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JEL Classification: F13

Keywords: COVID-19 vaccines, advance market commitments, Manufacturing, input shortages, Defense Production Act, priority-rated contracts

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1. INTRODUCTION

In February 2021, barely one year into the COVID-19 pandemic, the United States became the first economy outside of China to make 100 million doses of vaccines publicly available.¹ The United States was also the first to provide 200 million doses.² By the end of April 2021, more than 250 million doses of three vaccines—Pfizer-BioNTech, Moderna, and Johnson & Johnson—had been made available to the American public. This incredible feat was due in part to the federal government’s Operation Warp Speed. Under that initiative, the US Department of Defense and the Department of Health and Human Services worked together to create policy incentives, often by relying on the Defense Production Act (DPA) of 1950, to encourage and then help private companies and their global supply chains expedite the process of developing and manufacturing vaccines.

Despite this head start, growth of COVID-19 vaccine supply capacity in the United States stalled out. The European Union overtook cumulative US production in May 2021, and India did so in June. By the end of 2021, European plants had manufactured over 2.5 billion doses, and India had made 1.6 billion doses. The United States had produced only 1 billion doses.

In retrospect and from a worldwide perspective, the news was mixed. The combined output from the global supply chains behind only four COVID-19 vaccines—Pfizer-BioNTech, Moderna, Johnson & Johnson, and AstraZeneca—was enough that roughly 3 billion people could have been inoculated by the end of 2021. But the lack of an equitable distribution scheme to share vaccines with nonproducing countries, demand for boosters, waste in the system, and concerns about the weak or waning effectiveness of other vaccines meant that billions of additional doses were needed to address the pandemic. Larger scale and greater speed—having manufactured more doses earlier—would have saved lives and helped stem the trillions of dollars of losses to the global economy.³

These facts about US and global vaccine supplies raise important questions for policy. How did the US government incentivize the manufacturing of so many COVID-19 vaccine doses so early in 2021? Could the United States have implemented different supply-side policies—in, say, early 2021—to push companies to further expand their capacity? Did US policy choices in 2020 inadvertently make that more difficult?

As a first attempt to tackle these and other policy-related questions, this paper analyzes the legal-economic framework the United States deployed for COVID-19 vaccines, relying on information collected on the supply chains that emerged from scratch in 2020–21 from Bown and Bollyky (2022).

The paper is organized as follows. Section 2 describes the economic market failures for vaccine consumption and production that set up the basic problems policymakers faced. Early and throughout the pandemic, for example, experts proposed the use of advance market

¹ The focus of this paper is on US manufacturing; international comparisons are therefore limited to other countries’ production of the same pool of vaccines. International comparisons thus mostly exclude China, despite its enormous production of the Sinovac and Sinopharm COVID-19 vaccines.

² The data referenced here and below are from Airfinity, which estimates COVID-19 vaccine supply based on the amount of vaccine doses delivered to countries, not accounting for stockpiles, waste, or doses not yet delivered. These data are admittedly an imperfect estimate of production.

³ For estimates, see Cutler and Summers (2020) and Agarwal and Gopinath (2021).

commitments (AMCs) and related policies to accelerate and scale up COVID-19 vaccine research, development, and production.⁴ This section also introduces key elements of the fragmented COVID-19 vaccine value chains to emerge, which would complicate matters during the pandemic.

To achieve diversity, speed, and initial scale, in 2020 the US government adopted some elements of the AMC approach. Section 3 provides details on the DPA, the legal authority behind most of the COVID-19 vaccine-related contracts.

Section 4 describes Operation Warp Speed and the DPA “priority-rated” contracts the government agreed with vaccine manufacturers, with some input providers directly, and those subsequently passed along supply chains from vaccine sponsors to their input providers indirectly. These contracts facilitated considerable at-risk investment, contributing to the early success story of hundreds of millions of vaccine doses made available in the United States by April 2021.

Puzzlingly, US vaccine supply lagged other major economies over the rest of 2021. Section 5 thus investigates whether the US government could have changed tack in early 2021. Taking the institutional environment and supply chains to emerge as given, it examines the tradeoffs associated with the United States potentially recalibrating its approach under the DPA to encourage manufacturers to further expand production capacity to help meet global, not simply US, vaccine demand.

Section 6 then tackles the problem of input shortages—an economic, political, and contracting constraint—that contributed to firms struggling to increase production in 2021. Although the economics suggest some market failures similar to those facing overall vaccine production, both the price constraints implicit in DPA contracts passed along from vaccine sponsors in 2020 and business decisions to expedite the process of bringing new vaccine plants online globally may have inadvertently exacerbated input shortages. Getting closer to a nationally optimal policy may also have meant subsidizing input providers directly. Finally, the reliance of foreign plants on US exports of materials and capital equipment meant that globally optimal subsidies needed to have been much larger. They were more difficult to identify and coordinate, however, given the lack of information about the input needs of facilities operating outside of the United States. An international agreement may have facilitated sufficient subsidization of both output and input suppliers across countries.

Section 7 describes other side effects of DPA use for vaccine manufacturing and suggests directions for further research.

2. THE ECONOMICS OF VACCINES, ADVANCE MARKET COMMITMENTS, AND SUPPLY CHAINS

Vaccine development confronts multiple market failures, making it a rich area of policy-relevant economic research long before the COVID-19 pandemic. On the demand side, consumption of vaccines yields positive externalities by helping break the chain of disease transmission and reduce disease burden. The marginal social benefit for each vaccine consumed is thus greater than the marginal private benefit to individuals. One frequent policy, also adopted during the

⁴ See Athey et al. (2020); Snyder et al. (2020); Castillo et al. (2021); and Ahuja et al. (2021). Athey et al (2022) provide an excellent summary of the research, as well as policy recommendations, made by the experts at the Accelerating Health Technologies (AHT) project to tackle COVID-19.

COVID-19 pandemic, has been for governments to procure and distribute vaccines free of charge or at highly subsidized prices to individuals.

The supply side features other challenges. Many of them came to light through research seeking to tackle the under-development of vaccines needed to combat diseases encountered in primarily poor countries, such as malaria, tuberculosis, and HIV strains prevalent in Africa. Even if intellectual property rights for discovery are protected, a hold-up problem could emerge between vaccine purchasers and firms. Once a firm has sunk large investments into researching, developing, and manufacturing a vaccine, government purchasers have an incentive to renege and hold prices down to the marginal cost of production. Recognizing the time-inconsistency of purchaser (policymaker) promises not to do so, firms do not invest enough, resulting in too few vaccines invented and supplied.⁵

To help address these problems, around the turn of the century, experts began to propose new contracting mechanisms and institutional arrangements beyond research and development (R&D) subsidies and patent protection, including AMCs.⁶ In theory, the time-inconsistency problem could be addressed—by, for example, providing legal guarantees that someone (i.e., a “market”) commits to purchase enough vaccine doses to incentivize R&D and manufacturing.⁷

For COVID-19 vaccines, the supply side of the full value chain created additional challenges for policymakers. The basic model includes five separable fixed costs (figure 1). One is the research cost of finding a vaccine; a second is the fixed development cost of clinical trials, including the lengthy Phase 3 trial, which requires administering vaccines and placebos to tens of thousands of people and collecting data on their health outcomes and side effects over a number of months. The third and fourth costs are the manufacturing. Step 3 involves producing the drug substance in one facility before then formulating that into drug product for its “fill and finish” and packaging (step 4), assembly-line style, into tens of thousands of glass vials in a separate facility.⁸ Critical to the manufacturing stages are the creation of supply chains. Some inputs are COVID-19-vaccine-specific and, as described below, possibly available only from firms in foreign countries in the short run. The final step involves the costs associated with vaccine distribution and administration to individuals.

An additional problem during the pandemic was the time it would take to create a functioning supply chain from scratch for these new vaccines. Firms would have to locate and retrofit facilities to manufacture a completely new product. They would need to find suppliers of customized inputs, some of which may have never been required at pandemic scale. With a disease killing hundreds of thousands of people a month and costing the global economy trillions of dollars of losses, developing and manufacturing a vaccine quickly was critical. To

⁵ Another problem is the high R&D costs to invent new vaccines for consumers that are poor or are in small markets. This constraint was less binding for COVID-19, given demand from rich countries.

