

# Covid-19 vaccine supply chain bottlenecks and international policy cooperation

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### US export ban on vaccine supplies?



Respected @POTUS, if we are to truly unite in beating this virus, 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. Your administration has the details.

4:46 AM · Apr 16, 2021 · Twitter Web App

27.3K Retweets 2,544 Quote Tweets 107.8K Likes

### FINANCIAL TIMES

MARCH 14 2021

Mahima Datla, chief executive of pharmaceutical company Biological E, said US suppliers claim they may not be able to fulfil orders to global clients because of Washington's use of the Defense Production Act.

Calling for urgent international intervention, Datla told the Financial Times: "It's not only going to make the scale up for Covid vaccines difficult, but because of this it's going to make manufacturing of routine vaccines extremely difficult."





Spoke today with National Security Advisor Ajit Doval about the spike in COVID cases in India and we agreed to stay in close touch in the coming days. The United States stands in solidarity with the people of India and we are deploying more supplies and resources:

#### Statement by NSC Spokesperson Emily Horne on National Security Advisor Jake Sullivan's Call with National Security Advisor Ajit Doval of India

National Security Advisor Jake Sullivan spoke by phone today with National Security Advisor Ajit Doval, expressing deep sympathy for the people of India following the recent spike in COVID-19 cases. Mr. Sullivan affirmed America's solidarity with India, the two countries with the greatest number of COVID-19 cases in the world. Building on the seven-decade health partnership between the United States and India—including battles against smallpox, polio, and HIV—they resolved that India and the United States will continue to fight the global COVID-19 pandemic together. Just as India sent assistance to the United States as our hospitals were strained early in the pandemic, the United States is determined to help India in its time of need.

To this end, the United States is working around the clock to deploy available resources and supplies. The United States has identified sources of specific raw material urgently required for Indian manufacture of the Covishield vaccine that will immediately be made available for India. To help treat COVID-19 patients and protect front-line health workers in India, the United States has identified supplies of therapeutics, rapid diagnostic test kits, ventilators, and Personal Protective Equipment (PPE) that will immediately be made available for India. The United States also is pursuing options to provide oxygen generation and related supplies on an urgent basis. The U.S. Development Finance Corporation (DFC) is funding a substantial expansion of manufacturing capability for BioE, the vaccine manufacturer in India, enabling BioE to ramp up to produce at least 1 billion doses of COVID-19 vaccines by the end of 2022. Additionally, the United States is deploying an expert team of public health advisors from the Center for Disease Control (CDC) and USAID to work in close collaboration with the U.S. Embassy, India's health ministries, and India's Epidemic Intelligence Service staff. USAID will also quickly work with CDC to support and fast-track the mobilization of emergency resources available to India through the Global Fund.

The two National Security Advisors agreed that the U.S. and India would stay in close touch in coming days.

12:40 PM · Apr 25, 2021 · Twitter Web App

### US export ban on vaccine supplies? No

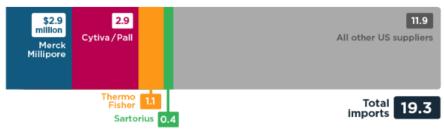


Figure 2

### Serum Institute received more US vaccine supplies during October 2020-March 2021 than in the previous six months

Serum Institute of India imports from the US by supplier, millions of dollars

Total imports from US, April-September 2020



Total imports from US, October 2020 - March 2021

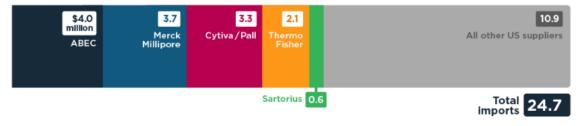


Figure 3

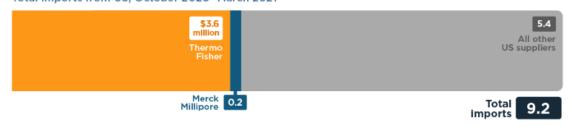
### Biological E received more US vaccine supplies during October 2020-March 2021 than in the previous six months

