

THE BROOKINGS INSTITUTION
FALK AUDITORIUM
SECURING PHARMACEUTICAL SUPPLY CHAINS
WASHINGTON, D.C.
Wednesday, March 15, 2023

WELCOME AND INTRODUCTION:

MARTA E. WOSÍNSKA (Moderator)
Visiting Fellow, Economic Studies, USC-Brookings Schaeffer Initiative for Health Policy

PARTNERS IN EXCELLENCE: TRANSATLANTIC COOPERATION FOR A MORE RESILIENT
PHARMACEUTICAL SUPPLY CHAIN:

HADJA LAHBIB
Minister of Foreign Affairs, European Affairs, Foreign Trade and the Federal Cultural Institutions,
Kingdom of Belgium

PANEL DISCUSSION:

MARTA E. WOSÍNSKA (Moderator)
Visiting Fellow, Economic Studies, USC-Brookings Schaeffer Initiative for Health Policy

TANYA ALCORN
Senior Vice President, Biotech and Sterile Injectables Operations Lead, Pfizer

TOM BOLLYKY
Senior Fellow for Global Health, Economics, and Development and Director of the Global Health
Program, Council on Foreign Relations

LIZ JURINKA
Managing Director, The Vistria Group
Senior Policy Fellow, Tobin Center for Economic Policy, Yale University

* * * * *

WOSIŃSKA: Good morning, everyone. I would like to welcome you to our event, “Securing Pharmaceutical Supply Chains,” which is sponsored by the USC-Brookings Schaeffer Initiative for Health Policy. My name is Marta Wosińska, and I'm a visiting fellow with the Schaeffer Initiative. Later in the program, we will hear from a distinguished panel of experts on what can be done to improve supply chain resilience in the face of global challenges. But first, we are pleased to welcome Minister Hadja Lahbib of the United Kingdom of Belgium for remarks on Belgium's role in securing pharmaceutical supply chains. Hadja Lahbib is the minister of foreign affairs, European affairs and foreign trade for the kingdom of Belgium. Prior to her experience as minister of foreign affairs, she was a presenter of daily news and cultural, social and political programs for the French-speaking public broadcaster RTBF. She is a journalist and documentary producer by training and spent many years reporting on the Middle East. Without further ado, we welcome Minister Hadja Lahbib to the stage.

LAHBIB: Thank you, thank you very much. Marta, let me say, first of all, how I'm happy, glad to be here. It's wonderful to be here in this institution and tell you that this is my first visit to Washington, D.C., in my capacity as the foreign minister of Belgium and getting to address an event at the Brookings Institution, one of the most prestigious think tank worldwide, is a great honor for me. And the subject that was selected is wonderful opportunity to explain, by the way, how Belgium represents and stands for in the world through the prism of one of our top industries. Now, you may be wondering maybe how pills, syrups, tablets, capsules, [inaudible] drops could be the yardstick by which a country, a country's economic health can be measured.

Let's take two of the most important global events of this last years. First, of course, the COVID-19 pandemic has provided us many lessons for our societies, from the importance of maintaining resilient healthcare systems, to the crucial role of life science in research and development. It is indeed a partnership between government research centers and pharmaceutical companies that led to the COVID-19 vaccines. Even more relevant for us today, transatlantic cooperation was at the basis of the development of these vaccines. The breakthrough came from the partnership between a German biotech research firm, Biontech, a large U.S. pharmaceutical company, Pfizer, and its production and distribution facilities in Belgium. And I am grateful that Tanya Alcorn of Pfizer is here today on the panel, and I am sure she will give you more details on how all that came possible. The development of these vaccines and their distributions around the world could not have taken place without our two countries. I believe it's fair to say this shared commitment to make it quickly and safely available has saved many, many lives.

And I want to be clear, the fact that Belgium played such a crucial role in the production of the Pfizer vaccine, but also in Johnson & Johnson and AstraZeneca as well as in treatments, is not the result of chance. For years, we have developed an ecosystem which connects academia, research institutions, incubator, SMEs and industry leaders. This ecosystem is reinforced by the presence of leading biopharmaceutical companies, many of them American like Pfizer, Johnson and Johnson and hundreds of biotech firms. The Belgian federal government has made it a priority to reinforce our country's position as the health and biotech clusters. Belgium is the country where spending on biopharmaceutical R&D per capita is the highest in all of all over Europe. We have also built a favorable environment for clinic trials as well as in-patent applications. We are the European leader in these two domains, and we are proud of it. This is truly a Belgo-American story. Pharmaceutical occupying the dominant position in all bilateral trade relationship with more than a half of our exports and imports from the U.S. being either pharmaceuticals or medical supplies. Recent announcement of a new large investment only reinforced this trend. I can point, for example, at the recent €1.2 billion announcement of Pfizer for its facilities in Bruges, [inaudible] a small town in Flanders, in Belgium, which will provide a large-scale platform for the development of new vaccines. I also want to see to the Bill and Melinda Gates Foundation's investment in the breakthrough biotech universals. The newly inaugurated production unit in Belgium will not only manufacture an average of 150 million affordable vaccine dose per years, so 150 million affordable vaccine dose per year, but also shared their know-how with partners in Africa like Senegal or Guinea-- Ghana, sorry. These are examples, but there is a larger picture. We remain much more invested in each other than one could think. Even before some Western companies start shoring

from China, the stock of U.S. investment in the Kingdom of Belgium was already much larger, and it remains so today.