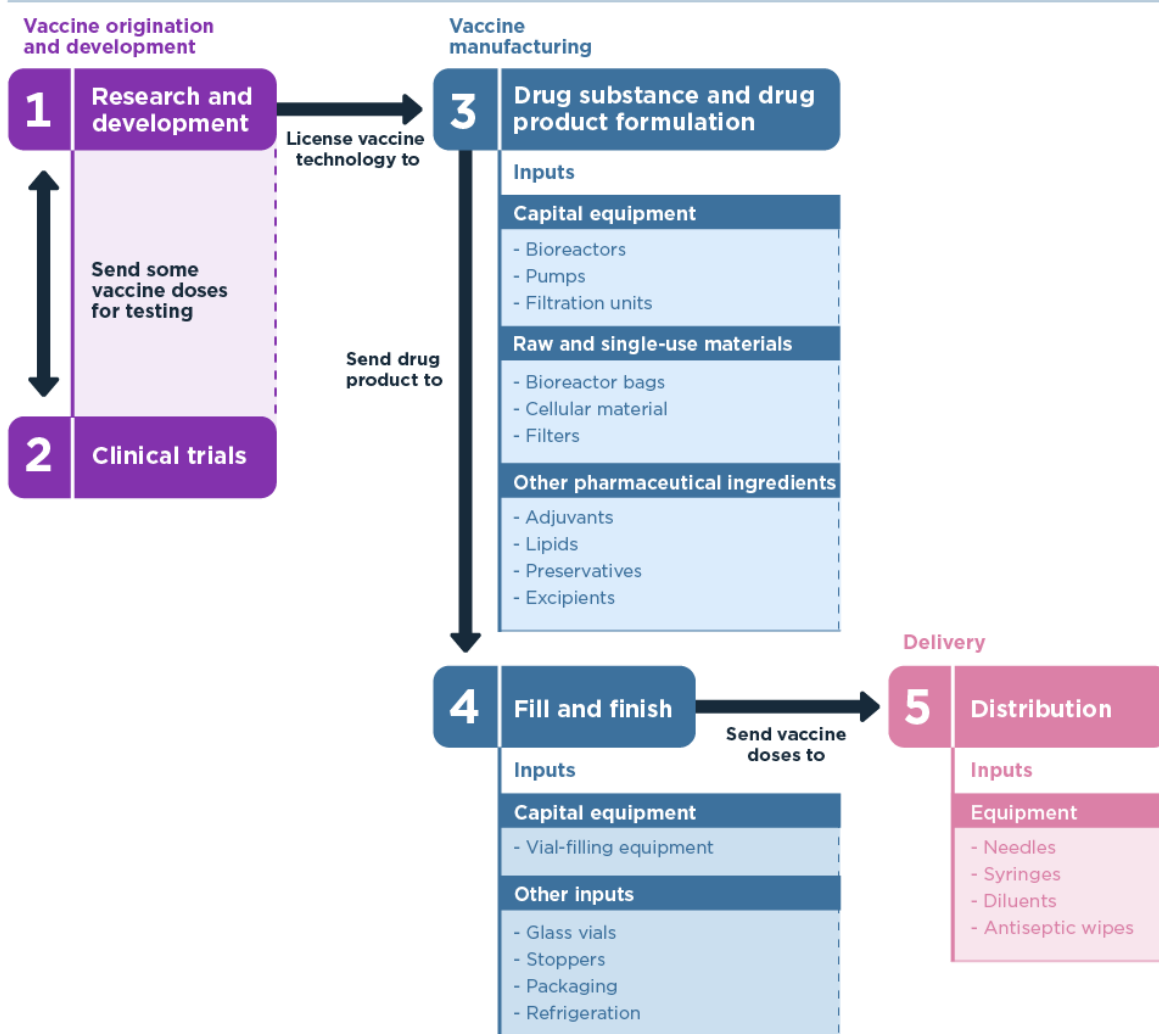
⁶ See Kremer (2001a, 2001b). Kremer and Glennerster (2004) provide a book-length treatment.

⁷ The approach has been applied in a pilot AMC to help purchase pneumococcal vaccine for poor countries (Kremer, Levin, and Snyder 2020).

⁸ For ease of exposition, “formulation” is included into step 3. In reality, for some vaccines and supply chain relationships described below, formulation occurs alongside the “fill and finish” process at the facility of step 4.

Figure 1

The five main steps of getting COVID-19 vaccines from start to finish



Note: Stages and inputs depicted illustrate general vaccine production process and are not comprehensive.

Source: Bown and Bollyky (2022).

hasten the process, in theory, firms could make their costly sunk capital investments (steps 3 and 4) simultaneously with the lengthy and expensive Phase 3 trials (step 2). (Firms typically waited to invest in manufacturing capacity until after the resolution of uncertainty associated with the Phase 3 trial, because most vaccine trials failed.) As stressed by Athey et al (2022), governments could use a combination of “push” (subsidizing inputs to expand capacity) and “pull” (rewarding expedited delivery of doses of approved vaccines) policies to incentivize firms to invest in manufacturing capacity at risk. Although some trials would fail and those resources

lost, success would create facilities capable of delivering vaccine doses immediately upon regulatory authorization.

The following sections rely on information from the COVID-19 vaccine supply chains that emerged, as collected by Bown and Bollyky (2022), to examine the legal environment and US policies designed to tackle the need for a diversified portfolio of vaccine candidates, speed in delivery, and scale in production.

3. THE DEFENSE PRODUCTION ACT AND PRIORITY-RATED CONTRACTS

On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic. Two days later, US President Donald Trump declared a national emergency. In April, the federal government announced the creation of Operation Warp Speed, a partnership between the Department of Defense (DOD) and the Department of Health and Human Services (HHS), to accelerate the development, manufacturing, and distribution of COVID-19 vaccines.⁹ The Trump administration also issued a number of executive orders invoking the Defense Production Act (DPA) of 1950. Dating back to the Korean War, the DPA has been amended to provide legal authority to shape emergency preparedness and response beyond armed conflict. In 2018, Congress reauthorized the nonpermanent provisions of the DPA through September 30, 2025.

Title I of the DPA gives the president authority to require companies to accept “priority-rated” contracts, which were used for COVID-19 vaccines under Operation Warp Speed. In 2012, the Obama-era Executive Order 13603 delegated such authority to heads of a number of federal agencies, including DOD and HHS. HHS subsequently promulgated its regulations under the statute, referred to as the Health Resources Priority and Allocations System (HRPAS), under which many of the contracts described below were written.¹⁰

Before the pandemic, DPA rules and priority-rated contracts were relatively unknown to most vaccine sponsors, pharmaceutical manufacturers, their input providers, and even HHS officials. Historical use of the DPA varied across federal agencies. DOD placed an estimated 300,000 rated orders a year to support military procurement needs (FEMA 2020).¹¹ By comparison, the Department of Homeland Security placed fewer than 400 rated orders in 2019, 60 percent of them for hurricane and other disaster preparedness or response.

Legislatively, the DPA creates a number of types of contracts. The benchmark is an “unrated” contract made on commercial terms between buyers and sellers. The DPA establishes two priority ratings—DO and DX—with DX (highest national defense urgency) given priority over DO (critical to national defense), which is given priority over any unrated order. DX ratings are relatively rare, requiring Cabinet-level approval. In 2018, for example, only 13 DOD programs were granted DX ratings, including the B-2 Stealth Bomber, the Minuteman III Intercontinental

⁹ In April 2021, Operation Warp Speed was renamed the COVID-19 Countermeasures Acceleration Group (CAG).

¹⁰ These HHS regulations, codified at 45 C.F.R. § 101.1–§101.93, were issued in 2015, pursuant to the Defense Production Act Reauthorization of 2009 (see 80 Federal Register 42408). This paper refers to DPA and HRPAS interchangeably, with citations to the HHS regulations.

¹¹ Rogerson (1994) provides an economic discussion of DOD procurement contracting.

Ballistic Missile, Air Force One, and Marine One.¹² The COVID-19 vaccine contracts were given priority ratings of DO.

Firms receiving a priority-rated contract from the government must pass that rating along their supply chain when placing orders with input providers. They “must use rated orders with suppliers to obtain items or services needed to fill a rated order. . . from contractor to subcontractor to supplier throughout the entire procurement chain.”¹³

The DPA does not allow for price flexibility: Suppliers are not permitted to charge higher prices or impose terms or conditions that would discriminate between rated and unrated orders.¹⁴ The DPA also disciplines government contractors by not allowing them to use priority ratings to obtain orders from their suppliers earlier than needed or to procure more inputs than needed to fulfill the priority-rated contract.¹⁵ Acquiring capital equipment requires additional sign-off, as rated orders may not be used to obtain “production or construction equipment” or “items for plant improvement, expansion, or construction” unless specific priority rating has been obtained from HHS.¹⁶

Suppliers can be coerced to accept contractual terms, within limits. For example, firms are mandated to accept and fill priority orders up to the amount they provided in the previous two years.¹⁷ Penalties for noncompliance include fines and jail time. There are also conditions for mandatory rejections, such as when suppliers cannot deliver by the needed date because they have already received higher or equally high priority-rated orders.

Anticipating the possibility of contractual conflict—say, between two firms, each with a government contract, seeking to simultaneously acquire the same scarce input from the same upstream provider—the regulation creates its own expedited special priorities assistance procedures for basic dispute resolution. Although the DPA is “designed to be largely self-executing. . . from time-to-time production or delivery problems will arise in connection with rated orders for health resources as covered under this part. In this event, a person should immediately contact the Secretary for guidance.”¹⁸ Suppliers receiving priority-rated orders are given basic legal protections. The DPA statute provides immunity from third-party claims when they are forced to break contracts with customers that had placed unrated orders (or suffered delays) because of fulfillment of priority-rated contracts.¹⁹

¹² Undersecretary of Defense. 2018. [Memorandum For Service Acquisition Executives Directors Of The Defense Agencies, Subject: Updated DX-Rated Program Listing](#). November 13.

¹³ See 45 C.F.R. § 101.35 (a) and 45 C.F.R. § 101.35 (b).

¹⁴ See 45 C.F.R. § 101.33 (a) (2)

¹⁵ See 45 C.F.R. § 101.38 (a) (2) (i) and 45 C.F.R. § 101.38 (a) (2) (ii).

