pandemic.** Congress and the FDA are already working to address sourcing and quality concerns. They need to keep doing so with all due deliberation, and continue doing so even after the current crisis has passed.
- **Utilize emergency measures in the case of a shortage of critical items.** If there is a pharmaceutical shortage emergency, the Defense Production Act could be used to provide a finite and targeted boost to necessary domestic manufacturers. The Strategic National Stockpile could also provide critical pharmaceuticals in a shortage, though policymakers will have to evaluate the stockpile's capacity to address a country-wide shortage.

## Conclusion

The Trump Administration has taken pragmatic steps to address supply shortages of N95 masks and other critical medical equipment. Unfortunately, other proposals by Congress and the Administration could worsen the supply issues being faced today and undermine America's ability to innovate and bring Americans the best treatments and cures in the future. Broader concerns about medical supply chains, while they may be reasonable, should be addressed independently of the pandemic. In the case of emergency shortages, the Administration should use targeted and temporary emergency measures to ensure a supply of critical pharmaceuticals and medical equipment.

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