The second global event that is reinforcing our relation is, of course, the war in Ukraine. More than any other events, this conflict has demonstrated the need for Western countries to develop and protect a strategic autonomy that goes much further than military defense. Access to resources and strategic supply chains have become as important either from semiconductor to natural gas, from batteries to fertilizers. The EU has recognized the need to rely on its own capabilities in such vital sectors. To this end, several initiatives have been launched to boost our strategic economy. Let's take a few examples, if you may. In the field of semiconductors, the EU has recognized that this is a key technology that underpins many of modern systems in all sectors, from smartphones to electric features to artificial intelligence. However, the EU currently relies heavily on imports from third country for semiconductors, particularly from Asia. To address this, the European Union has launched the European Chips Act, which aims to double the EU's share of global semiconductor productions to 20% by 2030. This involves investing in research and development, supporting the construction of new semiconductor manufacturing facilities in Europe and promoting public-private partnerships. Similarly, in the fields of pharmaceutical, the EU is taking steps to reduce its reliance on imports from third country and promote the development of new medicines within Europe. One key initiative is the creation of a European Health Emergency Preparedness and Response Authority, which will be tasked with accelerating development, manufacturing and deployment of medical responses to pandemic and other health crisis. Belgium is well-placed to have a central role in those efforts. I am convinced that it is also via transatlantic cooperation that we can advance towards this objective in a mutual benefit way.

And this is not about new protectionism. We have nothing to gain from that, but it is also deepening this relation, all relation with all close partners. There are several ways to do that. We can work together to promote global standards and norms in these sectors. We should support emerging technologies such as in artificial intelligence or in biotechnology. We should collaborate to address regulatory buyers, maintain a level playing field for companies in strategic sectors, and ensure that they operate in a fair and transparent manner. We should cooperate on the new threats, such as, of course, cyberattacks. The EU and U.S. Trade and Technology Council is crucial in this regard and I can assure of my country commitment to this initiative. My meeting this week in Washington are also an opportunity to reinforce this message. I had and will have the occasion to discuss pieces of US legislation like, of course, the IRA and the CHIPS Act, which raises issues of concern between Europe and USA. And these concerns should be addressed, of course, as eloquently put by Alan Wolfe in a recent Peterson Institute piece, "global leadership requires more than defense arrangements and a strong domestic economy. It requires fostering a world in which economic relations with other countries are considering in making policy choices." And it would be a pity if also, in Wolfe's words, America's global leaderships being undercut by US economy policies. Ladies and gentlemen, the pandemic and the conflict in Ukraine have reshaped our worlds and taken together. It is a kind of shock therapy for our economies and our supply chains. We have to draw the right lesson, among this lesson, a stronger co-operation among allies is paramount. This was the key to develop the vaccines which were so crucial in the management of the pandemic. And it will also be the key to meet all other challenges that are on our plate right now, from climate change to energy security. I thank you very much.

WOSIŃSKA Alright, so if I may ask the panelists to join me for a conversation. Excellent. So to those watching online, you can submit questions on Twitter by tweeting to @BrookingsEcon using the hashtag #RxSupplyChains, or by emailing events@brookings.edu and some online registrants have already submitted some questions, we'll get to them later. We'll have an opportunity to answer some questions towards the end. Also, for those in the audience, you should have received a note card when you entered. If you haven't, there should be some available in the back of the room and staff will be collecting them. You can write down your questions throughout our discussion and then we will then take some questions towards the end. So without further ado, let me introduce our esteemed panel.

First seated next to me is Tanya Alcorn. She is senior vice president for sterile injectables and biotech operations at Pfizer. She started her career at Pfizer almost two decades ago and now has oversight of 20 manufacturing plants globally, which produce more than 200 medicines and vaccines and more than 4 billion doses each year. Tanya and her team worked to distribute Pfizer's COVID-19 vaccine and COVID-19 oral treatment, distributing over 3 billion doses of the vaccine all over the globe.

Next is Tom Bollyky, who is director of the Global Health Program and senior fellow for Global Health Economics and Development at the Council of Foreign Relations. He is also an adjunct professor of law at Georgetown University and a senior consultant to the Coalition of Epidemic Preparedness Innovations, or CEPI on trade-related matters associated with vaccine manufacturing, supply chains and technology transfer. Prior to coming to the Council for Foreign Relations, Bollyky served in a variety of positions in the U.S. government, most recently at the office of the U.S. Trade Representative.

And last but not least, is Liz Jurinka, who is the managing director for health care policy at The Vistria Group and senior policy fellow at Yale's Tobin Center for Economic Policy. Prior to joining Vistria in Yale, Liz was at the White House as a special assistant to the President and before then the Chief Health Advisor for Chairman Wyden and the Senate Finance Committee. So welcome, thank you for joining. So let me actually begin with you, Tanya. The minister alluded several times to the concept of resilient supply chains. And I actually really liked her metaphor of shock therapy in that. Could you elaborate on the concept? What does it mean for supply chains, specifically pharmaceutical supply chains, to be resilient?

