TRADE, INVESTMENT AND COMPETITIVENESS

TRADE, INVESTMENT AND COMPETITIVENESS

EQUITABLE GROWTH, FINANCE & INSTITUTIONS INSIGHT

Why the World Trade Organization is critical for vaccine supply chain resilience during a pandemic

May 2022

Author: Chad P. Bown

WORLD BANK GROUP

1818 H Street NW
Washington DC 20433
Telephone: 202-473-1000
Internet: www.worldbank.org

Cover design and layout: Diego Catto / www.diegocatto.com

>>>

Abstract

Cross-border supply chains and international trade played a critical role in vaccinating much of the world to address the COVID-19 pandemic. Considering that experience, this note describes the changes needed to make the World Trade Organization (WTO) a more useful institution during such a public health emergency. It begins by describing the market failures confronting vaccines—especially on the supply side—to introduce the domestic subsidies and contracting arrangements needed to accelerate vaccine research and development, and to increase the scale and speed of vaccine production during a pandemic. As an application, it relies on illustrative examples of US subsidies that emerged during COVID-19. However, the challenge confronting policymakers is exacerbated in an environment characterized by cross-border supply chains, making input shortage problems impacting production even worse. Thus, the note highlights the need for new forms of international policy coordination, including initiatives on supply chain transparency, as well as agreements to increase subsidies across countries to jointly scale up vaccine output—*and* input—production capacity along the entire supply chain. It concludes that while the WTO was mostly absent this time around, it remains the best-positioned international organization to facilitate these novel forms of international economic policy cooperation.

Chad P. Bown
Peterson Institute for International Economics & CEPR
Bown: Peterson Institute for International Economics, 1750 Massachusetts Avenue, NW, Washington, DC 20036. Tel: +1.202.454.1306, email: cbown@piie.com, web: www.chadpbown.com.

Contents

1 Introduction

Upon the emergence of a pandemic, new and life-saving products like vaccines are critical. So are the size and form of government subsidies needed to accelerate their research and development (R&D); the establishment of supply chains; and to increase their scale of production. In the case of COVID-19 vaccines, trade would turn out to play two essential roles. First, cross-border supply chains would emerge, and imported inputs were needed to manufacture COVID-19 vaccines. Second, most countries would have no local vaccine production, relying entirely on imports to gain access to these brand-new products. The existence of that trade, as well as a number of other pandemic factors, made enhanced policy cooperation more essential. And yet, much of the demand for more international coordination went unmet, though not for traditional reasons.

Governments intervened too little into markets, not too much.

In response to COVID-19, the US government was an outlier, allocating $18 billion in "subsidies" through Operation Warp Speed beginning in early 2020 to accelerate research, development through clinical trials, and sometimes even the creation of manufacturing capacity, for an initial portfolio of seven vaccine candidates. Despite these enormous subsidies, economists have almost universally criticized US subsidy efforts as being orders of magnitude too small. The human and economic costs of the ongoing pandemic ran into the trillions of dollars.[1] In their modeling, for example, Ahuja et al. (2021) suggest that the United States should have spent more than three times that amount and diversified across 27 different vaccine candidates in 2020.[2] (See also Athey et al. 2022.) The motto has become "spend billions to save trillions."

Yet, where was the rest of the world? The United States was, in fact, one of the few to subsidize the acceleration of this process much at all. The explanation was not that the United States had a monopoly on COVID-19 vaccine intellectual property or technology: the Pfizer-BioNTech vaccine was invented in Germany, the AstraZeneca vaccine in the UK, and the Johnson & Johnson vaccine was co-invented in the Netherlands. Indeed, plants to manufacture these and other COVID-19 vaccines emerged all over the world, with vaccine technology licensed to multiple firms in India and other developing countries even by the summer and fall of 2020. While the United States may have been slow to export finished vaccines, its subsidies to accelerate and pay for clinical trials generated global externalities for vaccines subsequently manufactured in facilities located around the world.

1 See, for example, Cutler and Summers (2020) and Agarwal and Gopinath (2021).
2 These and other economists had made such policy recommendations early and throughout the pandemic—see Athey et al. (2020), Snyder et al. (2020), Castillo et al. (2021), and Kominers (2021).

The European Union (EU) and its member states offered very few subsidies to accelerate the process, focusing instead on allocating authority to the European Commission to negotiate procurement contracts and advanced purchase agreements to order COVID-19 vaccine doses at low prices.[3] Criticized for its slow, miniscule and poorly targeted policy response to COVID-19, the EU has since developed a major new initiative—the European Health Emergency Preparedness and Response Authority (HERA)—potentially modeled similar to the Biomedical Advanced Research and Development Authority (BARDA) in the United States. India, whose firms made it the largest vaccine-producing nation prior to COVID-19,[4] did not offer subsidies to vaccine manufacturers to expand production capacity until April 2021, more than 14 months into the pandemic. The Coalition for Epidemic Preparedness Innovations (CEPI), attempted a subsidy approach with some qualitative similarities to the US government, but its efforts were constrained.[5]

World Trade Organization (WTO) subsidy rules may have implicitly contributed to the problem. The WTO's Agreement on Subsidies and Countervailing Measures has a bias *against* government subsidies. Trade ministers and their staffs are trained in these rules; staff operating in vaccine-producing countries were unlikely to contribute usefully to the domestic policymaking process that should have sought to structure subsidies to accelerate vaccine development and to increase the speed and scale of production capacity. The WTO missed an opportunity to contribute meaningfully and showcase why enhanced policy cooperation was also economically essential, given that the manufacturing supply chains to emerge were cross-border in nature.

Vaccines alone showcase the outsized role for the WTO during a pandemic. Cross-border supply chains and foreign inputs are needed to manufacture vaccines. Trade is essential for delivering finished doses globally. Having the most experience with subsidy rules, the WTO should be at the forefront arguing that laissez-faire and markets alone are *not* the appropriate policy response during a pandemic. There should be a basic pandemic playbook for subsidies, describing in advance the funding, contracting frameworks, and "best practices" for domestic policymakers to use when confronted with the desire to accelerate the vaccine R&D and manufacturing process in such an emergency.

The WTO is also the best-positioned international organization to provide a forum for policymakers to convene upon the emergence of a pandemic to address the commercial problem of input shortages that will inevitably arise at the beginning stages of new vaccine production. Here, there are three distinct needs. First, in terms of pandemic preparedness, the WTO can help identify what critical inputs can be stockpiled in advance—the WTO's considerable expertise on transparency and diagnosing input-output relationships in supply chains can help organize such essential information. However, not everything can be stockpiled or worked out ex ante through a pandemic preparedness playbook; a new vaccine is likely to require at least some new specialized inputs. As such, there will be an inevitable period of input shortages. Thus, second, the WTO's ability to quickly gain insight into cross-border supply chains can help diagnose short-run input scarcity problems and assist policymakers as they facilitate the rationing of those inputs to their best (inclusive of public health) use. Third, the WTO can use that information about input shortages to help domestic policymakers coordinate capacity-enhancing subsidies to input suppliers to ensure the full, cross-border supply chain is scaled up.

The fact that the WTO is a permanent body already providing a forum for high-level government officials to continuously interact over trade, supply chains, and periodically even scientific issues—and where governments sometimes both dispute *and* negotiate mutually agreeable solutions—makes it capable of facilitating the additional international cooperation and policy actions required to accelerate the creation of new vaccines and the expansion of production capacity during a pandemic. The WTO also has a history of working with other major international organizations in good faith to bring in required scientific and technical expertise when needed.[6]

Unfortunately, but predictably, the world resorted to "vaccine nationalism" of various forms during COVID-19. In part, this was because countries had not developed a global framework that would allow them to share risk, pool resources, and rely on supply chain interdependence to manufacture and deliver vaccines globally during a pandemic.[7] In the absence of a guidebook, some governments acted unilaterally.[8] However, it is important in retrospect to better understand the various forms of "vaccine nationalism" that emerged if there is hope to create new rules or norms for government behavior and

3 Though relatively small in scale, exceptions include Germany's subsidies to BioNTech and CureVac, and UK at-risk subsidies to multiple candidates. See Bown and Bollyky (2022, Table 5 and Table 6).
4 See CEPI. 2020. Manufacturing Survey Results Analysis, June 29.
5 CEPI had fewer financial resources, more legal constraints, and lacked the political mandate.
6 Examples abound, but consider Codex Alimentarius, the World Organization for Animal Health, etc.—whether for issues arising under the Sanitary and Phytosanitary Measures Committee or in panels under WTO dispute settlement.
7 See Bollyky and Bown (2020a).
8 The notable and important exception was the emergence of COVID-19 Vaccines Global Access (COVAX), which was not allowed to succeed because it was not provided political support or with manufactured doses by the major economies where vaccines would be produced—that is, the United States, India, the EU, and China.

international cooperation during a future health emergency. This time, while trade flows were mostly kept open, avoiding the most disastrous outcomes, the WTO played a very minor role overall. And it played virtually no proactive role during the critical period of 2020 when most of the essential policy decisions were being made on subsidies for the acceleration of COVID-19 vaccines that would determine the speed and scale of production, and influence longer-term production and trade patterns.

This note begins with Section 2 describing how COVID-19 vaccine supply chains emerged from scratch during this pandemic. Ultimately, more than 11 billion doses were manufactured by the end of 2021, with 40 percent of those being exported. Section 3 then introduces the economics of the market failures for vaccines, with a special focus on the supply side and the need for special forms of subsidies and contracting to accelerate and commit to production capacity enhancement. Section 4 introduces the specific and illustrative example of US subsidies to emerge during COVID-19, highlighting parallels to the proposed structure (if not scale) identified in Section 3, as well as implications for international policy cooperation and trade rules. Section 5 tackles the problem of input shortages. Sections 4 and 5 both emphasize why the WTO is the best-positioned international organization to play a leading role in obtaining the international cooperation needed to accelerate vaccine production in the presence of cross-border supply chains and inevitable input shortages. Section 6 describes other areas of concern for policy coordination to emerge for vaccine production and distribution. Section 7 concludes.

The Emergence of Covid-19 Vaccine Supply Chains

Getting a new vaccine from beginning to end requires investment in a number of sizeable sunk costs (figure 1). This includes the scientific research to invent the vaccine, the clinical trials to develop and check that it is effective and safe, the creation of a dedicated manufacturing facility with specialized equipment needed to produce the vaccine's drug substance, and a separate manufacturing facility to formulate the drug substance into drug product for fill and finish, assembly-line style, into hundreds of thousands of tiny vials, for distribution.

Pre-pandemic, the world manufactured roughly 1.5 billion doses of vaccines annually. With COVID-19, the global pharmaceutical industry was tasked with reallocating production facilities, establishing new supply chains, and creating new input streams to suddenly manufacture roughly 11 billion additional doses of new vaccines—mostly a two-dose regime aiming to inoculate 70 percent of the world's 7.8 billion people. Even once COVID-19 vaccines had been invented and successfully passed clinical trials, such an effort would require a tremendous increase in dedicated production lines, as well as inputs into a sophisticated and highly regulated manufacturing process.

This section summarizes the results of Bown and Bollyky (2022), which describes the details behind the manufacturing supply chains that emerged from scratch over 2020-21 for six different vaccine candidates: Pfizer-BioNTech, Moderna, AstraZeneca, Johnson & Johnson, Novavax, and CureVac.[9] The focus here will mostly be on the first four, since Novavax was not authorized for use by anyone until late 2021 and CureVac was not authorized by anyone.[10]

Overall, dozens of different firms at nearly 100 different geographical facilities became part of even just the two most basic elements—that is, steps 3 and 4—of those vaccine manufacturing supply chains.[11] Contract development and manufacturing organizations (CDMOs) played an important role in manufacturing almost every vaccine.

9 Bown and Bollyky (2022) also includes a database mapping vaccine sponsors to the manufacturing facilities as well as the announced timing of those matches. Unfortunately, that exercise did not tackle the question of how supply chains emerged for Chinese firms Sinovac and Sinopharm, except to note that most of the production facilities appear to have been located within China.

10 Nevertheless, their supply chain formation strategies and preparation were informative. In broad terms, Novavax followed the AstraZeneca model of using CDMOs to establish region-specific supply chains—that is, sticking to one plant covering step 3 and another plant covering step 4 in the same region. CureVac's supply chain was entirely concentrated in Europe, and while it hired a number of different contractors to do its manufacturing, it was interesting that some of those arrangements were with large, global pharmaceutical companies—for example, GSK, Bayer, and Novartis—some of which may have found it worthwhile to team with CureVac to learn more about its mRNA technology, potentially to apply it to other pharmaceutical settings in the future.

11 This does not include the key input providers that fed into these manufacturing facilities, as will be described below.

Here are some of the key characteristics of the supply chains that were announced as forming over this period.