¹⁶ See 45 C.F.R. § 101.38 (a) (2) (v) (B) and 45 C.F.R. § 101.38 (a) (2) (v) (A).

¹⁷ 45 C.F.R. § 101.33 (c) (3) states that “if, however, a supplier has sold some of these items or provided similar services, the supplier is obligated to accept rated orders up to that quantity or portion of production or service, whichever is greater, sold or provided within the past two years.”

¹⁸ 45 C.F.R. § 101.40 (a).

¹⁹ 50 U.S.C. 4557 § 707 states that “no person shall be held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance with a rule, regulation, or order issued pursuant to this Act.”

Finally, there is a level of prioritization that goes beyond DO and DX, referred to as a “directive,” with different supply chain implications. A “priorities directive” takes precedence over any previously received DX, DO, or unrated orders. Although firms must comply with any government-issued directive, they may not use or extend it to their input providers, unless expressly authorized.²⁰ All else equal, this makes firm compliance more difficult than receipt of a DX- or DO-rated order.

4. OPERATION WARP SPEED AND US CONTRACTING FOR COVID-19 VACCINES IN 2020

Between March 2020 and September 2021, the US government used the DPA to sign 17 priority-rated contracts for vaccines and therapeutics and another 20 for vaccine supplies (GAO 2021a). This section describes those used for COVID-19 vaccines and the supply chains that emerged.²¹ Table 1 summarizes.

The US government began contracting with a variety of COVID-19 vaccine developers in early 2020. Although public versions of vaccine contracts contain considerable redactions, enough information is available to conclude that the approach was qualitatively—if not quantitatively—consistent with basic AMC principles of “push” and “pull” incentives, aiming for speed and scale, to obtain enough vaccine doses to inoculate the US population.²²

By the fall of 2020, the US government had addressed scale and diversification issues by agreeing to contracts, each potentially worth \$1 billion or more, for 100 million or more doses each with companies behind six vaccine candidates: Pfizer-BioNTech, Moderna, Johnson & Johnson, Novavax, AstraZeneca, and Sanofi-GSK. It tackled the speed problem by providing some payments at risk, months before the Food and Drug Administration (FDA) would be asked to grant even emergency authorization use of any vaccine. Doing so allowed companies to simultaneously conduct their Phase 3 trials and begin the lengthy process of setting up their plants, acquiring capital equipment, and contracting with suppliers of variable inputs.

The Government Accountability Office (GAO) was the watchdog Congress tasked, under the CARES Act, to monitor the federal response to COVID-19. After reviewing the contracts and interviewing HHS, DOD, and vaccine company officials, the GAO concluded that “the government aimed to balance financial risks and help ensure. . . a sufficient number of vaccine doses, even if one or more companies’ efforts failed to produce a viable vaccine.” Not all funding was guaranteed, as “the government also incorporated safeguards in the contracts and agreements to mitigate its financial risk, by including, for example, payment and termination language intended to limit the government’s liability if a vaccine candidate is not authorized or licensed” (GAO 2021b, 17).

²⁰ 45 C.F.R. § 101.31 (3) and §101.62.

²¹ The Excel file accompanying the working paper version of this paper includes hyperlinks to publicly available contracts. See also the database accompanying Bown and Bollyky (2022). Slaoui and Hepburn (2020) describe Operation Warp Speed.

²² Statements here about the US approach are meant to be qualitative. For example, of the \$18 billion of contracts spent on six vaccine candidates in 2020, model estimates by Ahuja et al. (2021) suggest that the US government under-invested. It should have spent more than three times the amount and diversified across 27 candidates. See also Athey et al. (2022).

Table 1. US contracts to COVID-19 vaccine sponsors, February 11, 2020–October 22, 2021

Company	Amount (millions of dollars)	Date	Task [DPA priority rating]
Johnson & Johnson (Janssen)	21	February 11, 2020	Support nonclinical studies and a Phase 1 trial
	436	March 27, 2020	Contract amendment
	1,002	August 5, 2020	Demonstrate large-scale manufacturing (100 million doses)
	85	August 21, 2020	Unknown
	0	September 21, 2020	Post-award modifications, including award of priority rating for contracts [DO]
	454	November 13, 2020	Support Phase 3 trial (contract amendment)
	269 ^a	March 2, 2021	Collaboration with Merck to repurpose its facilities for drug substance and fill and finish, DPA invoked (priority rating unknown)
	32	March 25, 2021	Expand Phase 2a trial for adolescent population
Sanofi-GSK	31	April 10, 2020	Accelerate nonclinical studies and Phase 1 trial
	2,042	July 30, 2020	Conduct Phase 3 trial, support manufacturing demonstration project for 100 million doses
	0	June 4, 2021	Priority-rating clause of US government contract removed
	7	August 6, 2021	Unknown
Merck and IAVI	38	April 15, 2020	Accelerate development of vaccine candidate
Moderna	430	April 16, 2020	Accelerate development of vaccine candidate
	53	May 24, 2020	Expand manufacturing capacity
	472	July 25, 2020	Support Phase 3 trial
	1,525	August 11, 2020	Support manufacturing of 100 million doses, with option for 400 million more
	0	September 8, 2020	Contract amendment to give Health Resources Priority and Allocations System (HRPAS) priority rating [DO]
	1,667	December 11, 2020	Purchase another 100 million doses
	1,750	February 11, 2021	Purchase another 100 million doses
	63	March 12, 2021	Support Phases 2 and 3 of adolescent study and booster for adults
	236	April 18, 2021	Support for clinical studies (cost increase)
	144	June 15, 2021	Support Phase 2 and 3 trials for children six months to 12 years old
	3,304	June 15, 2021	Purchase another 200 million doses
	AstraZeneca (Oxford)	413	May 20, 2020
1,200		October 28, 2020	Accelerate development and manufacturing to begin Phase 3 trial and make available 300 million doses [DO]
0		June 4, 2021	Priority-rating clause of US government contract removed
Novavax	60	June 4, 2020	Manufacture components for use in Phase 2 and 3 trials
	1,600	July 6, 2020	Demonstrate commercial-scale manufacturing for 100 million doses
	0	September 10, 2020	Contract modification awarding priority rating for procurement of raw materials, consumables, repair parts, and major end item assemblies [DO]
	0	June 4, 2021	Priority-rating clause of US government contract removed
Pfizer (BioNTech)	1,950	July 21, 2020	Purchase 100 million doses
	2,011	December 22, 2020	Purchase another 100 million doses, with option for 400 million more, add priority rating [DO]
	2,011	February 11, 2021	Pick up option to purchase 100 million doses
	4,870	July 21, 2021	Pick up option to purchase 200 million doses
	3,500	July 30, 2021	Purchase 500 million doses for donation to COVID-19 Vaccines Global Access (COVAX)
	1,230	October 22, 2021	Purchase 50 million pediatric doses (age 5–11), one third the strength of those intended for 12 years and up
<p>Note: a. Payment to Merck for the collaboration.</p> <p>Sources: Compiled by the author from Biomedical Advanced Research and Development Authority, 2021, <i>BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio</i>, BARDA's COVID-19 Domestic Manufacturing & Infrastructure Investments, and publicly available firm contracts.</p>			

Moderna was a biotech start-up with no product commercialization experience or commercial manufacturing capabilities. Its vaccine candidate was co-developed with researchers at the National Institutes of Health. Its initial April 2020 contract for \$430 million established

milestones at which the US government would make “go/no go” decisions.²³ Moderna received additional funding in May 2020 to help expand manufacturing capacity to create doses for its clinical trials and, in July, its Phase 3 trial. With these interim successes, in August 2020, the United States and Moderna agreed to a \$1.5 billion contract for 100 million doses that would allow the company to begin setting up its commercial manufacturing supply chain. The contract included a firm fixed price of \$12.25 per dose for the first 100 million doses and an incentive of \$3.00 per dose to meet an emergency use authorization deadline of January 31, 2021.²⁴ Its contract was ultimately given a DPA priority rating of DO.

Johnson & Johnson began its US government collaboration in February 2020, by modifying a 2017 contract with the Biomedical Advanced Research and Development Authority (BARDA), an office within HHS. It began with \$21 million to cover nonclinical studies and a Phase 1 trial; in March 2020, it received \$436 million to accelerate advanced clinical trials. In August 2020, Johnson & Johnson agreed to a \$1 billion contract to provide 100 million doses of its single-dose vaccine, which was also given a DO rating under the DPA.

AstraZeneca, Novavax, and Sanofi-GSK forged similar relationships and contracts with DPA priority ratings of DO. Operation Warp Speed also granted \$38 million to develop a candidate from Merck-IAVI based on an FDA-licensed Ebola vaccine platform in April 2020 that was later discontinued after a disappointing Phase 1 study. Pfizer’s case was distinct and is treated below.

4.1 US contracting to build out each COVID-19 vaccine supply chain

Moderna, Johnson & Johnson, and AstraZeneca each chose to rely primarily on contract development and manufacturing organizations (CDMOs), outsourcing the commercial manufacturing of drug substance as well as the formulation and fill and finish of their drug product in the United States and for their supply chains globally.²⁵ Figure 2 summarizes the key CDMOs and plants for the US and global supply chains—steps 3 and 4 of figure 1—for these three COVID-19 vaccines as well as for Pfizer-BioNTech.