ALCORN: Great, thank you and thank you, Marta, for the question. And it's really great to be here. So, yeah, I can give a perspective from the manufacturing side relative to how we think at Pfizer around resiliency. And I think there's probably not a greater example of that than our work on the COVID-19 vaccine, which really there's three main elements that went into how we thought about creating what was a brand new supply chain for a brand new technology writer and are on a technology platform, and understanding that we were going to need to manufacture more doses than we ever had before and do it at an enormous scale with an ultra cold, -70 degree vaccine, which was not a common infrastructure, you know, out there in vaccines. And so we thought about it in three ways. One, you know, we leverage our global supply chain. You know, we have, Pfizer has a little over 35 manufacturing sites around the world, and we didn't use one of them. We used several of them. We built in redundancy across the supply chain for the parts of the supply chain that we manufactured. And then the elements around our partners, we partnered with over 80 different suppliers that fed into, we have 280 materials that feed into the manufacture of the vaccine, right, and so it's not just about our supply chain, it's the resiliency in our partners' supply chain that supply us the critical materials that we need. So we really, I would say leveraged scale and we leveraged redundancy in those supplier network and redundancy within our own supply chain. And it was really because of the global nature of how we developed the supply chain that we were able to scale as quickly as we did.

I think the second piece was around efficiency. So we were really thoughtful around how we kind of ran the supply chain and we mapped out every minute of every day of every, you know, hour relative to, like, what happened from the start of manufacturing to the time that that vaccine dose was available for patients. And when we started off, it took us about 100 days from making the batch to having it available for patients, and we quickly reduced that by 50%. And we think about that as a resiliency. When you have an efficient supply chain that, you know, product flows and doesn't sit, that creates a level of resiliency. And I would say the third element was around the partnership that, you know, Minister Lahbib mentioned. We relied on trust in partnership with governments to allow our goods to flow. You know, Minister Lahbib mentioned our facility in Belgium, and we have a very proud and long-standing history with manufacturing in Belgium. But as an example, although the vaccine, the drug product was made in Belgium, actually, we had to ship several samples to the US to specialized labs to test them from a quality testing perspective. So again, not one country could do it alone. We had to ship samples and that ability for us to, you know, free flow of goods, including samples, across the Atlantic, was so important to that efficiency

in the supply chain. And so, you know, what is probably the most paramount is that ability for manufacturers to be able to move product freely and for governments to, and as Minister Lahbib mentioned, governments to work together versus the export restrictions we saw happened that actually slowed us down, unfortunately. And so our ability to for, you know, governments to work with manufacturers and then governments to work with each other is probably the most important element that we've learned that creates a resilient supply chain.

WOSIŃSKA: That's really helpful. Tanya, can I just follow up a little bit? So you spoke about a particular type of a shock, which is, you know, the pandemic basically is an incredible demand increase, right? But there are other types of shocks where you actually have a supply disruption. Can you just briefly talk to us, to what extent those kinds of, how do you think about resilience in those terms? And is it in any way different? And in what ways is it similar?

ALCORN: Yeah, I mean, as a manufacturing organization, we are constantly assessing risk and resiliency. And so we're assessing risk whether it's, you know, war like we've seen in Ukraine or natural disasters. So we think about risks in a lot of different ways, and we are constantly looking at opportunities to mitigate risk. And we do it again through scale, so through redundancy and suppliers, through, you know, inventory management that we have. And again, not relying on one supplier in one country and we really, I'll say, diversify our supply chain. For us, diversification is key. And then building a trust relationship with those suppliers and then with the governments to allow that free flow of material. So I would say regardless of kind of the risk, obviously the shock that came with the pandemic was just the scale of what we needed to do. And then some of the behaviors that we saw kind of was, you know, contrary to what we needed and we saw some of those export restrictions, so that was a bit of a shock for us because that's not what we had normally seen, right? So I think that's a learning lesson for us, is we can't go back to that. We need to allow that free flow of goods to keep us strong.

WOSIŃSKA: Thanks Tanya. So, Tom, you have spent a lot of time working on the policy side of the COVID-19 pandemic. Can you tell us what have we learned from that experience? So it was following up on just what Tanya said.

BOLLYKY: Great. Well, first of all, thank you so much for convening us. It's nice to be back at Brookings and have this opportunity to speak with all of you. So I think there's a good news story to the pandemic that's been underreported. And the good news story is that within the first two years, that's after vaccines became authorized and publicly available, we saw 11 and a half billion doses exported within that time, there were substantial volumes of inputs and finished products moving across borders during that time without interruption. That's remarkable. The annual production of vaccine doses prior to the pandemic was roughly around 5 billion on average. So this gives you a sense of the scale of production and the scale of what moved across borders to take a parochial perspective. Looking at the United States within the first three months of the vaccine becoming authorized for expanded use, the US produced 100 million doses. That is three times as fast as Europe over the same time period and much faster than other countries. So really a remarkable resilience and production story there. Intergovernmental institutions, whether it's the World Trade Organization, the World Bank, regulatory agencies, national governments, in many cases worked together to facilitate that trade, facilitate that investment, and to reduce regulatory barriers to getting products authorized for expanded use. But, and this is a significant but, there is a substantial imposition of export restrictions, and more than two thirds of countries impose export restrictions on essential medical products during the pandemic. The vast majority of them were longer than three months in duration, many of them over a year. Few of them, relatively few of them weren't notified to the WTO, according to WTO rules. And in many cases, that slowed the production by discouraging investment in cross-border supply chains and also just delayed the arrival of doses. And that had practical consequences after the expanded, authorization for expanded use of the vaccines, the highest death rates in the world were for countries that had the least access to vaccines. So it mattered. That leads to, in my view, really three major lessons of the pandemic that I think are worth taking into account on these supply chain issues moving forward. The first, of course, is around export restrictions, that this is a fundamental hurdle to resiliency and responding to pandemics in the future that production requires, depends, on the