First, none of the supply chains to emerge were in place prior to 2020. These all arose from scratch, and they almost all relied heavily on CDMOs. Even Pfizer, whose US-supply chain remained mostly in house through 2021, stated in May 2020 that it would turn to CDMOs to outsource production of their other (non-COVID-19 vaccine) pharmaceutical products.[12] While some partnerships formed for COVID-19 vaccine production had had prior commercial relationships before COVID-19, many were new, including between firms that might otherwise be "rivals" for other pharmaceutical products.

Production for every vaccine was fragmented across multiple facilitiesfor example, steps 3 and 4 were always done at separate plants. Even for the complex Pfizer-BioNTech mRNA vaccine that is, in the United States, this was the closest thing to an *integrated* production process since steps 3 and 4 remained in house (that is, *not* outsourced)—production took place across three different US facilities—that is, Pfizer plants in Missouri and Massachusetts combined to cover step 3, and a Pfizer fill-and-finish facility in Michigan contributed step 4 (Figure 2). (The vaccine patent itself, of course, had been offshored to those US Pfizer plants under an arrangement with BioNTech, a German biotech, where it had been invented.) And in the European supply chain for the Pfizer-BioNTech vaccine, the process was even more fragmented.

Each vaccine was manufactured by at least some CDMOs from the beginning, with the exception of Pfizer-BioNTech. (However, by mid-2021, even for the Pfizer-BioNTech supply chain in Europe, production needs expanded beyond available capacity at Pfizer or BioNTech facilities so they brought some CDMOs into the manufacturing process, especially for step 4.) At one extreme was Moderna, a biotech with no commercial scale manufacturing facilities prior to the pandemic, which outsourced every part of the production process to different CDMOs (Figure 3). But even Johnson & Johnson, a large, global, integrated pharmaceutical company, only relied on *one* of its own facilitiesthat is, some of its drug substance was to be manufactured at its own plant in the Netherlands (Figure 4). Fill and finish for Johnson & Johnson was done by contractors elsewhere, as was production of its drug substance to be done in the US market, first by Emergent BioSolutions and ultimately also by Merck.

All of the vaccine candidates set up parallel manufacturing supply chains across different geographies. Each had at least a US-based and Europe-based supply chain for steps 3 and 4, for example. Pfizer-BioNTech would export to other countries from those supply chains, as would Moderna.[13]

However, in addition to its US and European supply chains, AstraZeneca set up *additional* parallel supply chains in India, South America, the UK, South Asia, and elsewhere (Figure 5). Indeed, most of the total production of the AstraZeneca vaccine would take place at the Serum Institute of India. (Novavax, which started contributing to COVID-19 vaccine supplies late in 2022, adopted a similar supply chain model to AstraZeneca.)

Johnson & Johnson also subcontracted fill and finish facilities with a firm in South Africa (Aspen Pharmacare) that it was anticipated would receive drug substance imported from its plant in the Netherlands or from a contractor making its vaccine in the United States; Johnson & Johnson also shared its technology with a firm in India (Biological E.) in the summer of 2020 that, as of this writing, still had not come online.

Each vaccine sponsor faced challenges even as it contracted with partners to add production facilities. Companies like Moderna and BioNTech complained about the shortage of facilities and firms with the technological know-how with which to partner for their brand-new mRNA vaccines, including for fill and finish. In some instances, the shortage of plants caused CDMOs to break pre-pandemic contracts with other pharmaceutical companies—with which they had been scheduled to manufacture other products—to create the emergency space needed for COVID-19 vaccine production, especially for fill and finish.

Next, there were also critical inputs, sometimes feeding in through mini supply chains, coming into steps 3 and 4 (manufacturing) as well as step 5 (distribution).

For example, all vaccines required specialized inputs such as capital equipment (bioreactors) in addition to "single-use" or "consumables" (for example, bioreactor bags, filters) that would need a continual stream from input providers feeding into step 3. Over the course of scaling up production, there were shortages of such inputs—by early 2021, virtually all of the vaccine sponsors were publicly complaining about insufficient quantities of available inputs, indicating this was

12 Carl O'Donnell and Michael Erman, "Pfizer to Outsource Some Drug Production, Focus on Coronavirus Vaccine," Reuters, May 9, 2020.
13 Moderna did eventually sign up SK bioscience in South Korea to fill and finish some of its production as well.

holding up their ability to meet production and delivery targets. Indeed, in such a highly regulated and complex production process, missing one input could have devastating impacts for vaccine output. (While a convenient excuse, some of it may be standard slippage for scaling up a new product. Some workarounds were found and some of the complaints were by companies whose vaccine was never authorized or was authorized much later, in which case them not getting access to inputs during a period of shortage and rationing may have been efficient.)

However, some of the vaccines also required specialized inputs that may not have previously manufactured at volumes needed for commercial scale, let alone pandemic-level demand. Lipid nanoparticles (LNPs) were needed for the mRNA vaccines of Pfizer-BioNTech and Moderna, and each brought in a suite of contractors to supply it (see Figures 2 and 3), before Pfizer eventually also brought some production in house. The Novavax vaccine would have needed access to a highly specialized adjuvant derived from the Chilean soapbark tree.

All of the vaccines would also need relatively homogenous ancillary inputs like vials and glass stoppers (for packaging in step 4), as well as syringes and needles (for administering in step 5). Because of cold-chain requirements for the mRNA vaccines, refrigeration would also be needed for transport from the plant through to the point at which final doses would be administered to people.

By the end of 2021, estimates are that 11.5 billion COVID-19 vaccine doses had been supplied globally, over 90 percent of that by China, the EU, India, and the United States (Figure 6). (The Chinese firms deserve a lot of credit, but for transparency reasons, much less is known about their supply chains, as well as the long-term effectiveness of their vaccines.) Nearly 40 percent of that global production was exported.

The EU manufactured the largest portfolio of different vaccines for internal use, authorizing each of the big four—Pfizer-BioNTech, AstraZeneca, Moderna, and Johnson & Johnson—by March 2021, with Novavax being authorized in December 2021. All of these vaccines had local supply chains in the EU (drug substance manufacturing for Moderna's European supply took place in Switzerland but fill and finish was done in Spain and France). This helps explain why the EU's total COVID-19 vaccine production was so large.

At the other extreme was the United States. Even though US government subsidies (described below) funded seven different vaccine candidates, including five that have now been authorized by some regulator worldwide, the US Food and Drug Administration (FDA) only authorized three for use in the United States by the end of 2021. Of those, total US production in 2021 ended up being mostly Pfizer and Moderna, as the third vaccine authorized for use—Johnson & Johnson—had contamination problems at the primary drug substance manufacturing facility in the United States in March 2021 and had to be shut down for about four months. Thus, even though the US government helped set up and fund supply chains and capacity that was then reserved for Johnson & Johnson, AstraZeneca, and Novavax, most of that would sit idle, not in commercial use, even though doses manufactured at those facilities could have been put to use in other countries where the vaccine had been authorized. While the United States was arguably the early success story of 2021—in terms of its speed and initial scale of production, partially for the reasons described in Section 4—by the end of 2021, US total production significantly lagged both the EU and India.

Most of India's output was the Serum Institute of India's production of the AstraZeneca vaccine. While enormous in scale, the problem was that very few of its doses were exported in 2021 due to an Indian government export clampdown in April that mandated its output be kept local due to a devastating outbreak taking place in the country. The concern was that COVAX was relying on doses from the Serum Institute to allocate to low-income countries, which dried up.

By the end of 2021, the broad story was fourfold. First, it was an amazing accomplishment to invent, get through clinical trials, and manufacture 11.5 billion doses of COVID-19 vaccines in two short years. Few would have anticipated this outcome at the outset of the pandemic in early 2020.

Second, the doses did not arrive quickly enough. Accelerating their arrival by 1, 2, or 3 months was estimated to save hundreds of thousands of lives and the equivalent of trillions of dollars of economic activity (Athey et al. 2022).

Third, the distribution of COVID-19 vaccines was biased toward the countries and regions in which the doses were manufactured. While more supply chains were established by early 2020 than may have been capitalized on through production—often due to events outside of anyone's control,

such as input shortages or the failure of a vaccine to be authorized by regulators—the geographic concentration of production had this implication. Thus, it is understandable that there have been calls for post-pandemic efforts to diversify vaccine manufacturing capacity globally to better prepare for future global health emergencies.

Fourth, the scale of production was also too small. The lack of sharing meant less than 10 percent of the population in poor countries went inoculated by the end of 2021. Combined with the new demand for boosters (a third dose) as well as (normal) waste in the system of unused or expired doses put the overall demand for capacity at much higher than 11.5 billion doses.

These outcomes beg the question of why government policy in COVID-19 failed to address the market failures for COVID-19 vaccines. The next sections explore the policies that did emerge, the lack of international policy cooperation, and why the WTO is needed to help overcome challenges involving international externalities brought on by a world characterized by cross-border supply chains for vaccine manufacturing.

3 Vaccine Market Failures and Government Policy

How those 11.5 billion doses went from scientific ideas for a COVID-19 vaccine to the point at which they were injected into arms was not only left to markets. It was also the result of considerable financial support from the public sector.

For decades, governments have struggled with the policy question of how to tackle vaccine "subsidies." The environment is made difficult by a complex web of failures arising on both the demand and supply side of the market.

On the demand side, the consumption of vaccines enjoys positive externalities. An individual that takes a vaccine provides additional, uncompensated benefits to society by breaking disease transmission. Without government policy intervention, purely market-based outcomes would result in too few individuals consuming vaccines relative to the social optimum. To help overcome this market failure, governments typically procure vaccines from companies and distribute them to consumers either for free or at highly subsidized prices. Indeed, this is what took place during COVID-19.[14]

Tackling supply-side market failures for vaccines often proved harder. In the 1990s and early 2000s, the inability to invent vaccines to tackle diseases arising primarily in poor countries, such as malaria, tuberculosis, and certain strains of HIV prevalent in Africa, became increasingly apparent. Decades of failure were linked back to how policymakers were struggling to create the right incentives by focusing on subsidizing inputs (R&D), with informational asymmetries ultimately resulting in governments picking the "wrong" entities to subsidize.[15] The 2019 Nobel Prize winner Michael Kremer (2001a,b) and others have pioneered explorations into creatively solving the incentivization problem, such as by using advance market commitments (AMCs) in an effort to strike the right balance between incentivizing research and accelerating vaccine development and production.

The basics of the AMC approach provide a useful template to understand the key issues that emerged during the COVID-19 pandemic.

14 There are important issues involving procurement that will mostly go unaddressed here, which focuses on government support to address supply-side market failures.
15 For a discussion, see Kremer and Glennerster (2004).

On the supply side, one traditional market failure for vaccines can be characterized by a hold-up problem. Suppose a firm is contemplating sinking hundreds of millions of dollars into R&D and the creation of a vaccine-specific manufacturing supply chain. Once those costs are sunk, the purchaser (for example, a government, since most vaccine demand has not been left to markets) has an incentive to offer a price only just above the firm's marginal cost of production. Using backward induction, firms recognize the future difficulty they would face in recouping the sunk costs of R&D and vaccine-specific manufacturing, and they under-invest in the first place. In this outcome, too few vaccines are invented and produced.

To help solve this potential hold-up problem, beginning in the 1990s, experts suggested policymakers provide firms with advance market commitments and other contracting guarantees to incentivize them to make the investments necessary to invent and deliver viable vaccines. The practical idea was that companies could be incentivized if governments, international organizations, or even well-endowed foundations could provide a legal guarantee that a future market would exist for, say, 100 million doses of a new vaccine to combat an under-addressed disease.[16]

In the case of a global pandemic such as COVID-19, another layer of this supply-side problem arose—the need for speed in accelerating the process of getting vaccines manufactured. A group of experts proposed early and often that this problem, too, could be tackled by creative contracting and subsidy incentives with insights from the AMC approach, as well as forms of "push" and "pull" funding.[17]

Consider the following stylized example, represented in Figure 7, taken from Athey et al. (2022), but also substantiated through their formal modeling results. During COVID-19, estimates are that the global economy was losing the equivalent of about $1 trillion per month in terms of economic output, morbidity, and mortality. Suppose that eventually a vaccine could be invented, make it through clinical trials, manufactured, and distributed to a sufficient number of people—say 70 percent of the global population, enough to achieve herd immunity—to end the pandemic. Suppose the vaccine passes clinical trials at month zero. In their stylized example, it takes three months for the firm to install vaccine manufacturing capacity to begin producing doses for global distribution, and then another 21 months to vaccinate the world, ending the pandemic two years after the vaccine receives approval. In the absence of any vaccine, the economic harm from the pandemic in this example is $24 trillion, or the area given by the rectangle with base 24 months and height $1 trillion per month. The exercise examines how different policy choices reduce different-sized areas of economic harm the pandemic imposes on society captured by Figure 7.

Suppose first that the firm waits to install capacity until it is certain that it will receive regulatory approval. Then suppose administering the vaccine reduces harm linearly—for example, assume for simplicity, doses were randomly allocated—and the pandemic ends 21 months later, at month 24. In this scenario, the vaccine reduces economic costs by area "A."