For the US plants in their supply chains, three types of contracts emerged—two facilitated by the US government through Operation Warp Speed and a third written by the vaccine sponsors themselves. For Johnson & Johnson and AstraZeneca, one type of US government contracting arrangement sought to take advantage of capacity kept in reserve through two Centers for Innovation in Advanced Development and Manufacturing (CIADMs) that BARDA had established in 2012.²⁶ One was Emergent BioSolutions, which was tasked with manufacturing the drug substance for both vaccines.²⁷ Another was with a CIADM at Texas A&M University and

²³ See page 6 of Moderna’s contract of April 16, 2020.

²⁴ See GAO (2021b, 18) and pages 6–7 of Moderna’s contract of August 11, 2020.

²⁵ Novavax also relied on CDMOs, with its global network of supply chains most closely resembling the AstraZeneca approach (see Bown and Bollyky 2022, figure 10). Because of space constraints, Novavax is excluded from figure 2, as its COVID-19 vaccine was not supplied to the US market during this period.

²⁶ See BARDA. 2021. [Centers for Innovation in Advanced Development and Manufacturing \(CIADM\)](#).

²⁷ Emergent BioSolutions. 2021. United States Securities and Exchange Commission, Form 10-Q, quarterly report for the period ended March 31, 2021.

Figure 2

Core elements of COVID-19 vaccine supply chains for Pfizer-BioNTech, Moderna, AstraZeneca, and Johnson & Johnson

Partners and facilities involved in vaccine production as of December 31, 2021

Pfizer-BioNTech		AstraZeneca	
Drug substance and drug product formulation <small>(Firms handle different parts of production process)</small>	Fill and finish	Drug substance	Drug product formulation, fill and finish
US firms		US supply chain	
Pfizer, Missouri Pfizer, Massachusetts Pfizer, Michigan Exelead, Indiana	Pfizer, Michigan Pfizer, Kansas	Catalent, Maryland Emergent BioSolutions, Maryland <small>(Production ended in April 2021)</small>	AstraZeneca, Ohio
European firms		European supply chain	
BioNTech, Mainz, Germany BioNTech, Marburg, Germany Dermapharm, Brehna, Germany Pfizer, Puurs, Belgium Rentschler, Laupheim, Germany AGC Biologics, Heidelberg, Germany Pfizer, Dublin, Ireland Dermapharm, Reinbek, Germany	Pfizer, Puurs, Belgium Siegfried, Hameln, Germany Delpharm, Saint-Remy, France Sanofi, Frankfurt, Germany Novartis, Stein, Switzerland Thermo Fisher, Monza, Italy	Novasep/Thermo Fisher, Seneffe, Belgium Halix, Leiden, Netherlands	Catalent, Anagni, Italy Insud Pharma, Azuqueca de Henares, Spain IDT Biologika, Dessau, Germany
Firms in rest of world		UK supply chain	
	Biovac Institute, Cape Town, South Africa	Oxford Biomedica, Oxford Cobra Biologics UK, Keele	CP Pharmaceuticals (Wockhard), Wrexham
Moderna		Indian supply chain	
Drug substance and drug product formulation	Fill and finish	Serum Institute of India (SII), Pune	
US firms		Australian supply chain	
Lonza, New Hampshire Moderna, Massachusetts Aldevron, North Dakota	Catalent, Indiana Baxter, Indiana Sanofi, New Jersey Thermo Fisher, North Carolina	CSL, Broadmeadows	CSL, Parkville
European firms		South Korean supply chain	
Lonza, Visp, Switzerland Rovi, Granada, Spain Lonza, Geleen, Netherlands	Rovi, Madrid, Spain Recipharm, Monts, France	SK bioscience, Andong	
Firms in rest of world		Chinese supply chain	
	Samsung Biologics, Incheon, South Korea	BioKangtai, Shenzhen	
Johnson & Johnson		Latin American supply chain	
Drug substance	Drug product formulation, fill and finish	mAbxience, Garin, Argentina	Laboratorios Liomont, Mexico
US firms		Thai supply chain	
Emergent BioSolutions, Maryland Merck, North Carolina	Catalent, Indiana Grand River Aseptic Manufacturing, Michigan Merck, Pennsylvania	Siam Bioscience, Bangkok	
European firms		Japanese supply chain	
Johnson & Johnson, Leiden, Netherlands	Catalent, Anagni, Italy Reig Jofre, Barcelona, Spain Sanofi Pasteur, Marcy l'Etoile, France IDT Biologika, Dessau, Germany	JCR Pharmaceuticals, Kobe	KM Biologics, Kumamoto prefecture Daiichi Sankyo, Tokyo
Firms in rest of world		Brazilian supply chain	
Biological E., Paonta Sahib, Himachal Pradesh, India	Biological E., Paonta Sahib, Himachal Pradesh, India Aspen Pharmacare, Gqeberha, South Africa	Serum Institute of India (SII), Pune, India <small>(Initially)</small>	Fiocruz Institute, Rio de Janeiro, Brazil



Note: The Novasep plant in Belgium was taken over by Thermo Fisher in January 2021. Underlined plants had been announced by December 31, 2020.

Source: Bown and Bollyky (2022) with updates compiled by the author from firm announcements and media reports.

Fujifilm Diosynth Biotechnologies (FDB) to manufacture the Novavax vaccine.²⁸ BARDA also contracted directly with at least one other non-CIADM facility, Grand River Aseptic Manufacturing (GRAM) in Michigan, which agreed to reserve and expand fill and finish capacity. GRAM began work with the Johnson & Johnson vaccine in September.

Each vaccine sponsor also contracted directly with CDMOs to get access to manufacturing plants in 2020. Moderna signed a long-term agreement with Lonza, the CDMO that would manufacture its drug substance for US government contracts, at a plant in New Hampshire. Both Moderna and Johnson & Johnson hired Catalent to fill and finish COVID-19 vaccines at its Indiana facilities. A priority-rated contract passed along from a vaccine sponsor under the DPA forced Catalent to break its (unrated) contract with Horizon to fill and finish Tepezza, a thyroid eye disease drug.²⁹ (The number of contracts with third parties that were broken because of the DPA is unknown.)

4.2 US government contracts with Pfizer

Pfizer adopted a different contracting approach with the US government. In July 2020 it agreed to provide 100 million doses to the US government (for \$19.50 per dose, or \$1.95 billion), but it refused to sign a priority-rated contract. GAO oversight led it to conclude that the US government was taking on less financial risk with Pfizer than with the other vaccine manufacturers, because “the parties agreed that the government would pay Pfizer only after its vaccine received authorization or licensure from FDA and as the doses were delivered” (GAO 2021b, 18). The contract detailed actions already undertaken without US government funding, such as the initiation of Phase 1 and Phase 2 trials in the United States and Germany. Like other vaccine sponsors, Pfizer and BioNTech were simultaneously establishing manufacturing supply chains in Europe, some financed directly by the German government and the European Commission.³⁰

Pfizer was also unique in that its basic US manufacturing process relied exclusively on its own plants (see figure 2). One plant in Missouri developed DNA plasmids, which were sent to a second facility in Massachusetts, where they were turned into mRNA, which was then sent to a third plant in Michigan for formulation and fill and finish. Unlike other vaccine sponsors, Pfizer may not have needed DPA help to get access to production facilities. That is not to suggest that its plants had been idle. Pfizer created capacity by finding a different role for CDMOs. In May 2020, it announced that it would spend \$150 million to reallocate resources within the Missouri, Massachusetts, and Michigan facilities (as well as one in Belgium) to make space for COVID-19 vaccine manufacturing and that it would also be “tapping into its network of around 200 outside

²⁸ FDB’s Texas plant was also contracted to provide doses for the Sanofi-GSK candidate for clinical trials (Carr 2021).

²⁹ “[Horizon Therapeutics plc Announces Short-Term TEPEZZA® \(teprotumumab-trbw\) Supply Disruption Due to Government-Mandated \(Operation Warp Speed\) COVID-19 Vaccine Production](#),” press release, December 17, 2020.

³⁰ BioNTech also received €475 million from the European Union and the German government to expand manufacturing capacity in Europe and to fund late-stage clinical trials (Bown and Bollyky 2022, table 6). Moderna, AstraZeneca, Novavax, and other vaccine developers also received funding from sources other than the US government, including the Coalition for Epidemic Preparedness Innovations (CEPI; see Bown and Bollyky 2022, table 7).

contractors,” including Catalent, Lonza, and Thermo Fisher, to outsource more production of its existing medicines.³¹

Of the initial six orders the US government placed for vaccines in 2020, only the Pfizer contract was not given a DPA priority, something it would seek later. The GAO concluded that the contracting approach the United States took with the other five companies “gave the government insight into vaccine development or manufacturing that it did not have with Pfizer,” in part because Pfizer’s contract “did not include a ‘person in plant’ provision to allow a federal government official to observe its vaccine production process.”³²

US policymakers thus had both less knowledge about Pfizer’s supply chain and less legal authority to help if it ran into input sourcing problems. When it eventually did, perhaps because other vaccines had priority access to inputs, Pfizer’s CEO requested DPA assistance.³³ Its new contract, signed with the Trump administration on December 22, 2020, was granted a DO rating “for the procurement of raw materials, consumables, repair parts, and major end item assemblies by Pfizer.”³⁴ The Biden administration decided that even that was inadequate and announced, shortly after the inauguration, that it was “expanding the priority ratings for Pfizer to include filling pumps and tangential flow filtration skid units, critical components Pfizer needs to manufacture the COVID vaccine.”³⁵ The administration’s decision to highlight publicly how it was following through on a campaign pledge to use the DPA more actively had international repercussions, as described below.