cross-border movement of goods, services and investment. And restrictions on that prevent our ability to respond in a health crisis. There are opportunities to address this. Unfortunately, we missed a bit of one in the last WTO ministerial where I think we could have addressed these issues more productively. But there is meant to be a process ahead of the next one to be reviewing this in the WTO committee level and maybe generating some lessons there that can inform what we can do in the future. Second lesson. One of the reasons why the US was able to produce so much so soon or better than its peers is that it coordinated, not just finished products, it coordinated inputs into those vaccines and subsidized quite heavily in contrast to a lot of other nations. It did that through, on the coordination side and the investment side of Operation Warp Speed, but also by relying on the Defense Production Act to get visibility into the supply chain and that made a difference in this case. The story of the pandemic is not too much government intervention. In many cases, it's too little in terms of what we might have done to boost along the supply chain. The last fundamental lesson, I think, of the pandemic, which may not seem like a big change, but it is a big one for those of us in global health, is it established that pandemics are potentially profitable. And that is different than our response to, for instance, Ebola in the 2014 to 2016 epidemic in West Africa, or Zika, where it was hard to get companies to invest in countermeasures to address those processes. Some of the products in that address this current pandemic are among the most profitable pharmaceutical products in history. The good news from that is that will encourage more investment and, the space and more entrants. The challenge of that is many of the things I think people are proposing around trying to facilitate access in the future will be that much more complicated to negotiate in an environment where the potential profits involved are much larger. So let me stop there.

WOSIŃSKA: Thank you. Thank you, Tom. So, Liz, you have so much experience in the political sphere and, you know, to stay on the topic of COVID, this has been a very politicized pandemic. And so what does this politicization really imply for our ability to prepare for future pandemics?

JURINKA: So, Marta, thank you. I want to echo my colleagues in saying it's a privilege to be here at Brookings with such an esteemed panel and opening remarks from the foreign minister. I guess in some ways it's also a pleasure to be the Monday morning quarterback coming off of a government stint. So I do want to re-emphasize that, you know, my thoughts are my own, especially coming after two years of the White House, some time on the Finance Committee. I think the question is a good one. COVID has been politicized after, you know, the duration of this pandemic. I don't know that it was in the beginning and I think that speaks to the fact that in crisis, there are a lot of instances, this being an example of people coming together to say "what are we going to do to address this and how quickly can we move"? I remember being in Congress at the time, the first, I think, request for funds that came up to respond to this new virus that people were hearing about. I think it was around \$8 billion. And at the time, that was an extraordinary amount of money. And then several weeks later, that number multiplied by several fold, and then that was, you know, followed by even more funding for even more research, even more development, and then even more local response, need for local response. So we have kind of that story, and then this amazing story of Pfizer, of Moderna, of AstraZeneca coming together. But then we have a different story as this as the pandemic moved on. We have the vaccine. People wanted to give it the vaccine. People needed to figure out how to get the vaccine. And members of Congress are calling the administration saying, "where can I get the vaccine? Where can I get my tests? I'm very nervous and very scared". But politics also is local. And I think as we saw over time, different areas of the country were responding differently to the pandemic. And as time moved on, this need for more vaccines and the need for more testing, regardless of the policy and public health implications that I think we all knew to be true, also began to change. The reason why I kind of put that in the background is the idea of resiliency, and the idea of what is required to keep the supply chain going and active became harder the more the public didn't see the pandemic as something so instrumental in affecting their own individual experience. And so I remember towards the end of my time in the White House, as folks will recall, the president included in budget requests, continues to include in different requests, money for pandemic response. And there was a waning, let's call it, of interest, even when it came to things like keeping supply chain, or keeping supply lines for tests warm so that in the event that we had another variant or had another spike, we could

get back and supply those tests if necessary. We weren't able to do that, right? And so even though the pandemic has fundamentally, I think, changed our lives, in some ways, we talk about these lost years on a variety of levels. I have kids at home, I imagine other people also understand what that's like very, very personally. It has had an impact on whether or not the public understands what it means to have a resilient supply chain. And is the public willing, through taxpayer dollars and their elected officials, to continue to invest in what is required to be able to move on a dime, whether it's on a pandemic like we just saw with COVID or on a significant disruption, like, for example, baby formula. Right? The government in that moment stepped in, the president literally authorized flights carrying formula from other countries to get and respond to that need. But again, that's movement in a crisis. And I think it is really hard generally for policymakers, in a bipartisan way, to really go above and beyond, to always be prepared for the unknown when, again, it isn't necessarily hitting home immediately. So I will stop with that, see if there's any facts that's cause for further discussion.

WOSIŃSKA: Well, so, Liz, actually, let me let me follow up. Tanya alluded to other types of risks, right? So COVID and pandemic preparedness is one thing that we need to be thinking about but there are other risks that Tanya alluded to. One of the risks that we hear about are geopolitical concerns, right, you read the headlines. So, you know, as we're moving away from the pandemic and that's sort of waning from the radar screen for politicians, to what extent is resilience of supply chains, in particular in the context of geopolitical risks on the radar screen and, other than radar screen, is there money behind it?