Next, suppose policymakers can better allocate vaccines by targeting priority groups. This could be through public health and economic considerations—for example, providing early vaccine access to hospital personnel and other front-line workers, vulnerable populations with co-morbidities, or even workers in important economic sectors (to reduce economic losses). Better targeting alone avoids even more losses given by "B." (The convexity of the new border results from initial vaccinations having a greater marginal reduction of harm than later doses given to lower priority populations.)

Now consider what happens when governments also have policy instruments to incentivize when and how the firm sets up its vaccine production facility.

First, suppose the government can convince the firm to establish its capacity *earlier*, so that it is ready to begin distributing doses the moment the vaccine is granted regulatory approval (and not three months later). In this scenario, the policy shifts the risk of the vaccine failing in a Phase 3 trial from the firm to the government. But doing so generates the societal benefit (of an additional harm reduction) given by area "C." (Despite its unusual shape, C is equivalent to the $3 trillion gain from accelerating the end of the pandemic by three months, costing the world $1 trillion per month.)

Second, suppose governments also have a policy instrument to be used to convince the firm to *double* the size of its production capacity. This allows for the end of the pandemic 10.5 months after doses have begun being administered rather than 21 months later. This benefit is the reduction of an additional area of economic harm given by area "D."

16 For an application of the approach to tackling the need for a vaccine for pneumococcus, see Kremer, Levin, and Snyder (2020).
17 See Athey et al. (2020), Snyder et al. (2020), Castillo et al. (2021), Ahuja et al. (2021), Budish and Snyder (2021), and Kominers (2021). The approach described here follows Athey et al. (2022).

The policy problem here is now clear.[18] There are large societal gains to be made by convincing the private sector to both (i) accelerate manufacturing capacity investments at risk, and (ii) significantly expand that capacity beyond what may be in its private, commercial interests. Left to its own devices, a profit-maximizing firm would wait until after resolution of the uncertainty associated with the lengthy Phase 3 clinical trial. Furthermore, if prices for vaccines were relatively fixed—as they mostly were during COVID-19, in the range of $6–$40 per course, well below their estimated social value of $5,800 per course (Castillo et al. 2021)—the firm has little private incentive to substantially increase production capacity to fill orders more quickly, especially because there was little concern for market entry (or business stealing) by competitors if it delayed, given the lack of other options for consumers (Budish and Snyder 2021).

How could governments convince firms to start investing in manufacturing capacity in advance of—or in parallel with—regulatory approval? How could they convince firms to install additional capacity?

In the case of COVID-19, experts recommended policymakers subsidize by focusing on a mix of "push" (subsidizing inputs to expand capacity, regardless of whether the vaccine candidate proved successful) and "pull" (rewarding expedited delivery of doses of approved vaccines) contracts with firms. Thus, not only should governments provide subsidies across multiple vaccine sponsors to diversify scientific risk, but they should do so *at risk* so that firms could begin building their manufacturing infrastructure in parallel with the Phase 3 clinical trials. They should also directly contract on production capacity and on a specific delivery schedule—for example, a specific number of doses delivered by a specific date —and not simply contract on doses that would allow the firm to simply put their order into a queue.

18 Ahuja et al. (2021) model these scenarios for the United States and globally to suggest the size and scope of supply-side policy interventions during COVID-19. Their results suggest even the United States—which subsidized the most and across the largest portfolio of vaccine candidates in 2020—should have spent more than three times what it subsidized in reality and should have diversified across 27 different vaccine candidates.

4 US Subsidies for Vaccine Capacity in Response to Covid-19, International Reaction, and Implications for the WTO

When COVID-19 hit, the US government implemented some elements of this proposed approach of subsidizing at risk and on some capacity to accelerate the development and manufacturing of vaccines, especially in 2020.[19] Yet, because the United States did not export doses in the first few months after commercial production emerged, the world complained that these contracts were equivalent to the United States imposing export restrictions. This section re-examines these considerations in light of the types of subsidies and contracts the United States used, and then considers the implications for the WTO.

4.1 US subsidies to accelerate vaccine development and manufacturing capacity under Operation Warp Speed

To start, two of the most important features of US vaccine subsidies were that they emerged early and there was some diversification. The subsidies began right away, some of them arrived as early as February and March 2020 (Table 1). On diversification, the US government started by providing "subsidies" or contracts for seven different vaccine candidates. For five of those vaccine candidates—that is, Moderna, Johnson & Johnson, AstraZeneca-Oxford, Novavax, and Sanofi-GSK—it developed explicit elements of the at-risk subsidies and contracting on capacity suggested in Section 3. For a sixth candidate from Pfizer, it wrote an early procurement-only contract, as discussed below. A seventh from Merck-IAVI was given $38 million in April 2020, but the candidate did not pass through initial clinical trials and was abandoned relatively early.

For some of these vaccine candidates, the early subsidies helped facilitate completion of clinical trials, including the expensive, data-intensive, and time-consuming Phase 3 trials requiring 30,000 or more trial participants—sometimes with subsidies of $400–$500 million dollars per vaccine candidate. Furthermore, for biotechs like Moderna and Novavax, which did not have their own manufacturing facilities to make even enough doses for Phase 3 trials, subsidies also covered the costs of outsourcing production to CDMOs at that stage to acquire doses for trials.[20]

19 For a discussion, see Bown (2022).
20 See also AstraZeneca (Table 1).

Then, once five of these promising candidates reached the stage of starting advanced clinical trials in the summer and fall of 2020, the United States contracted with firms for over $1 billion each, including some funding so that they would begin to install capacity to manufacture 100 million or more doses.[21] The guaranteed funding allowed companies to begin to sink investments and establish vaccine-specific manufacturing facilities and supply chains in advance of the FDA's regulatory approval that, realistically (it turns out) were 4-6 months off into the future *at best*.[22] Some contracts also included pull-like incentives for speed. Moderna, for example, had a contractual term promising a higher price per unit for deliveries if the FDA granted the company emergency use authorization (EUA) for its vaccine by January 31, 2021.

Finally, and as expected, the uncertainty of the science meant the FDA ultimately did not authorize three of those vaccine candidates. For those candidates, the US government received little payoff for its investment. However, for three of the six candidates, the basic process worked. Overall, for the United States, Operation Warp Speed was a *relative* success, in that it resulted in multiple viable COVID-19 vaccines and millions of doses produced (at risk) early, to be distributed immediately upon authorization, saving lives and helping to limit the economic losses. Nevertheless, the United States clearly could also have done better (Athey et al. 2022), and its relatively positive outcome also involved considerable luck. However, for the purposes of cooperation of international trade and commercial policy, there were a number of important practical implications of these early, at-risk US subsidies:

First, this funding model shifted substantial financial risk onto the US government and away from private firms.

Second, since firm investment in manufacturing capacity and the creation of a brand-new supply chain could take place simultaneously with Phase 3 trials, vaccines that were granted regulatory approval would have millions of doses available for distribution almost immediately upon approval, and not many months later (after creation of the supply chain), saving lives and tens if not hundreds of billions of dollars of economic output. At least intuitively, a number of contracts were designed to help capture *some* of area "C" in Figure 7 (if not part of "D"—that is, depending on whether the contracts encouraged them to invest in more capacity than they would have otherwise, irrespective of timing).

Third, the US government contracting on capacity (and "owning" the initial output) for the firm's first 100 million doses would potentially generate positive externalities for other buying countries. That is, a buyer that contracts on capacity creates something that can be switched over to other buyers after its order has been fulfilled, whereas a buyer that contracts on doses only lengthens the vaccine queue, imposing a negative externality on others (Athey et al. 2022).

Fourth, the major vaccine sponsors created multiple, parallel manufacturing supply chains, in part because it would be impossible for US plants to export at first because of those contracts (Bown and Bollyky 2022). Paradoxically, the US contracts that incentivized the same vaccine sponsor firms to install additional capacity in other countries may have generated *positive* externalities for the rest of the world in the form of that forced diversification. There was also some gain to additional geographical diversification, should future shocks arise (export controls, manufacturing problems, and so on) that might be geographic- or plant-specific.[23] One tradeoff, however, was that forcing the creation of that extra capacity to be done in foreign countries may have been inefficient from a global perspective—that is, investing in additional capacity expansion at US plants could have led to more learning-by-doing or other local spillovers increasing production yields. That may have led to more doses produced more quickly, globally, than creating multiple supply chains for the same vaccine.

Fifth, there were contractual limitations on the US government preventing it from exporting the vaccine doses it was buying.[24]

---

21 Specific details of the contracts are unknown, as the publicly available versions are highly redacted. However, see GAO (2021), which reviewed the contracts and interviewed the firms for confirmation. Note also it was 200 million doses for the US government contract with AstraZeneca.

22 The exception in the United States was the initial contract with Pfizer, which negotiated a contract of $19.50 per dose for 100 million doses but which was not guaranteed and thus which Pfizer retained the risk if the vaccine failed in clinical trials. Furthermore, of the initial six US government contracts for $1 billion or more signed with vaccine sponsors in 2020, Pfizer's was the only not to be given a priority-rated contract under the DPA, which would have given it priority access to US-based input providers (Bown 2022b).

23 For the importance of geographic diversification to make medical supply chains more resilient, see Grossman, Helpman, and Lhuillier (2021). See also Miroudot (2020a,b), WTO (2021), and Baldwin and Freeman (2021).

24 The US government's July 2020 contract with Pfizer, for example, stated "The Government agrees that it will not resell any of the deliverables to any third party."

4.2 The international reaction to the US failing to export

Much of the reaction by the trade community to the US government approach was negative. For example, some have referenced the US government "owning" those first 100 million doses of production under such contracts as the same as if it had imposed an export restriction on vaccines.[25] While the contracts did result in *firms* not being allowed to export doses until those initial orders were fulfilled, it is worth exploring the argument against characterizing those contracts as export restrictions. At least in this instance, that is because 100 million doses would not have been available during that time horizon but for the US government investments in advance of regulatory approval.[26] That is, claims of export restrictions ignore the timing of the sunk costs, many of which were paid for by subsidies (at risk) by the US government to accelerate the timetable of production by 4-6 months.

Establishing the right comparison to make is nontrivial. Ideally it would take into consideration the market failures and subsidy policies. Put differently, the US policy decision to invest at risk gave it access to vaccines 4-6 months earlier than it might have otherwise. Thus, a better comparison would be to examine the US export decision 4-6 months after the vaccines had been granted emergency use. However, even that comparison would miss out on the fact that many foreign countries were only able to accelerate their vaccine production by benefiting from US subsidies to R&D, especially the considerable US subsidies that allowed for expedited Phase 3 trials that would not require repeating elsewhere.

4.3 What if the WTO banned all arrangements that did not immediately result in exports?

Suppose the WTO had a rule that prohibited export restrictions and that was interpreted as *de facto* also prohibiting a country from writing an AMC, because the AMC (by definition) resulted in zero exports, at least for an initial period of time while the first orders were being filled to satisfy the government's at-risk investment on capacity.

The biggest concern with such a rule goes back to the impact on firm behavior in the absence of an AMC guaranteeing the government's purchases. Firms bearing all of the risk would likely have meant many delaying sunk investment costs of manufacturing until *after* they had received regulatory authorization for their vaccine; this would have delayed scaling up production, learning by doing, and the delivery of millions of doses by many months.[27] Furthermore, without AMCs, firms may have had to worry about subsequently being held up—that is, government procurement agencies only offering prices high enough to cover the marginal cost of manufacturing and not the costs of research, clinical trials, and setting up a supply chain for the new product in the first place.

Some companies may have taken the risk. Pfizer took on the risk of investment prior to regulatory approval, but its compensation came in the form of a higher price ($19.50 per dose) than other vaccines in the US market, some of which also received grants covering the costs of their clinical trials. Importantly, Pfizer negotiated that contract in July 2020, before completion of its Phase 3 trial (the FDA granted emergency use for its vaccine in December), thus it was not held up on price. Pfizer may have had access to internal financial resources and access to its own facilities to overcome financial problems if its vaccine had failed in Phase 3 trials.

Yet, many of the other vaccine sponsors, even in the United States, may not have had the private resources to take on that risk. Moderna and Novavax had no production facilities of their own. Even Johnson & Johnson and AstraZeneca chose mostly to *outsource* COVID-19 vaccine production to CDMOs rather than use their own US facilities. Convincing CDMOs to invest to convert their plants to produce a new COVID-19 vaccine would have required financing, which may not have been available without government support, given the uncertainty involved before regulators had granted EUA for the vaccines.