5. TRADEOFFS OF TRYING TO USE THE DPA IN 2021 TO HELP MEET GLOBAL DEMAND

Early 2021 was a natural decision point for US policymakers to potentially recalibrate COVID-19 vaccine manufacturing policy. A new US administration took over on January 20. In many respects, the approach of 2020 had been successful; considerable uncertainty had been resolved, after the FDA granted emergency use authorization for vaccines from Pfizer on December 11, 2020; Moderna on December 18, 2020; and Johnson & Johnson on February 27, 2021.

Equally important were the early vaccine supplies. By the end of February 2021, plants in the United States had provided the US government with 55 million doses from Moderna and 48 million doses from Pfizer (figure 3).³⁶ The at-risk investments, including those facilitated under

³¹ Carl O’Donnell and Michael Erman, “[Pfizer to Outsource Some Drug Production, Focus on Coronavirus Vaccine](#),” Reuters, May 9, 2020.

³² See GAO (2021b) pages 17 and 24.

³³ [CNBC Transcript: Pfizer Chairman and CEO Albert Bourla Speaks with CNBC’s “Squawk Box” Today](#), December 14, 2020.

³⁴ See page 42 of Pfizer’s contract of December 22, 2020.

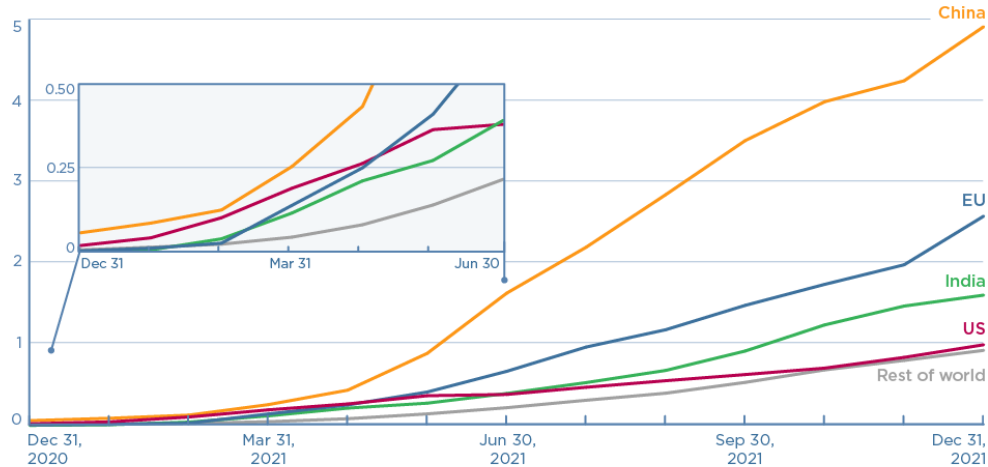
³⁵ White House. 2021. [Press Briefing by White House COVID-19 Response Team and Public Health Officials](#), February 5.

³⁶ Airfinity allocates vaccine production based on the country of drug substance manufacturing, not fill and finish. These data are estimates based on Airfinity’s approach. There is a divergence between its production estimates and those reported elsewhere, including by the companies themselves. One benefit of the Airfinity data is that they are collected based on a consistent methodological approach and are available by vaccine by country.

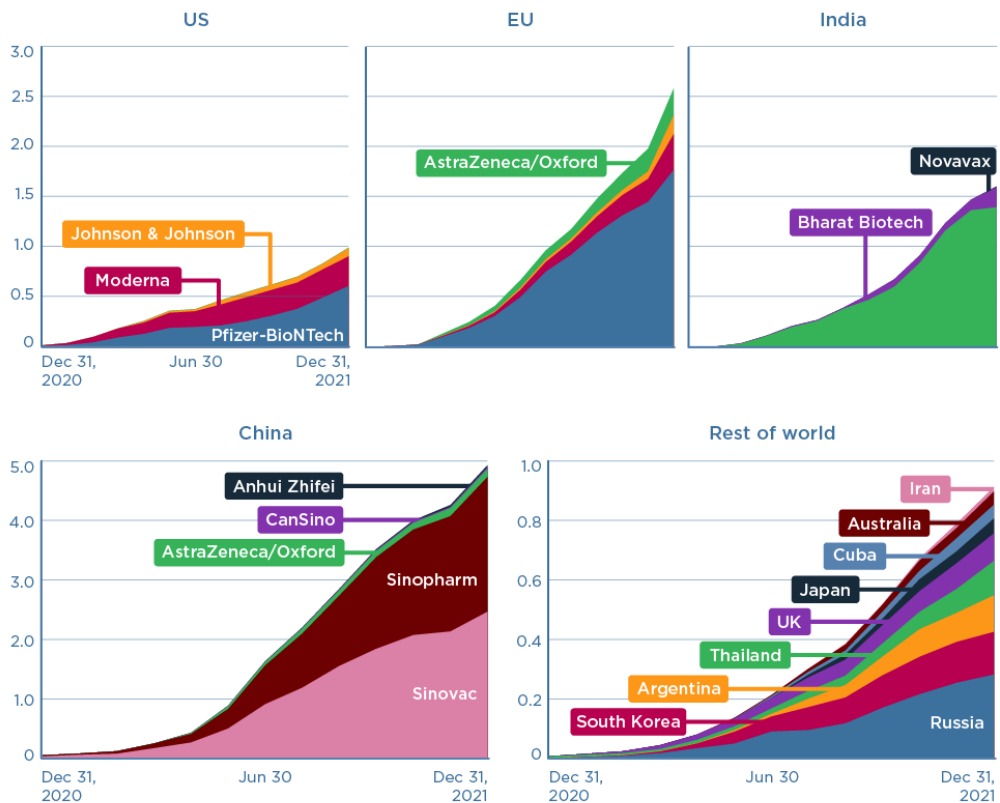
Figure 3

The United States started strong in 2021, but ended up supplying many fewer COVID-19 vaccine doses than the European Union, India, and China

a. Cumulative vaccine supply by economy, billions of doses, December 2020–December 2021



b. Cumulative vaccine supply by economy and brand, billions of doses, December 2020–December 2021



Note: Supply estimates based on the amount of vaccine doses delivered to countries as of the last day of that month, not accounting for stockpiles, waste, or doses not yet delivered. Supplying country determined by location of the drug substance facility. Moderna's drug substance facility in Switzerland is included with the European Union. US supply of AstraZeneca was 4 million doses in 2021 (not shown). Turkey also supplied 250,000 doses of the Turkovac vaccine in December 2021 (not shown).

Source: Constructed by the author with data from Airfinity.

DPA priority-rated contracts through Operation Warp Speed, were at least partially responsible for more early doses being made available in the United States than in the European Union, India, or any other country manufacturing one of these four vaccines.

This section explores legal, economic, and political questions—and tradeoffs—facing US policymakers regarding whether and how to potentially recontract with vaccine manufacturers at this point, given the possibilities (and constraints) of the DPA.

5.1 What happened to COVID-19 vaccine production in 2021 without re-contracting

As expected, some of the vaccines did not work out. Even by the end of 2021, the FDA had not authorized vaccines from AstraZeneca, Novavax, or Sanofi-GSK. Yet, evidence to date suggests US policymakers lived up to their 2020 contractual obligations with those companies, ensuring the credibility of future AMCs.³⁷

Nevertheless, US policymakers were pressed to act. In March 2021, the Emergent BioSolutions plant that was manufacturing both the Johnson & Johnson and AstraZeneca vaccines was forced to shut down for four months due to poor manufacturing practices.³⁸ (Roughly 195 million of the single dose Johnson & Johnson vaccine and 105 million of the two dose AstraZeneca vaccine had to be destroyed as they were subsequently found to have been contaminated or expired.³⁹) Plant management was handed over to Johnson & Johnson, and the AstraZeneca vaccine production went elsewhere. The Biden administration also attempted to salvage the Johnson & Johnson vaccine by negotiating a priority-rated contract with Merck to use its Pennsylvania plant to provide additional fill and finish of the vaccine, but even that took seven months to come online.⁴⁰ The more immediate need was for additional Johnson & Johnson drug substance, as a Netherlands facility was the only plant manufacturing the vaccine needed by fill and finish facilities in the United States (and South Africa). In March, Merck also agreed to manufacture the Johnson & Johnson drug substance at a facility in North Carolina, but time was needed to retrofit the plant, which did not yield any output in 2021.

That left US policymakers with Pfizer and Moderna. Results from both Phase 3 trials and the real world indicated that their mRNA vaccines were safe and effective.⁴¹ The companies reported that their production yields were improving. Expected US supplies were sufficiently large that on March 11, 2021, President Biden announced that every US adult would be eligible for vaccination by May 1. By the end of June 2021, Pfizer and Moderna had supplied the United

³⁷ In contrast, as the H1N1 pandemic of 2009–10 waned, some governments pulled funding, leaving some companies unable to recoup the costs of their investments, possibly affecting their willingness to act during COVID-19 (Evenett et al. 2021).

