

FOREIGN AFFAIRS

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The Real Vaccine Procurement Problem

Why America Should Make Its Supply Chain More
Transparent

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On the campaign trail, Joe Biden promised to accelerate the U.S. vaccination drive by invoking the Defense Production Act, a Korean War-era law that allows the government to require U.S. companies to prioritize federal contracts over other ones when doing so serves the national defense. President Donald Trump had used the law relatively sparingly to ensure that Pfizer and Moderna, among other vaccine manufacturers, had some of the crucial inputs they needed to produce the doses his administration had promised to Americans. But Biden pledged to invoke the DPA more aggressively, and early in his presidency, he intervened to help vaccine makers overcome acute shortages and rapidly expand production. “We’re using the Defense Production Act to launch a full-scale, wartime effort to address the supply shortages we inherited from the previous administration,” Biden said on January 26. “We’re going to be working across the government, with private industry, to ramp up production of vaccine and protective equipment.”

Use of the Defense Production Act, by both the Trump and Biden administrations, may have helped the United States alleviate manufacturing bottlenecks and quickly scale up vaccine production. Some companies even called on the U.S. government to invoke the DPA on their behalf. But one unintended consequence of ordering suppliers of specialized inputs to prioritize contracts with companies manufacturing vaccines in the United States has been to fuel popular belief, especially abroad, that the DPA is being used to halt exports of these inputs to other countries that desperately need them.

“On behalf of the vaccine industry outside the U.S., I humbly request you to lift the embargo of raw material exports out of the U.S. so that vaccine production can ramp up,” Adar Poonawalla, the CEO of the Serum Institute of India, the world’s largest vaccine manufacturer, tweeted at Biden on April 16. A few weeks later, French President Emmanuel Macron echoed this concern, calling on the United States to “end export bans not only on vaccines, but on ingredients of those vaccines.” Franz-Werner Haas, the CEO of the German vaccine manufacturer CureVac, piled on soon after, telling *Der Spiegel* that because of the DPA “we are simply unable to get certain products out of the U.S.” Vaccine makers in South Africa and the United Kingdom have also blamed use of the DPA for their production shortfalls.

But the DPA did not cause the global shortage of vaccine inputs, and ending or altering its use would not by itself fix the problem. The scarcity stems from the sudden need to produce billions of COVID-19 vaccine doses around the world, an unprecedented feat that would have depleted supplies regardless of what the United States did. Still, because it has invoked the DPA without disclosing how exactly it will use the law and whose supplies it will deprioritize, Washington has unwittingly fueled the perception that it is to blame for global supply shortages. The Biden administration should clarify how and when it has used the DPA to fight the coronavirus pandemic and work with partners—especially the European Union and India—to make vaccine-manufacturing supply chains and production processes more transparent.

A CONVENIENT SCAPEGOAT

Much of the anger and confusion over the DPA stems from the veiled circumstances of its use. Neither the Trump administration nor the Biden administration has disclosed the precise terms of its priority contracts, making it difficult to assess the full effects of its actions. What little is publicly known comes mostly from company announcements and news reports.

Trump invoked the DPA sporadically and selectively. After initially downplaying the severity of the pandemic, he used the DPA to suddenly limit exports of N-95 masks, hospital gloves, and other personal protective equipment. His administration also required U.S. manufacturers of vaccines to allocate hundreds of millions of doses to the U.S. government before shipping any abroad—a policy that carried over into the first three months of the Biden administration. By the end of 2020, the Trump administration had invoked the DPA to aid the manufacturers of all six of the vaccines being made in the United States as a part of its Operation Warp Speed initiative: Moderna, AstraZeneca, Novavax, Johnson & Johnson, Sanofi, and Pfizer.

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In some of these cases, Trump invoked the DPA at the request of vaccine makers. Pfizer, whose CEO publicly called on the Trump administration to use the act in December 2020, signed its second hundred-million-dose contract with the U.S. government later that month under terms that granted it priority access to some nine specialized vaccine components, according to *The New York Times*. The *Times* later reported that the DPA had also been used to help Pfizer obtain heavy machinery to expand one of its plants in Michigan. Although these contracts may have helped vaccine makers source only a limited number of inputs—and were a response to rather than a cause of global shortages—their opaque terms allowed critics to assume the worst and blame the United States when they, too, likely had trouble accessing supplies.

Biden's more aggressive use of the DPA only reinforced this perception. After Tim Manning, the Biden administration's COVID-19 supply

coordinator, announced in early February that the DPA had been used to help Pfizer get still more inputs—specialized pumps and filters, in this case—an onslaught of complaints erupted, including from Poonawalla, Haas, and Mahima Datla, the CEO of the Indian vaccine manufacturer Biological E. All three executives accused the U.S. government of banning exports of raw materials and critical equipment even as India experienced a horrible surge in cases.

Initially, Biden’s communications team did little to dispel this notion: at an April 22 press conference, a State Department spokesperson said that the rumored export controls were part of “an ambitious and effective and, so far, successful effort to vaccinate the American people.” Public outcry ensued. But it was only after China began publicizing its own shipment of essential medical supplies to India that the White House shifted gears and Manning attempted to explain that the DPA use “doesn’t mean an export ban. DPA doesn’t even mean a ‘de facto’ ban. Companies are able to export. In fact, companies that supply our vaccine manufacturing export their product all across the world. We are just one ‘client’ of the raw material companies. . . . [The DPA] also doesn’t create the shortages.” Even though supply chain data later confirmed that there had never been an export ban, the damage had already been done.