Furthermore, India's experience is also suggestive in this light. The failure of the Indian government to offer any subsidies on capacity—it did not subsidize Indian vaccine manufacturers until April 2021—meant Indian firms delayed expanding production. The Serum Institute of India was only able to pre-invest in some capacity in 2020 by relying on its own resources[28] and through funding from CEPI under an agreement to provide doses to COVAX; it subsequently reneged on that agreement when a wave of cases hit India and the Indian government

25 See, for example, Bown and Keynes (2021).
26 The exception was the initial contract in July 2020 signed by Pfizer, which was a procurement contract, and for which the US government took on less financial risk if the Pfizer vaccine was not granted regulatory approval (GAO 2021). Nevertheless, Pfizer's contract with the US still took on an aggressive timetable for regulatory approval and for the initial manufacturing and delivery of 100 million doses, and for which the US government held options. Furthermore, Pfizer ran into trouble acquiring the inputs needed to meet production goals and requested a second US government contract in December 2022, which was a priority-rated contract under the DPA.
27 Firms may have been wary of investing at risk, given the experience of prior pandemics. Evenett et al. (2021) suggest that as the H1N1 pandemic of 2009–2010 waned, some governments pulled funding and certain companies could not recoup the costs of their investments.
28 Jeffrey Gettleman, Indian Billionaires Bet Big on Head Start in Coronavirus Vaccine Race. *New York Times*, August 1, 2020.

imposed implicit export restrictions in the spring of 2021. (In a May 2021 interview with the *Financial Times*, the firm's CEO blamed the Indian government for not pre-ordering doses, stating he had decided against investing in capacity expansion earlier because "there were no orders, we did not think we needed to make more than [1 billion] doses a year."[29]) And other Indian firms, including Biological E., which had licensed the Johnson & Johnson vaccine in August 2020, were not able to expand capacity quickly at all.

Finally, lack of clarity in Europe about who had contracted on capacity (for example, the UK) and who had negotiated procurement contracts on doses (for example, the EU) led to political and legal disputes that could have turned out disastrous. A dispute between the EU and the UK over doses of the AstraZeneca vaccine even resulted in the EU temporarily invoking Article 16 of the Northern Ireland Protocol for a few hours in late January 2021.[30] The EU shutting off exports of vaccines to the UK could have resulted in the UK retaliating by shutting off exports of vaccine inputs needed to manufacture vaccines in the EU—such as lipid nanoparticles essential for the Pfizer-BioNTech vaccine—hurting both sides (Bown and Bollyky 2022, Figure 3).

Additional clarity is needed on these types of subsidies and contracts, in terms of where orders will be placed in a queue. However, a rule designed to stop export restrictions written in a way that would prevent policymakers from contracting on capacity that guarantees demand and shifts risk onto the government (and away from firms) would create additional and potentially bigger problems. It would eliminate an important mechanism needed to incentivize firms to scale up production larger and more quickly—satisfying the public health interest—than on their own profit-maximizing timetables.

4.4 Additional issues

From that perspective, any "export restriction" in the US case was less the result of the US government subsidizing the installation of capacity and committing in advance to purchase all 100 million doses of the initial COVID-19 vaccine production than its subsequent failure to allocate some of those doses internationally after having taken delivery. However, the US government would have needed to write different contracts to allow it to subsequently redistribute doses—for example, as through COVAX—to prioritize global public health needs, and not only the needs of American citizens.[31]

Nevertheless, new concerns could arise if the US government were to have planned to share those initial doses. The US government may not have subsidized as much in 2020 if it was going to subsequently share the doses because it would have captured fewer of the positive externality benefits locally that arose through a more quickly inoculated American population. Smaller US subsidies could have been in the form of smaller contracts to each sponsor (for example, enough initial capacity for only 50 million doses), contracts to fewer vaccine sponsors (for example, three instead of six), or contracts to sponsors granted closer to the FDA's emergency use authorization to reduce financial risk (for example, shortening the at-risk investment window to, say, two months lead time). Smaller initial capacity expansion would have then led to longer queues for other buyers, independent of the US sharing some initial doses. Fewer contracts would have increased the chance that none of the vaccines received regulatory approval—for example, what if the three it had chosen were Sanofi-GSK, Novavax, and AstraZeneca? Either way, in expectation, firms would have been even slower at sinking investments into capacity expansion, and fewer total doses in aggregate would have been delivered.

From this perspective, there were two bigger problems.

As previously noted, one was that other countries with manufacturing facilities mostly failed to provide similar subsidies at risk to convince firms to build capacity earlier and at greater scale.

However, countries without their own manufacturing facilities failed to coordinate with the US government to write at risk, capacity-enhancing contracts to further expand production taking place at plants within the United States.

Suppose all vaccine manufacturing capacity is located in only one country, for example, the United States. Optimal global policy would have been for other countries to collectively write contracts—say, through a multilateral entity like COVAX—with vaccine manufacturers that would guarantee purchases of doses for the commitment that companies invest in additional production capacity at risk, so that they could deliver more doses more quickly. The failure to act collectively meant companies simply allocated buyers to a longer queue and fulfilled orders (and expanded capacity) on their own timelines and according to their own profit-maximizing objectives, and not the global wellbeing.

29 Stephanie Findlay, India's vaccine shortage will last months, biggest manufacturer warns. *Financial Times*, May 2, 2021.
30 George Parker, Jasmine Cameron-Chile, and Michael Peel. 2021. EU pledges vaccine controls will not hit UK supplies. *Financial Times*, January 30.
31 Eventually, in July 2021, the US government did write such a contract with Pfizer ($3.5 billion for 500 million doses) to procure vaccines that would then be allocated to COVAX https://www.hhs.gov/sites/default/files/vaccine-donation-contract-with-pfizer.pdf. However, its initial contract prohibited the US government from selling doses to third parties.

Finally, consider potential contractual limitations on the United States exporting doses that it had procured to third countries, and why this too must be considered in advance. Suppose there were no global contracting arrangement, and so the United States was potentially interested in allocating doses globally from its orders from US facilities, as ultimately played out during COVID-19.

One concern involves whether the foreign country recipient has not waived potential liability for a given vaccine. This raises the question of who would bear the legal liability—the US government or the vaccine company—if there were to be a problem. This issue reportedly held up potential deliveries, including to India of the Pfizer vaccine in the summer of 2021.[32]

A second potential issue is whether allowing for such unexpected exports might inadvertently make matters worse for poorer countries over the long run. For example, Kremer and Glennerster (2004, p. 35) explain what happened in the early 1990s, when American politicians complained about US vaccine companies charging lower prices for children's vaccines allocated to poor countries than they were charging at home. The response of the companies was not to continue to supply vaccines to poor countries and lower the vaccine price in the US market to match the foreign price; doing so would have eroded the profits needed to recoup their R&D costs. Instead, the companies simply stopped submitting bids to UNICEF to provide any vaccine in the poorer foreign market. The implication is that tiered-pricing (international price discrimination) can be welfare-improving. Thus, any unexpected reallocation of supply—via, say, the United States re-selling or donating doses to foreign governments—must take into consideration the broader, long-run implications on incentives for supply availability elsewhere.

Ultimately, in July 2021, the United States did negotiate a contract with Pfizer to buy doses that would then be exported to COVAX for distribution worldwide. The US government paid the equivalent of $7.50 per dose ($3.5 billion for 500 million doses), much less than the $19.50 it paid for doses initially to inoculate Americans signed at risk in July 2020.[33] However, if events had evolved differently (and as they had in the 1990s), political pressure may have resulted in international price discrimination being made more difficult, reducing COVID-19 vaccine availability to poor countries.

4.5 Subsidies that accelerate and expand vaccine production capacity: Implications for the WTO

Why is this an issue for the WTO as opposed to some other international organization?[34] One fundamental reason is because the WTO is not simply a neutral, innocent bystander when it comes to subsidies that will impact industrial production. The WTO's Agreement on Subsidies and Countervailing Measures (SCM) not only exists, but it has a general anti-subsidy bias. While there may be nothing explicit in the SCM Agreement prohibiting subsidies in response to a global health emergency, trade ministers and their staffs are trained in these rules; their intuition can influence domestic policy. Yet, staff operating in vaccine-producing countries were unlikely to contribute usefully to the domestic policymaking process—one that would have benefited from structuring subsidies to accelerate vaccine development and to increase the scale of production capacity and it being made at risk, along the lines outlined in Section 3.

The WTO needs to play a proactive role by offering subsidies guidance and not simply meet such a situation with silence.

The WTO could assist by facilitating agreements—on the accelerated installation of capacity at risk—between vaccine sponsors and a multilateral entity that would also have pre-committed to handle global distribution.[35] Such an approach would internalize many of the externalities on both the demand and supply side and head off many of the subsequent problems that arose in the context of COVID-19.

However, if contracting takes too long, or a multilateral entity lacks sufficient enforcement powers with respect to firms in a domestic contracting environment (as arose in the United States under Defense Production Act [DPA]), or multilateral cooperation is politically impossible, it may be infeasible to coordinate all of these sufficiently quickly.

In the absence of a first-best global subsidy and allocation approach, the world must then account for governments taking on some of the risk by pursuing their own capacity-

32 See Neha Arora and Rupam Jain. "India close to giving indemnity to foreign vaccine makers like Pfizer—sources," Reuters, June 10, 2021.
33 https://www.hhs.gov/sites/default/files/vaccine-donation-contract-with-pfizer.pdf
34 Indeed, CEPI attempted to handle many of the issues raised here during the pandemic. A legitimate question is why an international organization like the WTO is needed.
35 Again, CEPI (and COVAX) developed a framework for much of this, but was not given the financial resources, as well as the political and legal authority to pull it off.

installation subsidies with firms to commit them to install additional production capacity at risk to facilitate the quicker and larger scaling up of production than they would arise in a purely market-driven outcome.

The subsidies needed in response to COVID-19 should have been earlier, focused on capacity expansion, and orders of magnitude larger than those that emerged. Furthermore, it is paramount for small countries and those without their own manufacturing facilities to subsidize to organize collectively—so that firms expand productive capacity overall rather than allocate their individual orders into a queue that they fill on their own timeline with existing capacity.

The WTO should help governments facilitate those subsidies and contracts.

Certainly, there is also a role for the WTO to discourage the use of implicit or explicit export restrictions. However, identifying the difference between a policy that imposes international externalities and one that does not require more information than simply examining data on whether or not exports exist. Again, arguably the suite of US subsidy policies—taken at risk, and to expand and accelerate production capacity—were not what was worrisome. (Paradoxically, the US government purchasing all of the initial doses may have actually generated some international positive externalities by triggering additional capacity expansion elsewhere.) The worrisome US policy was not its vaccine contracts, but its failure to share the output arising under those contracts.

India's suite of policies was quite different and was worrisome. It suddenly imposed export restrictions on the vaccine output of the Serum Institute. In isolation, the decision to prioritize doses toward the Indian population may have been well-founded for public health reasons, given the wave of cases facing India at that moment in early 2021. What was problematic was that someone else—in this case CEPI—had subsidized the production of those COVID-19 vaccine doses at risk, and they were destined for COVAX to be distributed to other low-income countries.

Rules and enforcement procedures are needed to prevent what India did from happening again. India did the opposite of the United States—it failed to plan ahead, and it expropriated the at-risk capacity investment of someone else. Without such rules and enforcement, entities will be discouraged from coordinating the cross-country subsidies that are needed to increase capacity at risk in the presence of cross-border supply chains, especially as described next.

The EU set up an export monitoring system in early 2021 to track the destination of vaccine shipments manufactured in the EU to countries outside of the bloc. In March 2021, Italy actually blocked exports of 250,000 doses of the AstraZeneca vaccine from a Catalent plant in Italy destined for Australia. While this singular action was problematic, it was small in scale. The broader action to set up the export monitoring system was also motivated by the lack of transparency by suppliers and about the queuing of contracts.

Additional transparency is recommended, and that should help reduce uncertainty and limit demands for export restrictions. The use of export restrictions ultimately creates the incentive for firms to invest elsewhere. However, and while export restrictions are not condoned, the larger problem is the lack of coordinated, at-risk public investment on capacity expansion which drove the shortages and highlighted the lack of cooperation.

5 Input Shortages for Vaccine Production During Covid-19

Virtually all of the vaccine sponsors complained about input shortages at the early stages of COVID-19 vaccine production.[36] This included big items, such as a lack of manufacturing facilities and contracting companies with which to partner, as well as shortages of skilled workers to whom the technology could be transferred, and a lack of specialized variable inputs, such as lipid nanoparticles, disposable bioreactor bags, filters, and more (see again Figure 1).[37]

There are numerous contributing explanations for the input shortages. The first and most important was the massive and sudden increase in demand for inputs by numerous vaccine sponsors all seeking to create new production facilities quickly and simultaneously for their brand-new product. A second was a potential concentration of demand into only a select few input providers, given that some vaccine sponsors were seeking to replicate the exact production process across potentially 10 or more different manufacturing plants globally to obtain a consistent drug product (Pall 2021)—see AstraZeneca's supply chains in Figure 5.

5.1 US policy to address input shortages: subsidies and rationing

Suppose that price signals from vaccine manufacturers to input providers—to convince them of the demand surge to scale up production capacity—were either slow, incomplete, or legally incapable of being sent.[38] Or suppose that input-providing companies did not have incentives to invest in additional capacity because it would become unproductive once the pandemic was over and sit idle, preventing the firms from recouping their investment costs. The failure to invest in new capacity meant input providers allocated orders for their inputs to companies in a queue that they would service on their own timetables. The failure of input providers to add capacity would have thus served as a bottleneck that slowed the expansion of downstream vaccine manufacturers.