Biological E imports from the US by supplier, millions of dollars

Total imports from US, April-September 2020



Total imports from US, October 2020-March 2021

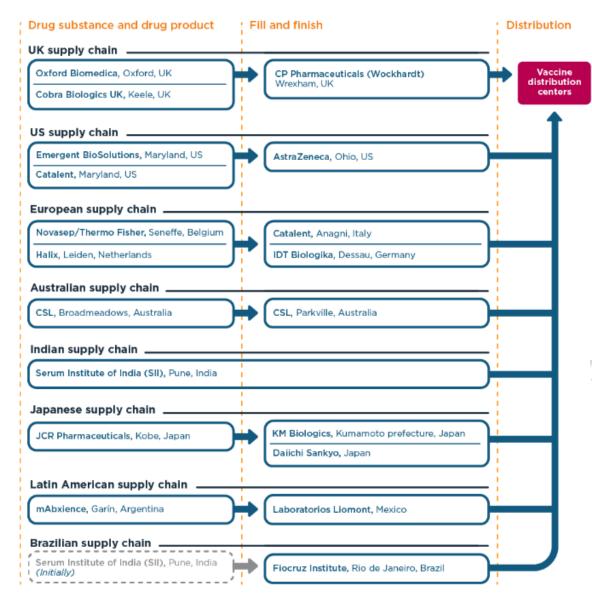


### Still, economic problem: shortages of specialized inputs

Source: Bown, Chad P. and Chris Rogers, <u>The US did not ban exports of vaccine supplies. But more help is needed</u>. PIIE Trade and Investment Policy Watch. 7 June 2021.

### AstraZeneca's global vaccine manufacturing network

Partners and facilities involved in Oxford/AstraZeneca vaccine production



### Why are there input shortages?



- 10 companies (plants) making the drug product
  - 9 companies (plants) doing the fill and finish
- They may all be going to the same input providers



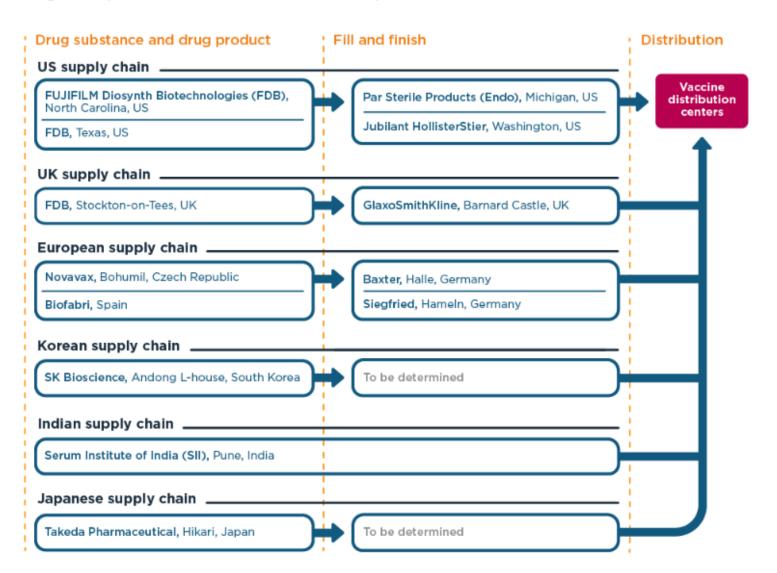
The need to standardize was a necessity for this project because there are more than 20 different sites manufacturing CHAdOxInCov-19/AZD1222, each using the 50 or so consumables required for the manufacturing process. If each site had its own customized version, there would need to be more than 1,000 parts!

By standardizing the SU manifolds as much as possible, the supply chain is simplified; it is possible to work with preferred components and ensure that these parts get to where they are needed on time rather than becoming a bottleneck for **vaccine manufacturing**.

And while the specific details of the process established for the Oxford/AZ COVID-19 vaccine cannot be disclosed, information on Pall's platform for scale-up of a typical Ad5 viral vector intended for use in a gene therapy product can be presented.

### Novavax's global vaccine manufacturing network

Stages and partners involved in Novavax vaccine production







- United States: Operation Warp Speed and Defense Production Act
- United Kingdom
- European Union, Germany and others
- CEPI and foundations