INEVITABLE SHORTAGES

Although the murky nature of the DPA makes it difficult to assess the full impact of its invocation, there is little evidence that it has caused the kind of damage its critics allege. A global shortage of inputs was inevitable the moment that ten billion doses of a new vaccine became necessary overnight. Giving some of the companies making these vaccines priority access to facilities, critical equipment, and raw materials had to come at the expense of other companies—likely those making drugs or other vaccines deemed less urgent. Suppliers of these vital supplies and equipment have made major investments to ramp up their production, but it will be another several months before they are able to meet demand. In the meantime, shortages are likely to continue, especially as regulators

authorize more vaccine candidates and additional vaccine production facilities come online.

Clearly, DPA priority ratings have altered the business operations of many suppliers of vaccine components and services, forcing some to shift their entire production lines to accommodate COVID-19 vaccine makers' needs. After the Trump administration invoked the DPA in December, Catalent, a contractor putting doses into vials for Moderna and Johnson & Johnson, had to prioritize COVID-19 vaccines at its Indiana plant over fulfilling an earlier contract for a thyroid eye disease drug called Tepezza. But the same kind of resource reallocation may have occurred even without a DPA invocation, given the enormity of demand and the lack of idle capacity. In Germany, for instance, a company called IDT Biologika also agreed to bottle more doses of the Johnson & Johnson and AstraZeneca vaccines by deprioritizing other companies' orders, including for doses of an experimental vaccine for dengue.

The extent to which Washington's use of the DPA has exacerbated shortages, moreover, is far from clear. Take the Serum Institute of India, whose CEO, Poonawalla, blamed the supposed U.S. export bans for its difficulty producing two different vaccines—one for Novavax and one for AstraZeneca. The cause of the Novavax equipment shortage remains unknown. According to *The Guardian*, ABEC—an important supplier of customized “bioreactor bags” used in the manufacturing process for the Serum Institute's Novavax vaccine—reports a lead time of 16 weeks for new orders. And, simply put, “The bag manufacturing capacity can't meet demand right now,” as an ABEC executive told the newspaper.

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Nor is it clear that scarce bioreactor bags should be devoted at present to production of the Novavax vaccine, which has reported promising clinical trial results but has yet to be authorized for use by regulators in India, the United States, the United Kingdom, or anywhere else. In fact, given the choice, U.S. policymakers would be right to prioritize sending scarce equipment and materials to plants manufacturing Johnson & Johnson,

Pfizer, and Moderna, the vaccines that the World Health Organization and regulators worldwide have already greenlighted for use.

When it comes to producing vaccines for AstraZeneca, the Serum Institute may have actually benefited from the DPA. In late April, the White House announced that it was sending the Serum Institute special filters that had presumably been bought by a company making the AstraZeneca vaccine in the United States under the Operation Warp Speed contract. In other words, because the United States had helped secure access to filters via the DPA, it was likely able to share some of its supplies with an Indian company in need.

The United States has taken other important measures to address global input shortages, unrelated to the DPA. It has invested heavily in the production of vaccine supplies, including by subsidizing the manufacture of cellular materials, bioreactors, bioreactor bags, and filtration equipment—all of which are in short supply globally. It has also begun informally coordinating vaccine supply chains with the European Commission, likely helping to resolve some input bottlenecks and potentially increasing the availability of supplies for Pfizer, Moderna, Johnson & Johnson, AstraZeneca, and other vaccines produced in Europe. Additional investment and coordination are needed, especially with India and other non-European countries key to the global COVID-19 vaccine supply chain.

TRANSPARENCY NOW!

The likely persistence of input shortages means that U.S. policymakers must do two things at once: incentivize production of scarce supplies and efficiently allocate those supplies that are available now. Although some producers of vital equipment and material have facilities in the United States, many also have plants in Europe, the United Kingdom, and elsewhere. Unlike the United States, however, governments in these countries have generally not subsidized the expansion of critical inputs. One way to spur greater global public investment in these supplies would be to forge an international agreement on COVID-19 vaccine investment

and trade that would help countries coordinate on the subsidization of raw materials and equipment.

Governments should also be more transparent about vaccine production. The United States should start by disclosing when and how it has invoked the DPA to reallocate supplies, enhancing the public's understanding of the law's effects and dispelling the myth that it is to blame for input shortages. Transparency around DPA use would have other benefits as well, including reducing the incentive for companies to hoard supplies in anticipation of priority orders from the U.S. government. Other players need to be more open, too. Much of the international conflict over COVID-19 vaccines and supplies has arisen because no one can reliably determine whether orders have been double-booked.

The United States should therefore work with the EU, India, and other allies to establish a system of global transparency for COVID-19 vaccines and inputs. Such an initiative has precedent. After dozens of countries imposed export restrictions on food staples during a perceived food crisis between 2008 and 2011, the G-20 created the Agricultural Market Information System to improve transparency and coordinate policy in the event of sudden scarcity. In the early days of COVID-19, AMIS arguably helped avoid a resurgence of agricultural export bans.

If the United States does not lead the way toward greater vaccine supply chain transparency, it can expect the rest of the world to mimic the worst behaviors of which Washington has been accused. Foreign laws similar to the DPA could proliferate, which would make supply chains even more opaque. In the end, it is American interests—and Americans—that would suffer.