36 See the vaccine-specific examples and discussion in Bown and Bollyky (2022).
37 Bown and Bollyky (2022) provide an extensive discussion of the various shortages reported by these firms.
38 On the latter, Bown (2022b) describes one of the side effects of the priority-rated contracts the US government wrote with vaccine sponsors under the DPA was that they could demand inputs to fulfill those orders from suppliers at fixed prices. The inability to send higher price signals may have worked as a disincentive for input suppliers to add capacity.

In this environment, there is an incentive for governments to subsidize vaccine input providers, in addition to vaccine manufacturers, through the same sort of push contracts on capacity installation (which generates positive externalities) and not simply the delivery of an input (which generates negative externalities by allocating other buyers to later in the queue). This would certainly apply for capacity into equipment that might be pandemic-specific, in terms of scale.

In 2020, the US government used Operation Warp Speed to also subsidize the additional capacity expansion for some input providers located in the United States. It agreed to push-style contracts to selected companies manufacturing relatively homogeneous inputs, such as glass tubing and vials for fill and finish facilities, as well syringes and needles that would be needed to administer doses of each vaccine (see Table 2).

Subsidizing the expansion of production capacity would prove harder for *specialized* inputs needed by each of the six vaccine candidates contracted under Operation Warp Speed. In October 2020, the US government also subsidized Cytiva—a recent spinoff from GE Healthcare—for $32 million dollars 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."[39] Cytiva was described by US policymakers as "the primary supplier to many of the companies currently working with the U.S. government to develop COVID-19 vaccines."

However, at the time the contract was signed, the US government was unlikely to be aware of the full range of input shortages that would arise, even for US manufacturing plants, given that it would take time for the firms to fully develop their supply chains. Even though the US government got access to knowledge about most of those supply chains—and input-output supplier relationships through the priority-rated contracts it wrote and had to administer under the DPA—it was unlikely to have learned details of Pfizer's input needs, for example, until Pfizer signed its first priority-rated contract under the DPA in December 2020.

In the very short run in 2020, US policymakers had to ration scarce inputs deriving from a number of suppliers, spreading them across a variety of manufacturing facilities (see Figure 8). The rationing itself was apparently assisted by logistics experts from the Department of Defense, one of the government agencies tasked with implementing Operation Warp Speed, which got access to information on supply chain relationships and input needs through the priority-rated contracts signed under the DPA. During this period, for example, the CEO of MilliporeSigma—a major vaccine 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," and that they were collectively forced "to start making trade-offs when you've got limited supply and limited capacity to focus on the need of the moment."[40] Informed rationing would require knowledge about the regulatory status of a particular vaccine candidate—that is, the emergence of new information that a vaccine candidate was unlikely to be authorized by regulators ideally would not have been prioritized for scarce inputs. (However, given that the FDA was independent from Operation Warp Speed officials, it is unclear how efficient even this rationing process could be.) Also note that in the US case, rationing would also be needed because price signals could not be relied upon to allocate inputs since input prices were fixed in the short run for priority-rated contracts signed under the DPA (Bown 2022).

Not only were the COVID-19 vaccine manufacturing supply chains to emerge in 2020-21 cross-border, but some of the critical inputs needed by vaccine manufacturers globally may have only been available from US suppliers. Rather than focus on the input shortage problem, however, companies operating plants in India and Europe alleged the United States' use of the DPA, which was rationing scarce inputs to manufacturers located within the United States, was creating an artificial shortage problem by banning exports from leaving the United States. While an export embargo was subsequently refuted by the data, this episode created unnecessary diplomatic and political problems, and even resulted in French President Emanuel Macron accusing the Biden administration of imposing an export ban on vaccine inputs.[41] Eventually US policymakers began liaising, at least informally, with their counterparts in the European Commission as well as with the Indian government, to ration scarce inputs to some of these foreign manufacturing facilities as well.

These responses to the input shortages revealed at least two fundamental problems. First, the rationing that was taking place in the United States was likely to have been inefficient from a global perspective. For example, the data subsequently revealed the Serum Institute of India was sourcing inputs

39 BARDA. 2020. Trump Administration expands manufacturing capacity with Cytiva for components of COVID-19 vaccines. News Release, October 13.
40 Riley Griffin, "A Cold War-Era Law and Vaccines," Bloomberg, January 2, 2021.
41 See Bown and Rogers (2021), Bollyky and Bown (2021b), and Sam Fleming, Jim Brunsden, Mehreen Khan, Michael Peel, and Guy Chazan. EU leaders confront US over vaccine patent waiver demands. Financial Times, May 8.

during this period from a roster of vaccine supplier companies in the United States that included MilliporeSigma, Thermo Fisher, ABEC, and Sartorius, in addition to Cytiva/Pall (Bown and Rogers 2021). US policymakers were unlikely to have insight into the input needs of foreign manufacturers, some of which may have been producing higher-priority vaccines than some of the ones in the United States.

Second, with this missing information, any US subsidy policy designed to tackle the input shortage problem was likely both too small and incorrectly targeted from a global perspective.[42] Nevertheless, while input shortages were ubiquitous, it is also worth reiterating that there is little evidence that any entities aside from the United States subsidized input capacity expansion. It is possible, though highly unlikely, that this is because input providers were located exclusively in the United States.

Thus, there is a need to incentivize and coordinate subsidies across countries along the full vaccine supply chain. In this case, that would have meant other governments (for example, in Europe and India) subsidizing US input supply companies to expand capacity to get sufficient inputs to their firms quickly.

5.2 Reallocating scare resources upon revelation of new information

During the period of input shortages, there was a role for a secondary market to help redistribute newly freed up inputs in high demand elsewhere. Newly available inputs would be expected to emerge, for example, when a vaccine candidate realized poor Phase 3 results. Many such candidates had been preparing facilities at risk, in advance of regulatory authorization—that is, establishing supply chains and accumulating inputs that would be freed up and could potentially be put to use elsewhere.

For example, in June 2021, CureVac revealed the disappointing results of its Phase 3 trial for its mRNA-based vaccine candidate, freeing up resources to equip a supply chain of multiple CDMOs it had lined up to manufacture 1 billion doses by the end of 2022. Yet, no one took advantage of the opportunity to quickly repurpose those facilities to engage in the manufacturing of other vaccines.[43]

CEPI ultimately created "COVAX Marketplace" to help make such matches for equipment and other variable inputs in July 2021, provided that the firm seeking to acquire the inputs was providing COVID-19 vaccines to COVAX for distribution.[44]

5.3 Input shortages: implications for the WTO

Given the nature of cross-border supply chains, there are four complementary roles for the WTO to play in helping to address the inevitable problem of input shortages that arise for vaccine production during a pandemic.

First, the WTO could be the international organization tasked with helping to diagnose where input shortages will arise. This would require liaising with vaccine manufacturers to survey them and then their input providers in their supply chain (see again Figure 8). The WTO has the capacity to provide a secure platform for sharing and protecting confidential business information. It has done so in the past in the context of WTO litigation—see, for example, the confidential information in the lengthy and politically contentious Boeing-Airbus disputes between the United States and the EU that the WTO Secretariat was trusted to keep secure.

Second, the WTO could be the entity that helps coordinate rationing of scarce inputs to their most beneficial use during the very short run when dire shortages are inevitable.

Third, the WTO could provide the forum for policymakers in key countries agree to coordinate implementing subsidies—including contracting on the capacity expansion of input providers—across the full cross-border supply chain to take advantage of positive externalities and ensure input shortages do not hold back vaccine production.

Fourth, the WTO could work to reallocate resources when some are unexpectedly made available because of newly realized information from Phase 3 trials. CEPI had been doing some of this during COVID-19, but the WTO would be better positioned to make it part of their contribution.

42 In a (non-pandemic) model of trade in specialized inputs and offshoring, Antràs and Staiger (2012) find the lock-in effect results in equilibrium imported inputs being inefficiently low, with subsidies to inputs being the optimal policy.
43 See Bown (2021).
44 CEPI. CEPI launches COVAX Marketplace to match buyers and sellers of critical manufacturing supplies and speed up global access to COVID-19 vaccines through COVAX, July 15, 2021.

During COVID-19, each of these functions was done piecemeal and incompletely. The WTO could be the entity needed to ensure the full suite of policy cooperation happens. For example, incentive compatibility may require compensating a country that gives up scarce inputs (through rationing to facilities located abroad) with guarantees of some of the resulting benefit (a share of the doses manufactured from those scarce inputs). In normal times and for normal goods, this is largely achieved through the price mechanism, markets, and trade. In a pandemic, some of those price incentives were severed and markets disappeared, especially in the very short run, requiring other institutions instead to help intermediate and facilitate those benefits arising through trade.

6 Other Multilateral Policy Issues for Vaccines

Insufficient attention was paid to two substantial problems holding back earlier and larger vaccine production: subsidizing vaccine capacity directly and at risk as well as input shortages. Holding back vaccine production held back vaccine *trade* and thus access for countries that would only acquire doses through imports. Nevertheless, other issues emerged impacting international commercial cooperation and trade.

One was regulatory cooperation. Regulatory oversight is critical for both the clinical trials—ensuring that vaccines given to otherwise healthy people are effective and safe—as well as the production process.

A number of issues arose in light of the COVID-19 experience.

On clinical trials, there was considerable coordination globally between the relevant regulators to help limit the need for redundant clinical trials, especially the lengthy and costly Phase 3 trials. Nevertheless, a number of vaccines were ultimately accepted in some markets but not others; this has implications for output coming from unused supply chains. As examples, take the AstraZeneca and Johnson & Johnson vaccines. The fact that the FDA did not approve the AstraZeneca vaccine for the US market ultimately wasted valuable resources given that a US supply chain had been established at risk to manufacture 200 million doses of the vaccine. In theory, output from that US supply chain could have been used to inoculate people in other countries that had authorized that vaccine for use, even if the United States did not choose it for the American population.[45] India only approved the Johnson & Johnson vaccine in August 2021—it had been approved in the US, the EU, and by the World Health Organization in February and March, respectively—potentially holding back domestic production by Biological E., that had licensed the technology in August 2020.

Second, there are numerous examples confirming the difficulty in manufacturing COVID-19 vaccines and thus the need for regulatory oversight. One was the contamination arising at the Emergent BioSolutions plant impacting US supply chains and severely limiting the output of the Johnson & Johnson (as well as the AstraZeneca) vaccine. Another was that, in January 2021, a fire at the Serum Institute of India—the world's largest vaccine manufacturer—impacted production to such an extent that the company reportedly used it to declare *force majeure* and

45 This example was admittedly complicated by one of the US facilities established to manufacture the vaccine—an Emergent BioSolutions plant in Maryland —failed to follow good manufacturing practices and contaminated doses, forcing the FDA to shut it down for four months. However, if the United States had not had other manufacturing capacity—via the Pfizer and Moderna supply chains—for authorized vaccine supplies available, an open question is whether policymakers may have faced pressure to act more quickly to resolve problems at that plant. Furthermore, the fill and finish capacity reserved for the AstraZeneca vaccine in the US market was also left unused.

get out of contracts to supply doses to Brazil, Morocco, and Saudi Arabia.[46] Administering the Pfizer-BioNTech vaccine in Hong Kong was also temporarily halted when defective vials and packaging were found in vaccines bottled in Germany but transported, stored, and distributed by BioNTech's Chinese partner, Fosun Pharma.[47] Finally, Moderna had to recall COVID-19 doses after stainless steel contaminants were found in vials destined for Japan after being filled and finished at its CDMO partner Rovi's plant in Spain.[48] The implication is that regulatory oversight is needed to ensure the manufacturing process delivers a safe and effective vaccine, and this may have been a (necessary) barrier to entry for firms even had the issue of patent protection allowed for more firm entry into vaccine production.

In addition to geographic concentration, there was also the issue of market concentration. Despite 11.5 billion manufactured doses, these were dominated by relatively few vaccines on the market even by the end of 2021. Early evidence suggests the price implications of this concentration were not enormous—economists have estimated the social value of a course of vaccines to be $5,800, and the social and political pressure managed to keep prices relatively low, at $3–$40 per course. However, the lack of competition meant that firms did not face an incentive to expand production capacity more quickly to prevent "business stealing" from other suppliers.

However, the additional entrance by more firms could have resulted in additional challenges. It would have meant more demand for inputs, potentially further exacerbating the problem of shortages. Finally, there was unused capacity that could have been reallocated but was not (for example, CureVac, Novavax, and so on).

Thus, even eliminating constraints on intellectual property protection, such as might have arisen had patents been waived, as was proposed by India and South Africa, the result could have been the creation of new problems.

Finally, trade facilitation was another important area during the pandemic. The need for cold-chain transportation and storage for the mRNA vaccines of Pfizer-BioNTech and Moderna, in particular, meant trade logistics could have operated as a bottleneck preventing some individuals from being able to access vaccines, this was especially a problem in lower-income countries.