³⁸ FDA. 2021. "[Memorandum: Assessment of Certain Janssen COVID-19 Vaccine Batches](#)," June 11.

³⁹ See p. 10 of US House of Representatives. 2022. "[The Coronavirus Vaccine Manufacturing Failures Of Emergent BioSolutions](#)." Select Subcommittee on the Coronavirus Crisis, Committee on Oversight and Reform Staff Report, May.

⁴⁰ Jared S. Hopkins. 2021. "[The Big Vaccine Pivot: Merck Falters on Covid-19 Shots, Then Makes One for Rival J&J](#)," *Wall Street Journal*, December 11.

⁴¹ Isabel Kershner and Carl Zimmer. 2021. "[Israel's Vaccination Results Point a Way out of Virus Pandemic](#)," *New York Times*, February 5.

States with over 360 million doses (see figure 3). The United States had contractual options it could trigger if needed, and DPA contracts in place gave US policymakers improved access to information on the two companies' supply chains. There was also significant new demand for both vaccines from other governments.

The question is whether US policymakers missed out on an opportunity to collect and organize the orders for Pfizer or Moderna into new, capacity-expanding contracts rather than simply allowing for each country's government order to be put "in line." In November 2021, for example, officials explained that to facilitate Moderna's delivery of doses to the African Union, the United States had given it "our place in line. We have plenty of doses of Moderna for boosters and primary series here in the US."⁴²

In the absence of such an approach, both Pfizer and Moderna expanded production capacity, in different ways over 2021 (see again figure 2). For its US supply chain, Pfizer added another fill and finish line at its Michigan plant and started use of a separate facility in Kansas. It contracted with Exelead and announced it would be producing some lipid nanoparticles at its Michigan and Connecticut facilities. In Europe, the company started using its Irish plant and expanded fill and finish capacity at its Belgian facility. BioNTech opened up a new plant in Germany and added fill and finish capacity via five more CDMOs. Moderna contracted with three more CDMOs in the United States, one in France, and one in South Korea. It expanded vaccine production by adding on to its own small manufacturing facility in Massachusetts and contracting with a second Lonza plant in the Netherlands and a Rovi facility in Spain.

As a result, Pfizer-BioNTech and Moderna each added much more production capacity to their supply chains in Europe than they did in the United States. By the end of 2021, Pfizer-BioNTech combined to supply over 2.3 billion doses globally, with European plants providing nearly three times as many doses as the United States (see again figure 3). Moderna was much less successful at scaling up its total production, but it also supplied considerably more doses from its European supply chain than its US facilities.

To summarize, the 2021 performance of COVID-19 manufacturers in the United States was both impressive and disappointing. On the positive side were diversification and speed: The government's early at-risk investments to multiple vaccine sponsors paid off. Four candidates failed (or were compromised) at some level, but two delivered over 90 million doses each to the US government by the end of March. Vaccines from Pfizer-BioNTech and Moderna, plus a third from Johnson & Johnson, combined to supply roughly 1 billion doses in the United States by the end of 2021. More than half of these doses were exported to help address demand in other countries (WTO and IMF 2022).

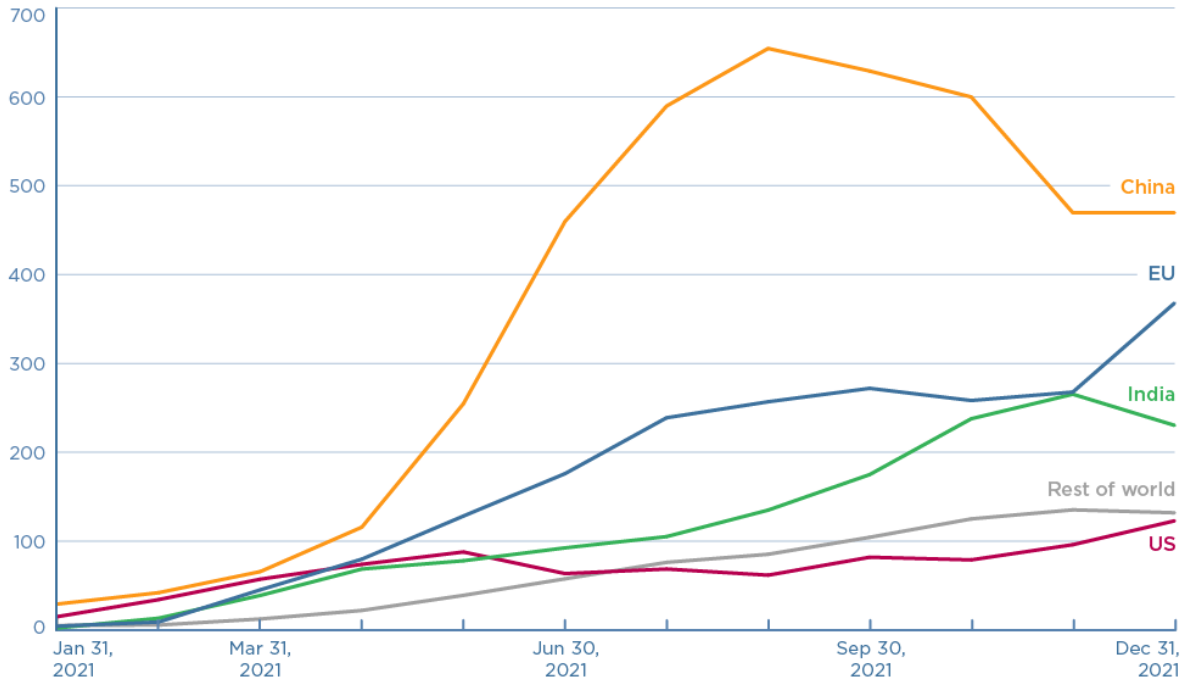
US plants performed relatively poorly over the rest of 2021, however, despite their head start and continued high global demand. European supply chains provided nearly 160 percent more total doses than the United States, and the Serum Institute of India alone produced 40 percent more doses (of the AstraZeneca vaccine) than the combination of all COVID-19 vaccines supplied by plants in the United States. In summary, COVID-19 vaccine supply capacity in the United States peaked at much lower levels than the European Union and India, in addition to China (figure 4).

⁴² White House. 2021. "[Press Briefing by White House COVID-19 Response Team and Public Health Officials](#)," November 22.

Figure 4

US COVID-19 vaccine production capacity peaked at lower levels than other major economies

Monthly vaccine supply by economy, millions of doses, 3-month moving average, January 2021–December 2021



Note: Supply estimates based on the amount of vaccine doses delivered to countries as of the last day of that month, not accounting for stockpiles, waste, or doses not yet delivered. Supplying country determined by location of the drug substance facility. Moderna's drug substance facility in Switzerland is included with the European Union.

Source: Constructed by the author with data from Airfinity.

The next sections consider whether US policymakers could have re-contracted with manufacturers in early 2021 to incentivize their expansion of capacity—to contribute to meeting global demand—not just the fulfillment of orders on their own timetables. To fix ideas, consider the private incentives facing firms like Pfizer-BioNTech and Moderna at that stage. There may have been little profit motive to invest in the costly capacity expansion necessary to produce enough doses to meet global demand, because shortly after they did, the pandemic would end, and much of that pandemic-specific capacity would then sit idle. The question is whether the US government could have deployed policies in early 2021 to overcome those disincentives.

5.2 Potential legal constraints preventing DPA use for global demand

A first question is whether the DPA tied the hands of the US government by allowing it to incentivize only enough production of COVID-19 vaccines to inoculate people in the United States. The public health case *against* such a legal argument—the possibility that vaccine-

evading variants might emerge, endangering people until the virus was eliminated everywhere—seems obvious.⁴³

Implementing that legal argument required a shift in US policy, however. “We understand that several of the larger companies with whom we contracted also have agreements to provide vaccines all over the world,” Operation Warp Speed Senior Counsel Gregory Gillette said in a December 2020 interview (Simunaci 2020). “It is our obligation to ensure that a company only uses the Defense Production Act to benefit US Government orders.”

The US government could have tackled such a legal constraint by ordering doses for global consumption and then allocating them to foreign governments and COVID-19 Vaccines Global Access (COVAX), the global facility created early in the pandemic to pool procurement and help allocate vaccines equitably, especially to lower-income countries. Eventually, on July 30, 2021, the United States did conclude such an agreement with Pfizer. The \$3.5 billion contract ordered 500 million doses of its vaccine for donation to COVAX. However, the contract came relatively late and did not appear conditional on Pfizer expanding its overall production capacity. This order was also just allocated a place in the queue.

5.3 Using the DPA to compel Pfizer and Moderna to expand capacity to meet global demand

Could DPA have been invoked to “force” companies to significantly expand their capacity to produce COVID-19 vaccines in 2021? The HHS implementing regulation suggests that a firm may be compelled to supply only the amount of a good or service it had produced over the previous two years. Even by the end of 2021, the US plants manufacturing Pfizer and Moderna had provided only an estimated 600 million and 300 million COVID-19 vaccine doses, respectively (see figure 3). A US policy to act noncooperatively vis-à-vis the companies by forcing them under the DPA to make noneconomic decisions would thus have done little to boost global supply.