JURINKA: I think, look, but the timing is really interesting also, because obviously the president's setting up his budget. People are talking about, you know, how we're going to end up funding the government. We royally, I should say, not that we, in that old hat of mine, and the debt limit and all these things so spending is very, very much on top of mind, I think, for people, especially in Washington. The other point to your, the other thing I'll say to your point, Marta, is this kind of overarching theme of what is going on with China and what is going on now geopolitically with Russia in the war in Ukraine. It's another good example of of, you know, as the as the foreign minister was talking about, the CHIPS and Sciences Act, there was such a huge movement and interest in semiconductors and investing in that supply chain for our kind of global competitiveness, right, with these other countries, with these huge countries and actors. Interestingly enough, and we had a conversation about this last week, the interest in semiconductors and the interest in our intelligence and the interest in getting ahead in those in those capacities with these other countries on semiconductors, on some of these other things does seem to be different than the discussion related to pharma and, you know, to state maybe the obvious, but to state also the elephant in the room, pharma does have an interesting relationship within the United States and policymakers. Yes, we have this idea and reality, right, that pharmaceutical manufacturers and innovators are truly creating therapies that are life-changing. There's no question. There is also a real concern by the American public about cost and access and whether or not you can have a therapy that can change your life. Does that make a difference if you can't afford it? And so there's this really interesting tension between those two things, and that's on the branded side, right? We have not really talked about the generic side, the resiliency and the kind of redundancies that Tanya was talking about on the generic side are different, right? They are, in fact, different. And yet, I think because of this relationship, whether it's the political relationship and people's again, take on the industry generally or not, that distinction between resiliency of these two types of products, even within a potentially political industry, not by not on purpose, but as a result of maybe people's perception of pricing practices makes this more complicated, I think, than, you know, the CHIPS and Sciences Act and some of the other investment in DARPA and our defense and our intelligence community.

WOSIŃSKA: Yeah, actually, I think it's worthwhile for us to explore a little bit to what extent there is a role for onshoring, but before, I wanted to, especially if funds are limited, right, but before I turn to that question, I wanted to ask you, Tanya, so you spoke, you know, the minister spoke about the footprint that you have in Europe. And, you know, Pfizer has facilities across the globe. From your perspective as a manufacturer, how do you think about where to locate?

ALCORN: Yeah, it's a great question, and kind of building on what, you know, some of Liz's points as well. I mean, first of all, you know, we have done tremendous investments across the globe in our manufacturing footprint. In the U.S. alone, from a capability, capacity, and infrastructure, we've invested over \$8 billion since 2017, right? And that investment's important, and the policies that enable the private sector to invest and allow that innovation to flourish is important. So we think a lot about when we're investing in different countries, the prerequisites that help us, you know, make sure that our investment is safe and that we're able to innovate and that's in those countries and then globally supply both with, you know, supply locally in the country, then globally supply out of the country. As a guiding principle, when we think about how to design a very resilient manufacturing network, we think global sites and we think scale. So we have a lot of large sites located all over the world. We have outside predominantly Europe in U.S., but we you know, we have sites all over, and we try to leverage scale. We're all about leveraging scale. So, you know, big global sites that can mass produce medicines and lifesaving, you know, medicines and vaccines, and then therefore, we rely on, you know, the country in which we operate to allow, you know, free movement of goods to then globally allow access to, you know, the hundreds of countries that are out there. But, you know, we're always assessing. Our goal is access, you know, that every patient has access to any of our medicines. That is ultimately the goal. And so we are all in favor of any strategy that allows more access to our medicines. So we are always assessing, okay, should we build another site or should we, you know, in a certain country? And I think the one thing we've learned is, you know, the economic health is so tied to the public health, right? So you have a healthy population, you have a thriving economy, right? So for us, when we think about where to localize, it's about some of the points I mentioned. So, you know, we would, you know, partner with governments to make sure that our investment is protected, that are the IP that we're going to have within that country is recognized and protected, that there is strong regulatory guidance that leverages international standards. So we have, you know, seamless regulatory review processes that the, you know, the governments are willing to, you know, to partner with us on R&D development. And then the last point, which I keep bringing up is, is that free movement of goods out of the country as well. So those are some of the things that we think about when we think about where we can best localize to expand access.

WOSIŃSKA: So actually, maybe I will turn to you, Tom, to talk about this. I mean, so, Tanya, you know, spoke about diversification and then we'll come back to onshoring for a little bit. So in your universe, that's called trade, right? So can you talk to us, you know, what is the administration doing in this space right now or what could they be doing to sort of promote a lot of what Tanya has described is really critical to the, you know, her company's ability to operate in an efficient way.

BOLLYKY: Great. So this is an interesting manifestation of the politics you heard before, I think, in that there has been substantial efforts around, not to jump ahead to our onshore in conversation, but there has been substantial efforts around creating domestic production in the pandemic of essential medical supplies. There have been multiple executive orders from the president calling for studies in this regard, there were large purchases during the pandemic of test therapies, vaccines from domestic sources. There has been the creation of a defense, Title III Defense Production Act facility through HHS to invest in future domestic production as a way of creating that resilience. What you have not seen as robust of an effort on is on the diversification of global supplies to create that resiliency. There's been some talk about it so nearshoring or friend shoring, depending on the term you like, the idea of locating some production in friendly countries as a way of being more resilient in the future, but not a lot that is actually happened to put that into effect. You want to point to some positive signs. There was recently a mutual recognition agreement concluded with Switzerland by the FDA. This is not, this has been in the works for quite some time, so it is not just a COVID initiative, but that might create more flexibilities, too, to address supply shortages of different products in the future. There have been some conversations organized by, for instance, the State Department around supply chain resilience with other countries, but not a lot that has actually moved forward to result in cooperative agreements to bring that into effect. Most notably, I think there was a tremendous missed opportunity around the last World Trade Organization ministerial, and I mentioned this before, but it's worth going into greater detail. There was a pandemic declaration negotiated. There was some early signs that this might