46 Indrani Bagchi, "SII Fails to Deliver, New Delhi's Vaccine Diplomacy Hits Hurdle," Times of India, March 21, 2021.
47 Sui-Lee Wee, Alexandra Stevenson and Tiffany May, "Hong Kong Halts Use of Pfizer-BioNTech Vaccine Over Packaging Defects," *New York Times*, March 24, 2021.
48 Rocky Swift and Carl O'Donnell, "Moderna to recall COVID-19 doses in Japan after stainless steel contaminants found," Reuters, September 1, 2021.

7 Conclusions

By the end of 2021, more than 11 billion doses of COVID-19 vaccines had been manufactured globally. Yet, more international policy cooperation on vaccines and supply chains was needed, and one lesson is the numerous areas for the WTO to play a more active role. It was surely unprepared heading into the pandemic. But some of the WTO's disappointing engagement during the first year of COVID-19 especially may have been due to a leadership vacuum. In May 2020, the WTO Director General (DG) suddenly announced plans to depart the organization that summer, more than a year earlier than the August 2021 expiration of his term.[49] Installing a new DG amid an ongoing pandemic was a challenge in its own right and was further held up for months by an intransigent US administration. Finally, as a member-driven organization, the lack of any positive engagement by one of its major members—the United States—was also likely partially responsible.

To their credit, when the new DG Ngozi Okonjo-Iweala and her new team arrived in February 2021, they prioritized addressing the pandemic and access to COVID-19 vaccines and served to facilitate useful dialogue between the private sector and policymakers. Unfortunately, the world was more than a year into the pandemic by then, already well onto the vaccine delivery path set by policymaker and commercial decisions made much earlier in 2020. By then, it was too late. Thus, the lack of much WTO engagement on a positive agenda in 2020 meant the only policy issue on the docket was a proposed waiver for intellectual property rights protection, a politically divisive item between members, and yet one that was unlikely to have much positive impact in the short term, given the complex and highly sophisticated nature of vaccine production.[50]

The WTO has long been understood as an institution that helps facilitate cooperative policymaking, improving global economic well-being by providing a forum and mechanisms that allow governments to coordinate their actions to minimize their negative international externalities.[51]v In a world now characterized by cross-border supply chains, there was an unmet need to help coordinate WTO member subsidies and contracts to expand vaccine supply chain capacity at risk, as well as to address the inevitable input shortages that arise early in a pandemic. The WTO would have been the logical institution to take on such a role.

49 Bryce Baschuk and Jenny Leonard. Azevedo Stepping Down Early From a WTO Already on the Brink. Bloomberg. May 13, 2020.
50 See Bollyky and Bown (2020b). The only other initiative was the Trade and Health Initiative, a modest proposal highlighted by actions on trade facilitation and addressing export restrictions.
51 See Bagwell and Staiger (1999, 2002) and for evidence, see Bagwell, Bown, and Staiger (2016).

References

Agarwal, Ruchir and Gita Gopinath. 2021. A Proposal to End the COVID-19 Pandemic. IMF Staff Discussion Note 2021/04, May.

Agarwal, Ruchir and Tristan Reed. 2021. How to End the COVID-19 Pandemic by March 2022. World Bank Policy Research Working Paper 9632, April.

Ahuja, Amrita, Susan Athey, Arthur Baker, Eric Budish, Juan Camilo Castillo, Rachel Glennerster, Scott Duke Kominers, Michael Kremer, Jean Lee, Canice Prendergast, Christopher Snyder, Alex Tabarrok, Brandon Joel Tan, and Witold Wiecek. 2021. Preparing for a Pandemic: Accelerating Vaccine Availability. *American Economic Association Papers and Proceedings*, 111: 331-335.

Antràs, Pol and Robert W. Staiger. 2012. Offshoring and the Role of Trade Agreements. *American Economic Review* 102, no. 7: 3140-83.

Athey, Susan, Juan Camilo Castillo, Esha Chaudhuri, Michael Kremer, Alexandre Simoes Gomes, and Christopher M. Snyder. 2022. Expanding Capacity for Vaccines Against Covid-19 and Future Pandemics: A Review of Economic Issues. Dartmouth College working paper, January.

Athey, Susan, Michael Kremer, Christopher Snyder and Alex Tabarrok. 2020. In the Race for a Coronavirus Vaccine, We Must Go Big. Really, Really Big. *The New York Times*, May 4.

Bagwell, Kyle, and Robert W. Staiger. An Economic Theory of GATT. *American Economic Review* 89, no. 1: 215–48.

Bagwell, Kyle, and Robert W. Staiger. 2002. T*he Economics of the World Trading System*. Cambridge, MA: MIT Press.

Bagwell, Kyle, Chad P. Bown, and Robert W. Staiger. 2016. Is the WTO Passé? *Journal of Economic Literature* 54, no. 4: 1125–31.

Baldwin, Richard and Rebecca Freeman. 2021. Risks and global supply chains: What we know and what we need to know. NBER Working Paper No. 29,444, October.

Bollyky, Thomas J. and Chad P. Bown. 2020a. The Tragedy of Vaccine Nationalism: Only Cooperation Can End the Pandemic, *Foreign Affairs* v99, n5 (September/October): 96-109.

Bollyky, Thomas J. and Chad P. Bown. 2020b. Vaccine Nationalism Will Prolong the Pandemic. A Global Problem Calls for Collective Action. *Foreign Affairs*, December 29.

Bollyky, Thomas J. and Chad P. Bown. 2021. The Real Vaccine Procurement Problem: Why America Should Make Its Supply Chain More Transparent. *Foreign Affairs*, June 24.

Bown, Chad P. 2022. COVID-19 vaccine supply chains and the Defense Production Act. PIIE working paper, May.

Bown, Chad P. 2021. Don't let CureVac's COVID-19 vaccine supply chain go to waste. *PIIE Realtime Economic Issues Watch*, August 9.

Bown, Chad P. and Thomas J. Bollyky. 2021. Here's how to get billions of COVID-19 vaccine doses to the world. *PIIE Trade and Investment Policy Watch*, March 18.

Bown, Chad P. and Thomas J. Bollyky. 2022. How COVID-19 vaccine supply chains emerged in the midst of a pandemic. *The World Economy 45*, no. 2: 468-522.

Bown, Chad P. and Soumaya Keynes. 2021. The murky world of export restrictions for COVID-19 vaccines, *Trade Talks*, Podcast episode 152, March 21.

Bown, Chad P. and Chris Rogers. 2021. The US did not ban exports of vaccine supplies. But more help is needed. *PIIE Trade and Investment Policy Watch*, June 8.

Budish, Eric and Christopher Snyder. 2021. Bigger is better when it comes to vaccine production. *Wall Street Journal*, March 17.

Castillo, Juan Camilo, Amrita Ahuja, Susan Athey, Arthur Baker, Eric Budish, Rachel Glennerster, Scott Duke Kominers, Michael Kremer, Greg Larson, Jean Lee, Canice Prendergast, Christopher Snyder, Alex Tabarrok, Brandon Joel Tan, and Witold Wiecek. 2021. Market Design to Accelerate COVID-19 Vaccine Supply. *Science* 371 (6534): 1107-1109.

Cutler, David M. and Lawrence H. Summers. 2020. The COVID-19 Pandemic and the $16 Trillion Virus. *Journal of the American Medical Association* 324: 1495–1496.

Evenett, Simon, Bernard Hoekman, Nadia Rocha, and Michele Ruta. 2021. The Covid-19 Vaccine Production Club: Will Value Chains Temper Nationalism? European University Institute Working Paper, March.

GAO (Government Accountability Office). 2021. COVID-19: Efforts to Increase Vaccine Availability and Perspectives on Initial Implementation. GAO Report to Congressional Addressees GAO-21-443, April.

Grossman, Gene M. Elhanan Helpman and Hugo Lhuillier. 2021. Supply Chain Resilience: Should Policy Promote Diversification or Reshoring? NBER Working Paper No. 29330, October.

Kominers, Scott Duke. 2021. World Can Have Covid Boosters and Its First Doses, Too. Bloomberg, September 28.

Kremer, Michael. 2001a. “Creating Markets for New Vaccines Part I: Rationale,” in Adam B. Jaffe, Josh Lerner, and Scott Stern (eds.) *Innovation Policy and the Economy, Volume 1*, pp. 35–72, Cambridge, MA: MIT Press.

Kremer, Michael. 2001b. “Creating Markets for New Vaccines Part II: Design Issues,” in Adam B. Jaffe, Josh Lerner, and Scott Stern (eds.) *Innovation Policy and the Economy, Volume 1*, pp. 73–118, Cambridge, MA: MIT Press.

Kremer Michael and Rachel Glennerster. 2004. *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases.* Princeton, NJ: Princeton University Press.

Kremer, Michael, Jonathan D. Levin and Christopher M. Snyder. 2020. “Advance Market Commitments: Insights from Theory and Experience,” NBER Working Paper No. 26775, February.

Miroudot, Sébastien. 2020a. Reshaping the policy debate on the implications of COVID-19 for global supply chains. J*ournal of International Business Policy* 3: 430–442.

Miroudot, Sébastien. 2020b. Resilience versus robustness in global value chains: Some policy implications. in Richard E. Baldwin and Simon J. Evenett (eds.), *COVID-19 and Trade Policy: Why Turning Inward Won’t Work*, London, UK: CEPR Press.

Pall. 2021. Supporting Rapid Development with a Standardized Single-Use Manifold and AAV Platform Process. Available at https://www.pall.com/en/biotech/blog/technologies-supporting-covid19-vaccine.html, February 3.

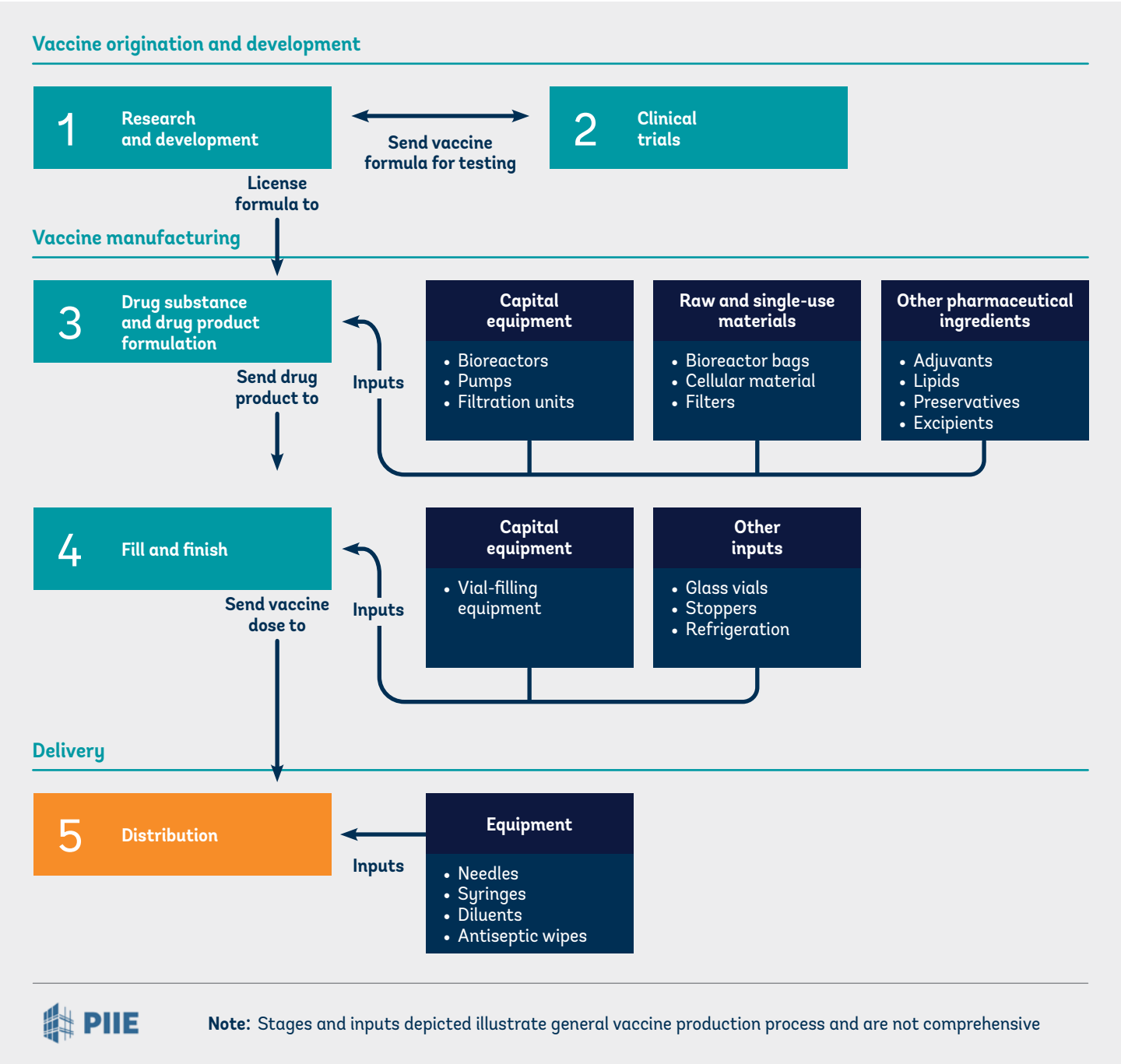
Snyder, Christopher M., Kendall Hoyt, Dimitrios Gouglas, Thomas Johnston, and James Robinson. 2020. Designing Pull Funding for A COVID-19 Vaccine. *Health Affairs* v39 n9: 1633-1642.