Another reason not to have compelled the companies to boost production may have been the dynamic implications in the midst of a still evolving pandemic. There was concern about disincentivizing the R&D needed to tackle the potential emergence of viral variants, especially via modified mRNA vaccines.

Thus, financial as well as legal incentives were needed to convince companies to greatly expand US production capacity.

5.4 Using the DPA to contract with facilities outside the United States

Did the DPA limit the US government to contracting only with entities on US soil? Although it clearly would not have the same legal effect on firms (or their supply chains) operating in

⁴³ Indeed, 45 C.F.R. § 101.3 states that “certain programs to promote the national defense are eligible for priorities and allocations support. These include programs for military and energy production or construction, military or critical infrastructure assistance to any *foreign nation*, deployment and sustainment of military forces, homeland security, stockpiling, space, and any directly related activity” (emphasis added).

foreign jurisdictions, the DPA could have been used to contract with US–headquartered firms with facilities operating outside the United States.

In April 2020, the Trump administration invoked the DPA to compel 3M, a US–headquartered multinational, to ship 167 million N-95 respirators manufactured at its Chinese plants to the United States (Bown 2022).⁴⁴ And again, in July 2021, Pfizer was contracted to procure vaccines to donate to COVAX. That contract stated only that the US government “expressed a *preference* that Pfizer manufacture all doses for delivery under this contract at facilities located in the continental United States” (emphasis added).⁴⁵ It did not prohibit Pfizer from manufacturing the doses elsewhere.

5.5 Other constraints to US government and vaccine sponsors significantly expanding capacity

Politics was another contributor behind the decision by the US government and vaccine companies against such an agreement. The enormous profits that companies like Pfizer and Moderna were already making from their COVID-19 vaccine sales in 2021 meant that US policymakers risked a public outcry for providing financial incentives of the size necessary to significantly increase their production capacity. But a final, contributing economic constraint may have arisen from shortages of inputs, described in the next section.

6. THE COVID-19 VACCINE INPUT SHORTAGE PROBLEM

The major vaccine sponsors publicly disclosed problems with input shortages, including for capital equipment and variable inputs (see step 3 in figure 1).⁴⁶ Shortages would have made it difficult to expand vaccine manufacturing capacity in 2021, both in the United States and globally. This section explores the economics behind the shortages, how policy decisions in 2020 may have exacerbated the problem, and some potential policy alternatives to tackle it.

In the very short run during the pandemic, US policymakers—including DOD staff—used DPA access to help acquire and then ration scarce inputs across vaccine manufacturers.⁴⁷ In a January 2021 interview, the CEO of MilliporeSigma—a major input provider whose supplies were being rationed—said his company was “in nearly daily communication with ‘colonels and majors,’ the pharmaceutical companies and their contract manufacturers,” who were forced “to start making trade-offs when you’ve got limited supply and limited capacity to focus on the need of the moment.”⁴⁸ In theory, US officials would ration inputs across US plants to their most productive use. In reality, it was unclear how efficient that process could be given that the FDA—the agency in charge of evaluating the scientific evidence to determine whether to authorize

⁴⁴ In April and May 2021, the US government also shipped inputs to the Serum Institute and CureVac (Bown and Bollyky 2022).

⁴⁵ See page 22 of the July 30, 2021 Pfizer contract.

⁴⁶ See the numerous examples of input shortages catalogued in Bown and Bollyky (2022).

⁴⁷ Army General Gustavo Perna was chief operating officer of Operation Warp Speed. According to HHS Deputy Chief of Staff for Policy Paul Mango, “instead of waiting weeks for trans-oceanic delivery, General Perna ordered contracted US military planes to places such as France, Germany, and Belgium to secure the specialized equipment and fly it back to the United States in hours” (Mango 2022, 79-80).

⁴⁸ Riley Griffin. 2021. “[A Cold War-Era Law and Vaccines](#),” Bloomberg, January 2.

public use of any particular vaccine—was independent of the Operation Warp Speed officials facilitating the allocation of scarce inputs.

6.1 The economics of shortages of vaccine inputs

Shortages of COVID-19 vaccine inputs arose for many reasons. One was the enormous increase in demand, often for highly specialized inputs. The more customized the input, the larger the entry barriers by new firms, further limiting the supply response.

Certain inputs may face elevated demand only during a pandemic. Take ABEC, a major supplier of giant bioreactors and disposable bioreactor bags to vaccine manufacturers like the Serum Institute, a vaccine manufacturer scaling up its production facilities during the pandemic.⁴⁹ In a May 2021 interview, ABEC’s vice president stated that the company’s lead time for bags was about 16–18 weeks and that “many customers are telling us they’re waiting 10–12 months just for bags, and that’s just extraordinary.”⁵⁰

In the absence of a pandemic, there may not be enough revenue to cover the costs of additional production lines manufacturing such specialized inputs. Similar to the economic incentives facing Pfizer-BioNTech or Moderna described earlier, once the vaccines end the pandemic, demand for such inputs falls, leaving the input provider potentially unable to recoup investment in new capacity capable of producing for peak pandemic demand.

6.2 DPA contracting with vaccine manufacturers and input shortages

DPA contracting with vaccine manufacturers in 2020 may have introduced another problem that inadvertently exacerbated the shortages. Signing a DPA priority-rated contract obligates the manufacturer to pass that priority along to its supply chain to input providers. However, under the regulation, input providers are not allowed to *raise* their prices or otherwise discriminate between rated and unrated orders.

Thus, if the DPA contracting environment with input providers was expected to be long lived and the fixed price was too low, that price signal would work *against* creating incentives for input suppliers to invest in new capacity to expand production.⁵¹

6.3 Business decisions to further concentrate demand

Industry business decisions may have further concentrated an already concentrated demand shock, further limiting the pool of available input providers. For example, Pall—an input provider and participant in the Oxford consortium behind the AstraZeneca vaccine—indicated that the AstraZeneca strategy was to use the same capital equipment and variable inputs across

⁴⁹ See ABEC. 2020. “[Serum Institute Selects ABEC for Large-Scale, Single-Use COVID-19 Vaccine Manufacturing](#),” Press release, September 30. In 2018, Emergent BioSolutions had procured similar equipment; see ABEC. 2018. “[ABEC 4,000 Liter Single-Use Bioreactor to Expand Emergent BioSolutions Manufacturing Capability](#),” Press release, September 24.

⁵⁰ See Sarah Kominek. 2021. “[Biopharmaceutical Supplier ABEC Inc. Sees Demand Overflow](#),” *Plastics News*, May 28.

⁵¹ Note this is a different argument from the original 1950 DPA provisions which allowed for price (and wage) controls. Those provisions terminated in 1953, when Congress chose not to renew them.

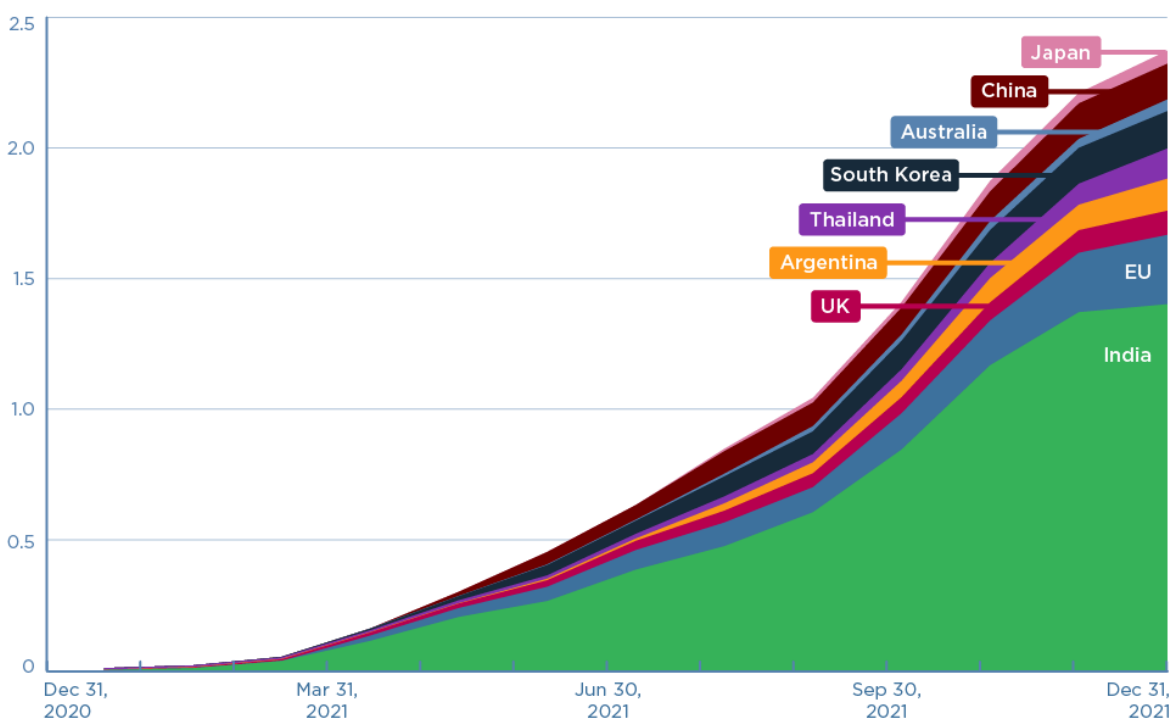
each of the 20 plants manufacturing that vaccine globally (Pall 2021; Bown and Rogers 2021; see also figure 2).