include some disciplines on the use of export restrictions, at least for products that are destined for humanitarian mechanisms. That was ultimately walked back to broad principles, and we didn't get as much at that moment, too, to address this issue, again, this is hugely important because cross-border movement is fundamental. There's no future diversification of manufacturing globally without cross-border movement of goods. Even a country like the U.S., even a storied company like Pfizer can't produce everything domestically. We have to rely on international sources of that. That's only going to be more so for small pharmaceutical markets, where they're going to have to rely on cross-border production. And this failure to act in a way that we can create some predictable rules of what's going to apply in a crisis so that people can make those investments and assure those goods in the future is going to be a real problem. So we're not seeing as much, I'm sad to say, on the trade side as I would like.

ALCORN: Can I just add maybe just a key stat I want to reiterate, because we talk a lot about, you know, the investments we made in Europe and in the U.S. to enable more vaccine doses ever made in one year than, you know, history. We, in order to make those vaccines, we needed, you know, hundreds of materials from, you know, over 80 suppliers that were located in about 20 different countries to allow that those materials to flow into Europe and the U.S. So that's why this whole idea, of like, of onshoring maybe makes us feel better, but it's not really the answer, right, and I think that's what Tom was alluding to. You know, having incentives, agreements that incentivize governments to play together, you know, in a fair way to allow that trust and that free movement of goods in open trade is really the way you get to resiliency, not trying to bring everything into one country because one country can't, you know, can't solve it all.

WOSIŃSKA: Yeah so let's talk, I mean, so, Liz, you mentioned, you know, that the reality of potentially funding onshoring might be somewhat limited, but let's think about, you know, is there a case for onshoring? How do we think about onshoring and--

JURINKA: Yeah I mean it's a, it's not really a trick question, I know Marta, but it feels a little bit like a trick question. I mean, as I'm listening to this, I'm taken by the fact that we really, we continue to talk about COVID and of course, we continue to talk about COVID because we can't escape COVID. And the fact that we've had this lived experience over these last several years. But that was a multinational global response, having affected quite literally the globe, right? We needed to respond. The United States also wanted to make sure that we were helping countries that were not able to necessarily do what we were doing here, right? And so there was a multinational not only to assist and aid other countries, but figure out what we as the United States could do for the over 300 million people that live here domestically. But that is a little bit different also than a disruption that is not caused by a pandemic. And I think that's a little bit of a different, a different dynamic and potentially something that onshoring, to the extent that it is going to be helpful, could be helpful with. Tom mentioned various executive orders, the administration put out an executive order about, you know, biopharmaceutical supply chain last fall, OSTP had a comment period for folks, for folks, it's very, you know, we're all family here I guess, for people to respond by the beginning of January related to the \$2 billion that the administration said they wanted to reallocate to determine how to better, you know, create a type of biopharmaceutical response. Again, you know, the administration had \$20 billion in pandemic response, ten and a half of that going through Asper. Again, those are for some type of public health emergency. But we do see disruptions related to lack of API or sterile facilities, I think, you know, Marta and her colleagues actually have written a great piece on resiliency in the pharmaceutical space that folks should check out in health affairs in January of this year. And in it, it speaks to the fact that, you know, the FDA says 78% of API is not in this country. And so it doesn't take a global pandemic for people to feel the impact of this if something domestically goes awry, right? In those moments, we again see Congress and the administration working quickly and closely together in 2012, President Obama signed a bill that was meant to address shortages. We saw another one in 2020. Senator Collins led that in the Senate and I believe with Senator Casey and Congressman Peters in the House to expand the notification of manufacturers to the FDA in a kind of confidential and safe way, if you will, to make sure that before a shortage happens, the FDA and others can step in. GAO, this last week, put out a report on advanced manufacturing and technology, you know, related to, you know, printing, right? And very, and where are we in terms of that I.T. modernization, and I think the spoiler alert is

we're not as far along as we might like to be. I don't think, though, to this point about money, there's never going to be or rather people are going to want to spend more probably than others are willing to spend. And so then the question is, what do you do with the money that is actually, you know, provided or resourced? I think that's where you get into kind of whether it's efficiencies of scale, or data sharing, or technology or, you know, efficient use within the programs themselves. Last thing I guess I'll say, and I know Tom, I can tell Tom wants to talk about this. What we saw in COVID was a learning curve that even lawmakers and policymakers were up against in terms of where money goes and how does it flow and who works together? And you had people behind the scenes in the administration, in all various departments, working around the clock to figure out how to facilitate money being able to go where it was most needed. And there are some barriers to that even within our own, you know, our own government, right, our own departments about where money can be transferred and not. And rightfully so, potentially, Congress doesn't necessarily want to sign a blank check and not have some level of accountability of where those dollars are being used. So, yes, it is complex, but I think hopefully there are folks thinking through, whether it's in the private sector and innovating on different ways of being more efficient and resilient. And also for lessons learned on the administrative side to figure out how could we have done this a little bit better so that when something else inevitably happens, not maybe a pandemic, but a disruption, you know, people can respond to that much faster. Tom, Go, please, go ahead.