WTO. 2021. World Trade Report 2021: Economic resilience and trade. Geneva, World Trade Organization.

WTO-IMF. 2022. WTO-IMF COVID-19 Vaccine Trade Tracker, last accessed January 18.

> > >

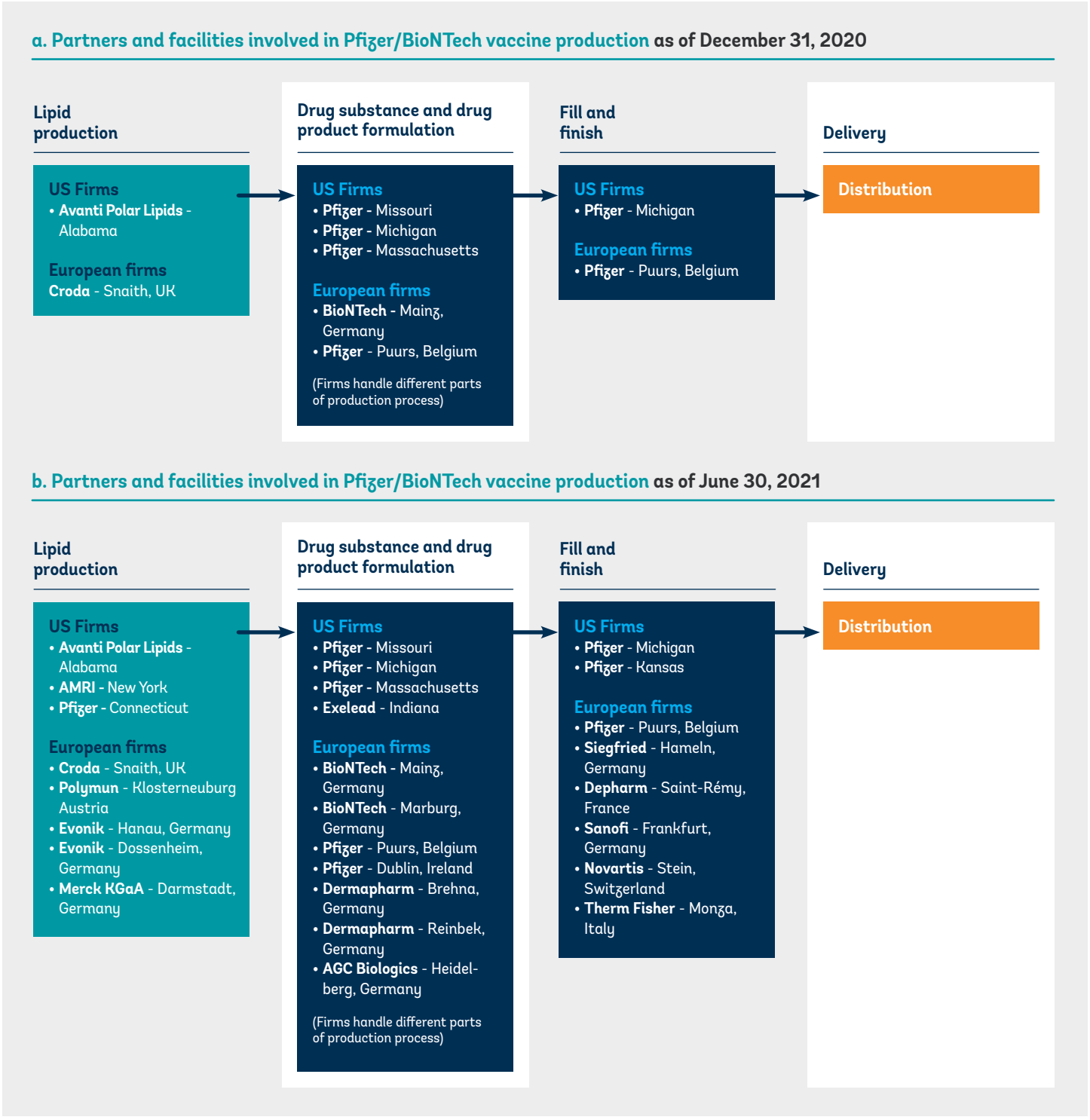
FIGURE 1. The vaccine value chain



Source: Bown and Bollyky (2022, Figure 1).

> > >

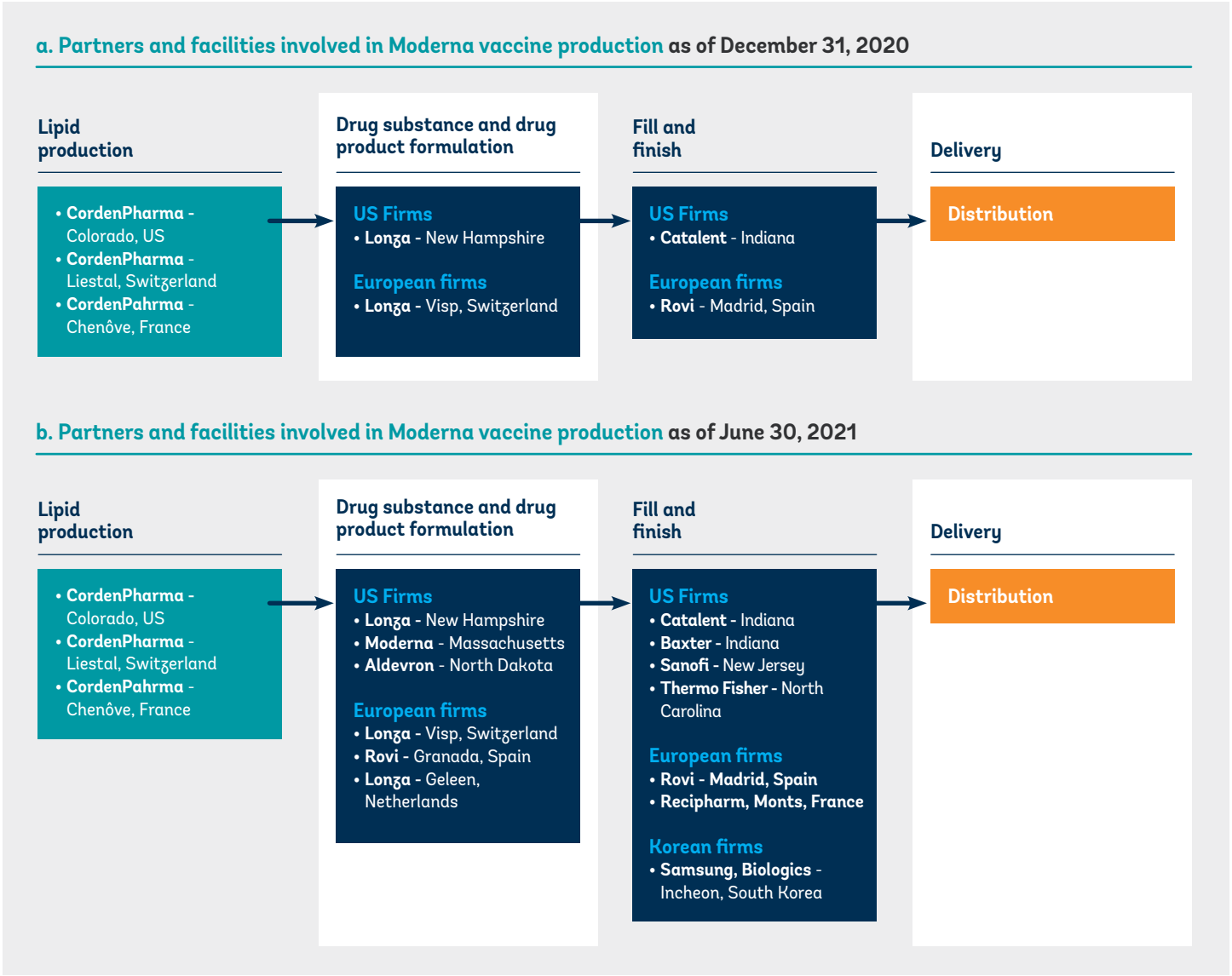
FIGURE 2. The Pfizer-BioNTech COVID-19 vaccine manufacturing supply chain



Source: Bown and Bollyky (2022, Figure 2).

> > >

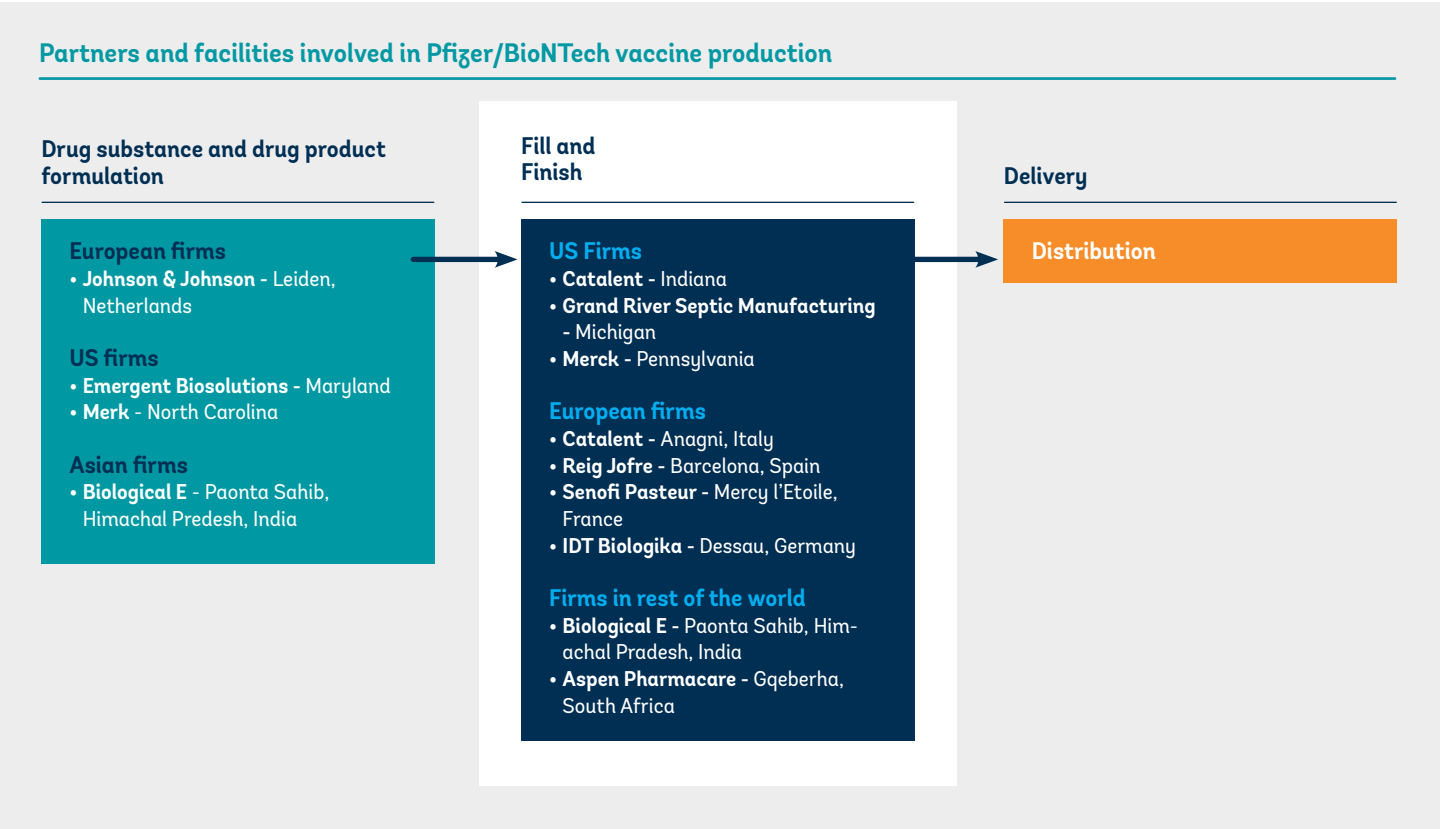
FIGURE 3. Moderna's COVID-19 vaccine manufacturing supply chain



Source: Bown and Bollyky (2022, Figure 2).