Such a strategy may help obtain consistent vaccine output across facilities, but it limits the pool of input suppliers, potentially slowing vaccine production if Pall has insufficient capacity to meet demand from AstraZeneca plants as well as the other COVID-19 vaccine facilities contracting with Pall for inputs. Although input shortages were only one factor, they may have contributed to the various facilities manufacturing the AstraZeneca vaccine coming online at different times and producing different volumes over 2021 (figure 5), even though most of the firms producing the vaccine had agreed to do so in 2020.⁵²

Figure 5

The facilities manufacturing the AstraZeneca COVID-19 vaccine differed in their speed and scale of production in 2021

Cumulative AstraZeneca vaccine supply by economy, billions of doses, December 2020–December 2021



Note: Supply estimates based on the amount of vaccine doses delivered to countries as of the last day of that month, not accounting for stockpiles, waste, or doses not yet delivered. Supplying country determined by location of the drug substance facility. US supply of AstraZeneca was 4 million doses in 2021 (not shown).

Source: Constructed by the author with data from Airfinity.

⁵² Bown and Bollyky (2022, Appendix Table A.3) provide dates of announcements signaling when each facility agreed to join the AstraZeneca COVID-19 vaccine global supply network.

6.4 Operation Warp Speed subsidies and input shortages

Optimal policy would have involved contracts with input providers that were conditional on their expanding production capacity, similar in spirit to some of the contracts the US government signed with vaccine manufacturers in 2020 to commit to the capacity necessary to manufacture 100 million doses of a new vaccine.

In 2020, US policymakers attempted to tackle part of the problem.⁵³ They used the DPA to write priority-rated contracts with companies making glass tubing and vials to bottle the vaccines (see step 4 in figure 1). The US government signed similar contracts with firms making syringes and needles (step 5 in figure 1). These subsidies addressed relatively homogeneous inputs, which did not require as much policymaker understanding of vaccine-specific supply chains as other inputs did.

In October 2020, the US government signed a priority-rated contract with Cytiva for \$32 million, to expand capacity “for vaccine-related consumable products, such as liquid and dry powder cell culture media, cell culture buffers and mixer bags, as well as hardware including XDR bioreactors.”⁵⁴ These kinds of inputs are needed at manufacturing facilities handling step 3 of the vaccine value chain (see figure 1). Cytiva had recently been spun off from GE Healthcare and fell under the same corporate umbrella as Pall. US policymakers described it as “the primary supplier to many of the companies currently working with the U.S. government to develop COVID-19 vaccines.”⁵⁵

Although helpful, the Cytiva subsidy was likely insufficient.⁵⁶ By early October 2020, US policymakers would have lacked the information needed to predict the emergence of critical shortages, such as lipid nanoparticles, given that companies were manufacturing mRNA vaccines for the first time anywhere at commercial scale. Moderna signed a modified contract to include an explicit priority rating only in September,⁵⁷ and Pfizer’s input providers may have remained unknown to US officials at least until its priority-rated contract of December. Beginning in late 2020 and through 2021, major COVID-19 vaccine input providers did announce plans to eventually add capacity,⁵⁸ but open questions remain about the specifics.

⁵³ See table 4 in Bown and Bollyky (2022).

⁵⁴ BARDA. 2020. “[Trump Administration Expands Manufacturing Capacity with Cytiva for Components of COVID-19 Vaccines](#),” News release, October 13.

⁵⁵ Furthermore, the FDB plant in Texas had a job opening for a manufacturing supervisor in May 2021 that required operational oversight including “single use mixing systems (Pall & GE)” —where “GE” was likely in reference to GE Healthcare (now Cytiva).

⁵⁶ In April 2021, the United States provided \$13 million to Meissner Filtration Products to expand production capacity for products necessary for the manufacturing of COVID-19 vaccines and therapeutics.

⁵⁷ See page 2 of Moderna’s contract amendment P00002 of September 8, 2020.

⁵⁸ See Fraiser Kansteiner. 2020. “[Merck KGaA's MilliporeSigma Lays out \\$47M Upgrade for New England Sites Tapped in Pandemic Manufacturing Push](#),” FiercePharma, December 8; Gareth Macdonald. 2021. [Pall Investing \\$114m, Adding 1,100 Jobs, on Back of COVID Single-Use Demand](#),” BioProcess International, January 14; Dan Stanton. 2021. [Thermo Fisher Doubling Single-Use Capacity through \\$100m Nashville Plant](#),” BioProcess International, September 9; Joseph Keenan. 2021. [Responding to Global Vaccine Demand, Cytiva Pledges \\$52.5M to Build South Korean Factory](#),” FiercePharma, September 24.

6.5 Concentration of input providers into the US market and international policy coordination

The Biden administration’s decision to draw attention to Pfizer’s new DPA access in February 2021 was condemned internationally (Bollyky and Bown 2021). The combination of input shortages and DPA contracts that gave priority input access to the six US vaccine manufacturing networks created an obvious scapegoat whenever foreign plants were unable to meet delivery promises: They could blame the US government rather than the shortages themselves.

The loudest complaints were from the CEO of the Serum Institute of India, who accused the Biden administration in April 2021 of imposing an “export embargo.” The CEOs of Biological E., CureVac, and Novavax also highlighted the problem. Even French President Emmanuel Macron accused the United States of imposing an export ban on vaccine ingredients.⁵⁹ Although factually incorrect, the political problems contributed to the US decision to remove DPA priority ratings for AstraZeneca, Novavax, and Sanofi-GSK in June 2021.

This episode revealed a number of additional and related challenges. First, when rationing was required in the very short run because of a fixed (and insufficient) supply of certain inputs, the lack of DPA–equivalent US government understanding of the needs of vaccine manufacturers in Europe and India meant that its global allocation decisions were almost certainly suboptimal. Eventually, in early 2021, US policymakers began to remedy the situation by liaising with counterparts in Europe and India, to allocate some scarce supplies outside US borders, including to the Serum Institute and CureVac.⁶⁰ However, lack of insight into those input suppliers in 2020 meant that the US government would not have known which input providers beyond Cytiva to subsidize. Even if they had, US policymakers may not have subsidized input providers—feeding into step 3 of figure 1—to the globally optimal level, because some of the beneficiaries of those subsidies would have been outside the United States.

Cross-border vaccine supply chains thus create the need for policymakers in output- and input-providing countries to coordinate their subsidies. This need to cooperate was one of the motivations behind a proposed COVID-19 Vaccine Investment and Trade Agreement (Bollyky and Bown 2020, Bown and Bollyky 2021) that never caught on.⁶¹

7. CONCLUSIONS

Many factors other than the ones catalogued here limited the global supply of COVID-19 vaccines. Policymakers in other countries often made much worse decisions than the US government. Some governments completely failed to tackle diversification, speed, or scale. Despite its sizable vaccine industry, India, for example, did not offer subsidies to vaccine manufacturers until April 2021. Resources also could have been allocated and reallocated more

⁵⁹ Sam Fleming, Jim Brunsten, Mehreen Khan, Michael Peel, and Guy Chazan. 2021 “[EU Leaders Confront US over vaccine Patent Waiver Demands.](#)” *Financial Times*, May 8. See also Bown and Rogers (2021) for evidence of US vaccine exports to the Serum Institute and other Indian vaccine manufacturers.

⁶⁰ The White House and the European Commission began collaborating in March 2021; the US–India collaboration began in April 2021, after the Serum Institute accusations.

⁶¹ Bown, Snyder and Staiger (2022) explore these issues in a formal theoretical model.

efficiently. CureVac, for example, built from scratch a 1 billion dose supply chain that was not repurposed and went to waste when its vaccine did not pass clinical trials.⁶²

The US government failed to make use of its considerable investment in AstraZeneca, even though the vaccine was authorized for use in many other countries. Supplies of Pfizer-BioNTech and Moderna vaccines to poor countries may have been held up not by production but by the lack of local investment in the ultra-cold chain delivery and storage infrastructure that those vaccines required for distribution. Finally, although the United States may have under-subsidized input capacity expansion, it was one of the few governments to offer such subsidies at all.

How the United States used DPA likely had other unintended consequences. The 2020 DPA contracts made clear that the US government would own all of the initial vaccines manufactured on US soil by Pfizer, Moderna, Johnson & Johnson, and the others. Lack of certainty on when their US plants would be allowed to export surely contributed to vaccine sponsors' decisions to set up parallel supply chains elsewhere. That decision led to more globally diversified production, but it also meant smaller scale at US plants, potentially reducing the benefits of learning-by-doing. This uncertainty also helps explain why the firms behind even the most successful vaccines (Pfizer-BioNTech and Moderna) chose to increase production capacity much more through their European supply chains than through their supply chains in the United States. Finally, drawing inputs toward COVID-19 vaccine manufacturing impacted supplies of other products, sometimes with an offsetting, negative impact on public health.

Additional research remains needed to understand how best to incentivize diversity, speed, and scale. Understanding the relative magnitudes of the contributing factors identified here is critically important for policy. Doing so requires more formal theoretical modeling as well as empirical analysis once detailed data on outputs and inputs become available.

⁶² See Bown (2021).

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