# **US: Operation Warp Speed and Defense Production Act**



Company	Amount	Date	Task
Vaccine sponsors			
Johnson & Johnson (Janssen)	\$21 million	February 11, 2020	Support nonclinical studies and a Phase 1 clinical trial
	\$436 million	March 27, 2020	Amendment
	\$1 billion	August 5, 2020	Demonstrate large-scale manufacturing, 100 million doses
	\$85 million	August 21, 2020	(Unknown)
	\$454 million	November 13, 2020	Amendment, funding for Phase 3 clinical trial
Sanofi and GSK	\$31 million	April 10, 2020	Accelerate nonclinical studies and a Phase 1 clinical trial
	\$2.04 billion	July 30, 2020	Phase 3 clinical trial, manufacturing demonstration project
Merck and IAVI	\$38 million	April 15, 2020	Accelerate development of vaccine candidate
Moderna	\$430 million	April 16, 2020	Accelerate development of vaccine candidate
	\$53 million	May 24, 2020	Expand manufacturing capacity
	\$472 million	July 25, 2020	Support Phase 3 clinical trial
	\$1.53 billion	August 11, 2020	Support Lonza's manufacturing, 100 million doses
	\$1.67 billion	December 11, 2020	100 million doses
	\$1.75 billion	February 11, 2021	100 million doses
Novavax	\$60 million	June 4, 2020	Manufacturing components for use in Phase 2/3 clinical trial
	\$1.60 billion	July 6, 2020	Demonstrate commercial-scale manufacturing
Pfizer (BioNTech)	\$1.95 billion	July 21, 2020	100 million doses
	\$2.01 billion	December 22, 2020	100 million doses, option for 400 million more
	\$2.01 billion	February 11, 2021	100 million doses
AstraZeneca (Oxford)	\$1.6 billion	October 28, 2020	Accelerate development and manufacturing to begin Phase 3 clinical trial

Contract manufacturers						
Efficial and Biosolutions	\$628 million	May 30, 2020	Contract manufacture, fill and finish			
	\$20 million	August 6, 2020				
Fujifilm Diosynth Biotechnologies (Texas A&M University)	\$265 million	July 24, 2020	Contract manufacture			
Grand River Aseptic Manufacturing (GRAM)	\$161 million	August 6, 2020	Fill and finish, including for Johnson & Johnson's vaccine			
Ology Bio	\$106 million	August 17, 2020	Fill and finish			
Merck	\$269 million	March 2, 2021	Produce drug substance, formulate and fill vials of Johnson & Johnson's vaccine			
Equipment and other input suppliers						
SiO2 Materials Science	\$143 million	June 5, 2020	Glass tubing and vials			
Corning	\$204 million	June 5, 2020	Glass tubing and vials			
Becton, Dickinson and Co.	\$42 million	July 1, 2020	Syringes and needles			
Retractable Technologies	\$54 million	July 1, 2020	Syringes and needles			
Smiths Medical	\$21 million	July 11, 2020	Syringes and needles			
Cytiva	\$31 million	October 13, 2020	Cellular material, mixer bags, and bioreactors			
ApiJect Systems	\$590 million <sup>a</sup>	November 19, 2020	Prefilled, single-dose injectors			
a. Loan to finance 75 percent of the project's capital costs.						
Complete the other feet Blandfell Advanced Brown band Development Authority 2021 BARDAY						

Sources: Compiled by the authors from Biomedical Advanced Research and Development Authority, 2021, BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio □ and BARDA's COVID-19 Domestic Manufacturing & Infrastructure Investments □; Novavax □; Merck □; □ GRAM □; and US International Development Finance Corporation □.

#### Figure 6

## How to use supply chain transparency to minimize COVID-19 vaccine input shortages



Five policy steps

- Survey vaccine production facilities about their inputs to establish what they need, where they source from, and on what schedule.
- Aggregate the information by input-supplying firm to determine the volume that each firm needs to provide.
- Survey each input supplier to cross-check the data and determine if their existing capacity can meet demand.
- 4 Identify input shortages.

### For shortages of customized inputs

#### Short-term solution:

Increase production at existing facilities, e.g., incentivize addition of second, third, and weekend shifts.

#### Long-term solution:

Incentivize investment to expand capacity. Use subsidies when there is insufficient private (market) incentives.

#### For general inputs

Use data accumulated in step 3 to identify alternate suppliers with spare capacity.

If input shortfalls still arise, policymakers can help ration limited supplies.







### **Implications**

- 1. Everyone needs to subsidize their part of the supply chain to address the global externality
- 2. Without coordination/cooperation, everyone subsidizes too little

### **Practical challenges**

- 1. Fear of noncooperation (export restrictions) on vaccine *output* leads to too little subsidization of vaccine *input*s
- 2. Some vaccine input countries may be *fiscally constrained* and unable to subsidize





# Five principles

- Leverage COVAX distribute based on global public health (attack externality at its source)
- 2. Investment: coordinate (and fund) subsidies across the full supply chain
- 3. Enforcement: make explicit that export restrictions on vaccine output will be met with (joint) limits on vaccine inputs
- 4. Transparency: AMIS-like information on availability of vaccine inputs and outputs
- **5.** Administrator: one part general contractor (DPA/OWS), one part ombudsperson (resolve frictions)



# References

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  <u>A Global Problem Calls for Collective Action</u>. *Foreign Affairs*, December 29.
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  <u>Cooperation Can End the Pandemic</u>, *Foreign Affairs* v99, n5 (September/October): 96-109.