> > >

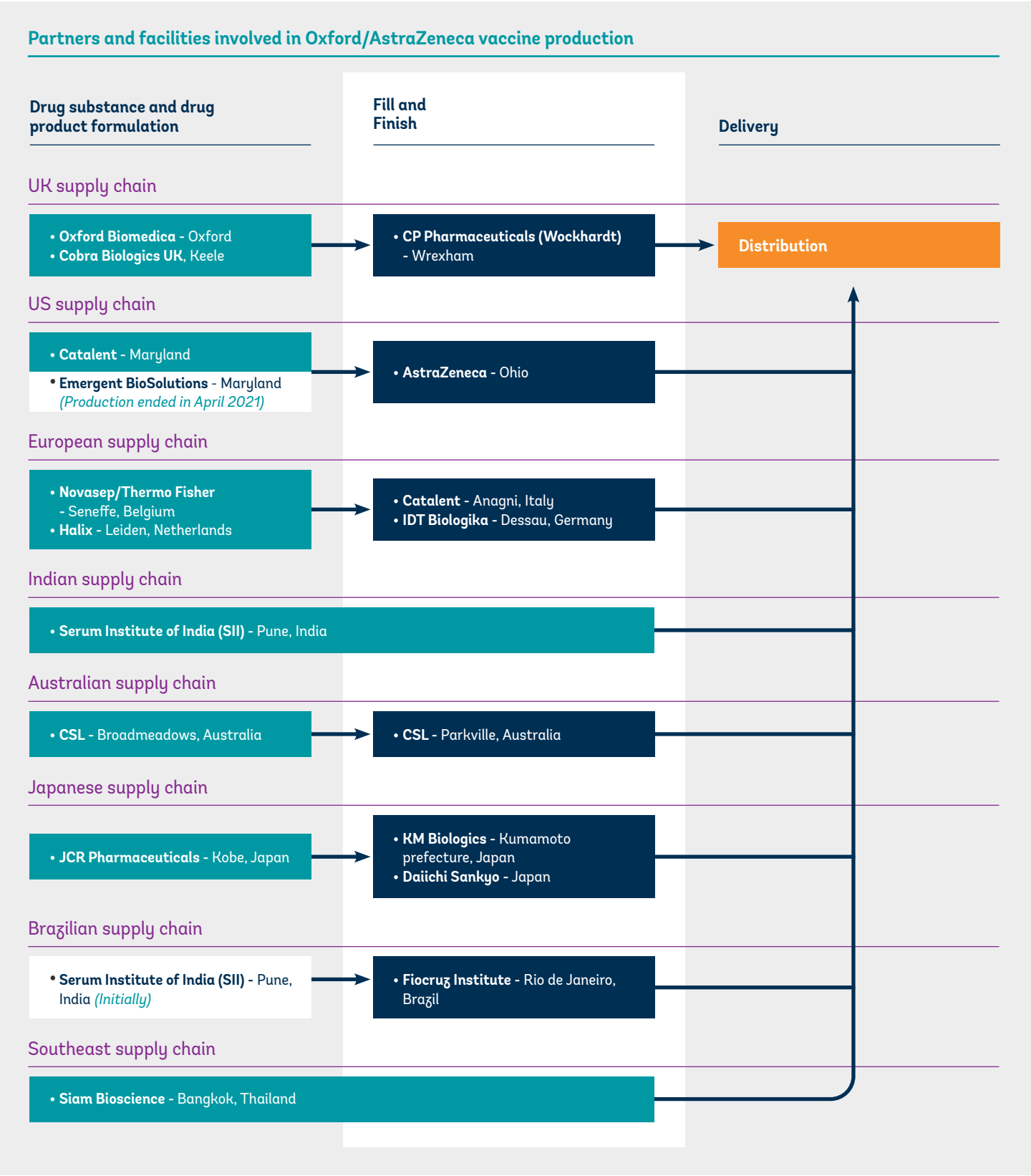
FIGURE 4. Johnson & Johnson's COVID-19 vaccine manufacturing supply chain



Source: Bown and Bollyky (2022, Figure 8).

> > >

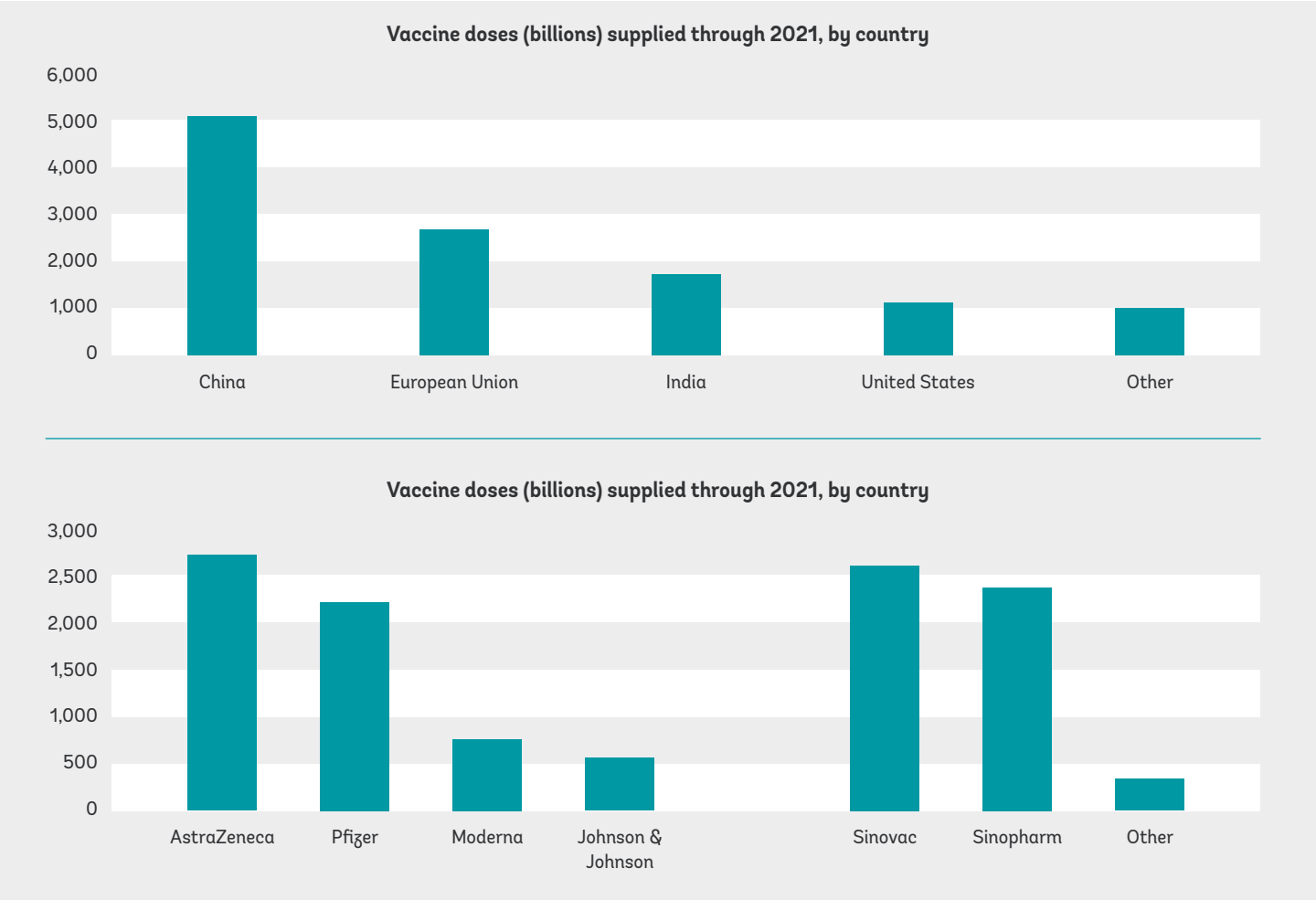
FIGURE 5. AstraZeneca's COVID-19 vaccine manufacturing supply chain



Source: Bown and Bollyky (2022, Figure 8).

> > >

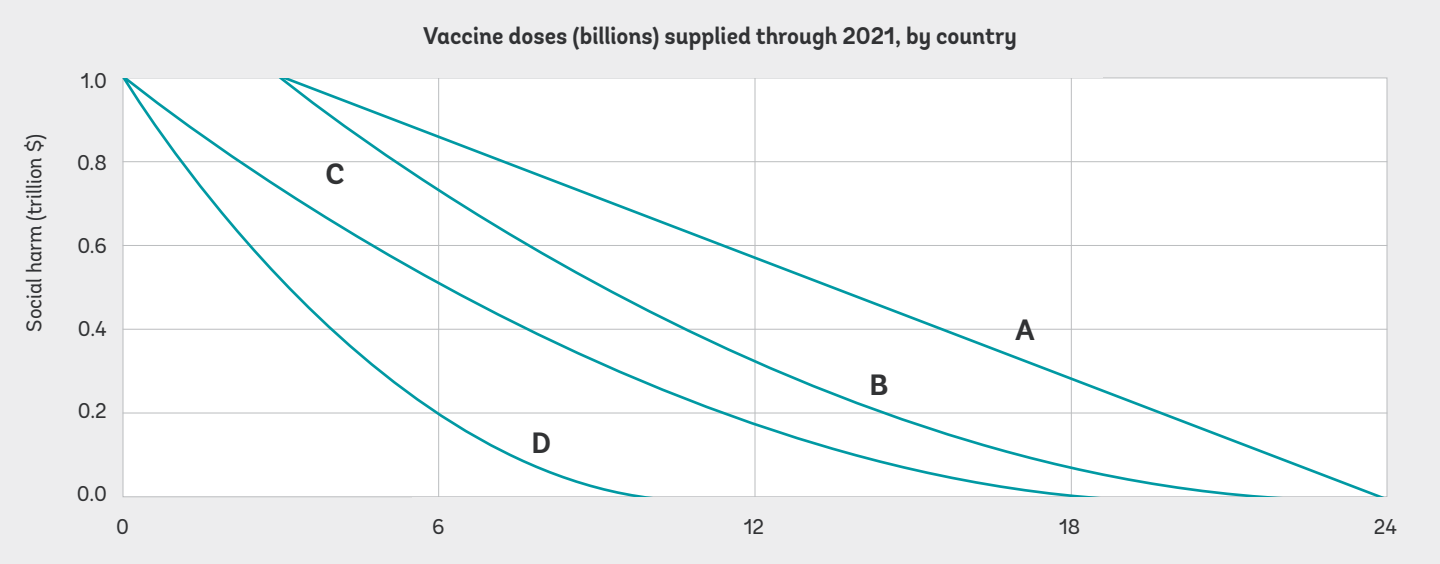
FIGURE 6. COVID-19 vaccine doses supplied by country and by company, through 2021



Source: WTO-IMF COVID-19 Vaccine Trade Tracker, as of December 31, 2021.

> > >

FIGURE 7. Example illustrating benefits from accelerating and expanding vaccine capacity



> > >

FIGURE 8. How to use supply chain transparency to minimize COVID-19 vaccine input shortages

Five policy steps

1 **Survey vaccine production facilities** about their inputs to establish what they need, where they source from, and on what schedule.

2 **Aggregate the information** by input-supplying firm to determine the volume that each firm needs to provide.

3 **Survey each input supplier** to cross-check the data and determine if their existing capacity can meet demand.

4 **Identify input shortages.**

5

Shortages of customized inputs

Short-therm solution:
Increase production at existing facilities, e.g., incentivize addition of second, third, and weekend shifts.

Long-therm 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 suppliers.

Source: Bown and Rogers (2021, Figure 6).

> > >

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
	6	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	Support clinical development and manufacturing
	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 (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

Note: a. Payment to Merck for the collaboration.
Sources: Compiled by the author from Biomedical Advanced Research and Development Authority, 2021, BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio, BARDA's COVID-19 Domestic Manufacturing & Infrastructure Investments, and publicly available firm contracts.

> > >

TABLE 1. **US federal subsidies or contracts to COVID-19 vaccine input suppliers, February 11, 2020–June 30, 2021**

Company	Amount (Millions of dollars)	Date	Task (DPA priority rating)
SiO2 Materials Science	143	June 5, 2020	Establish US-based production for glass tubing and vials
Corning	204	June 5, 2020	Expand capacity for glass tubing and vials
	57	March 23, 2021	
Becton, Dickinson and Co.	42	July 1, 2020	Expand capacity for syringes and needles
Retractable Technologies	54	July 1, 2020	Expand capacity for syringes and needles
Smiths Medical	21	July 11, 2020	Expand capacity for syringes and needles
Cytiva	32	October 13, 2020	Expand capacity for cellular material, mixer bags, and bioreactors
ApiJect Systems	590a	November 19, 2020	Expand capacity for prefilled, single-dose injectors
Meissner Filtration Products	13	April 1, 2021	Expand capacity for filtration products for vaccine manufacturing

a. Loan to finance 75 percent of project's capital costs.

Sources: Bown and Bollyky (2022, Table 4), compiled 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*; and* US International Development Finance Corporation.


WORLD BANK GROUP