BOLLYKY: Great. So the only thing, I completely agree with those points, I do think it's important, though, I just want to be clear that this is not a matter of focusing on global sources of production at the absence of doing anything domestically, they're largely two buckets, or at least I think of it, things you can do to address supply constraints in a crisis. There are things, investments to be made to increase supply, and then there are investments to be made to find ways of satisfying demand otherwise. So on the increasing supply, this might be creating a warm manufacturing base. This might be investing in reshoring or building a more robust stockpile. All of that is going to cost money. It's going to cost money either through taxpayer resources, so funding that the government gives out to make that a possibility, or through higher prices for the products that are ultimately produced, because they're being produced in an environment where the economic incentives may not otherwise support that manufacturing to occur. There's also a number of things you can do on the demand side that are worth investing in domestically. So for instance, on PPE, the idea of creating more reusable PPE as investing in different products, standardization of inputs, this big issue in vaccines where so much of it is bespoke, what can we do to try to create more resilience in? All that costs money, both to invest in the innovation, but also to convince people to redo their supply chains, and for that we have to look at more low cost measures to make that feasible, because this, the United States, unfortunately, it's not just a matter of post-COVID that we have a lousy reputation for sustaining investments in resilience. Epidemic, pandemic, crisis after crisis, we have invested in these spaces and then had those investments dissipate. So we have to look at manufacturing innovations where we can and investing in ways where we can get imports from abroad to try to address shortfalls. So it really has to be a combination. But unfortunately, we have a terrible history of sustaining it in terms of investing in that preparedness or resilience domestically.

WOSIŃSKA: I wanted to pick up on something, Tanya, you said earlier, and I am now missing the statistic. How many different pieces go into a vaccine? How many different?

ALCORN: So for the COVID vaccine, we had over, about 280 different materials that went into manufacturing of the vaccine across about 80 suppliers sourced from about 20 different countries.

WOSIŃSKA: Which is really incredible. I mean, there's the saying that a chain is as strong as its weakest link, right? So a question kind of related to onshoring, a lot of this onshoring discussion has been around API. So let's say we identify, we prioritize which APIs we onshore. And then what? Have we minimized the geopolitical risk?

ALCORN: I mean, not really, right? Because there's starting materials that are needed to produce the API. I mean, you know, Pfizer has actually one of, our largest API facility in our Pfizer

global network is in Kalamazoo, Michigan. So we domestically produce a lot of API here, and we have brought in some starting materials. And I think one thing to keep in mind is there is an added infrastructure that goes around API manufacturing that's very different than, I'll say your classic drug product manufacturing. And as you start to want to bring in more key starting materials, you know, there's a large environmental management and control, so there's a large infrastructure around the chemicals that you're bringing in and producing in those facilities and ensuring that you have proper environmental health and safety controls is another added cost that goes into the idea of bringing more, you know, in-house and onshoring, and ultimately you're not going to solve, you're not really solving it. Again, you're maybe making it as, you know, making ourselves feel better, but there is so many starting materials. There are hundreds of starting materials that go into an API and you're not going to be able to insource all those starting materials. So again, the importance of, you know, and now I'm a broken record, we have many suppliers that we source raw materials from and starting materials from around the world. So we don't put our eggs all in one basket in one country. We diversify across different suppliers, we have redundancy in suppliers, and we'd rather create that trustful partnership with suppliers versus trying to do everything ourselves. We can't do everything ourselves, just not it's not feasible. It's not practical.

WOSIŃSKA: Okay. Okay. I will now turn towards questions from the audience. So I will ask if you have written down a comment, please raise your hand and share it with, in the meantime, I will take a couple of questions that were submitted in advance of this of our event. So first question is, "which products or categories of products do you think are most vulnerable to supply chain disruptions in the U.S. in the coming years and why"? Liz, maybe.

JURINKA: Yeah, I think, I think that this is a hard one, right? This is a, we didn't know, I think if, I used to always say that my crystal ball was cloudy at best at any given time, so it's hard to predict what exactly it is that we're going to need. I do think it goes back to this conversation and maybe one, we haven't really been touched on this essential medicines list. And what is it that the FDA is looking at and how are they categorizing or how are they how are they looking at what needs to be on that list? That list is also intended to respond to a pandemic or some type of huge crisis. But I think, again, to the extent that there is a shortage of saline, to the extent that there is a shortage of amoxicillin for your child that has an ear infection, you know, speaking for myself. We're seeing access to those seemingly, you know, household products ebb and flow in terms of shortage and so I think, thinking through what does that mean again, for kind of domestic need absent a pandemic is also going to be important. I don't know that we have an answer to that either. But I also do think that, you know, again, kind of to this point, COVID does seem to have overshadowed this discussion. But at some point, perhaps, it kind of bleeds into a different discussion about what it means to be ready for even something unintentionally created, like a disruption in a manufacturing plant or something of that nature. So, I don't know.

WOSIŃSKA: I mean, if you look at the statistics from the FDA about where we have had shortages, it tends to be generic, sterile injectables. You know, saline is a great example, or cancer for your, for cancer drugs that are old, old products. So these haven't gone away. We've been dealing with them for more than a decade. So probably those won't go away. Okay. Another question is, "many governments in the developing world felt that they were left behind in the pandemic, which is why they're hoping to build to more vaccine making capacity at home. How do you respond to those concerns"? I think this is a good question for both Tanya and Tom. So maybe, Tanya, I'll start with you.

ALCORN: Yeah, thanks, Marta. I mean, I mentioned earlier that, you know, we support any effort to increase access of Pfizer medicines or all medicines and vaccines to patients, especially those in developing countries. What we learned and have learned through our experience in, you know, working with these developing nations is, you know, putting a plant in the country is not really the answer. It may make us feel better, but it's not really the answer. What we found is really the primary, and I think one of the primary barriers is infrastructure, right? So, you know, the infrastructure that surrounds the, you know, storage, distribution, administration of all vaccines and medicines, we found to be, you know, more of the barrier. And we, you know, we've partnered with the COVAX facility, actually one of the largest partners with the COVAX facility, and we've done,

you know, donation agreements and we've actually, you know, we, our supply of our vaccine to the COVAX facility that works to provide access to these developing countries, we represent 30% of that supply. So, you know, we are all in. But what we've learned is it's not enough to just, you know, provide access to our vaccine. If there's no way for the actual patient in a village in Africa to actually receive it. So that infrastructure, like the building of that infrastructure and that health care system is, I think, the most important thing. And we've done a few a few things, so, you know, one example I'll mention before passing it to Tom is, you know, an example of how we're trying to increase access is a partnership with Zipline. So Zipline is a company that has drone delivery. And again, when we started to work with these developing nations trying to increase access to the vaccine, again, we very quickly learned, you know, there was not the roads, there's no storage, they have no temperature-controlled storage and they had no way to access, you know, into these remote villages. So we partnered and expanded our partnership with Zipline, and we created a packaging that allowed our vaccine to, you know, be drone shipped and dropped into villages. And that's how we expanded access. And it was really successful versus if we built a plant in now in the country, it still wouldn't have solved the fundamental access question and we've done a few other partnerships, again, aimed at improving infrastructure, and we've actually lent Pfizer expertise in-country to do that. So in our kind of opinion, that's really the biggest priority to expand access in developing nations.

BOLLYKY: Great. So I'll say a few things. The first is that I, you know, it hasn't escaped governments awareness globally that the countries that receive vaccine doses first are, by and large the same ones that made them. And I think for many low and middle-income countries, this has been a searing experience in terms of those delays in getting vaccines at a point where there was demand domestically to administer them. That is from the broader conversations being had now about global health and how do we make ourselves safer collectively from future pandemics. That is the first and last thing you hear from low and middle-income countries, is what are we going to do to address that shortcoming? I think we have to be responsive to that. The challenge with that is that whether you're looking at countries' specific approaches or regional approaches, they're going to have to overcome a number of significant hurdles. One is this issue, again about the ability to have cross-border supply chains, because particularly in small markets, there is absolutely no way. I mean, the U.S. can't do it. You're not going to do it in a country or region where there's very little manufacturing now, there is no way to build any of that without having some confidence that those supply chains can be cross-border. The second is, what is the market plan to support this manufacturing, expanded manufacturing in peacetime, between crises, and what are the routine products that are going to be made. There, particularly post-pandemic was a proliferation of manufacturing platforms targeting mRNA vaccines. We know how to make one mRNA vaccine. I mean, for one disease. This idea that we could make it for a variety of things that we have yet to discover and make it on a regular basis is, we're not doing people favors by investing in that and allowing that to persist. There has to be a market plan that supports this overall. There has been heavy conversation around intellectual property barriers to this manufacturing occurring, not enough on market plans, what sustains this in the long run, what the supply chains are, how this gets financed moving forward. And I worry a lot that high-income country governments are investing in this space without having enough conversations around those other issues and prioritization in a way that countries that are building these vaccine manufacturing platforms now when they fail, will not thank us for. So I worry a lot about that.

WOSIŃSKA: So actually, there's a related question that just came here from the audience that I think picks up on some of the things that both you and Tanya and Tom just have said. So that Foreign Minister Lahbib mentioned deepening of relations with close partners. What efforts do you see companies and governments doing to deepen these relations among trusted close partners? So how, you know, when you talk about, to your remarks just right now about how US government is thinking about its partners and what does it mean to have a good relationship? Just either Tom or you, Tanya or Liz.

ALCORN: I mean, from a manufacturing lens, it's I mean, it's agreements across governments that incentivize that free trade, you know, open borders, which I know everyone would agree on when we're not in a pandemic or we're not in a crisis or we're not in a war or a

natural disaster or pick the shock that that that hits us because sometimes bad behavior comes out in those in those moments, right? So agreements that incentivize, but, you know, across governments, you know, maintaining those free open trade. And then from a private sector perspective, the investments that we make, making sure that our, the IP is protected in those countries and then continuing to allow, you know, partnerships that allow us to feel that innovation.

WOSIŃSKA: Tom?

BOLLYKY: No, I would, I would, on the, obviously having confidence in one another. I mean, you saw relatively few export restrictions being imposed by the U.S. against European nations or vice versa. And the reason why is that there's dependence. We were making stuff that they need. They were making stuff that we need. And from that standpoint, there's reciprocity in a trade person fundamentally. So reciprocity matters in terms of spurring cooperation. One of the things I worry a lot about this push for onshoring or proliferation of manufacturing platforms is it goes against that reciprocity. And from that sense, it sort of undermines the international cooperation that's going to inevitably be necessary in a crisis. So I do think having the arrangements set up where you create an enabling environment for mutually beneficial relationships across the production of essential medical supplies is going to be important.

WOSIŃSKA: So actually, let me follow up before I take one other question here. The minister also alluded to regulatory harmonization, and I wanted to ask you, she didn't really elaborate on that, I wonder whether this is something you could speak to and what role that plays. So one is trade, right, between governments, but this seems to be a different level of coordination or agreements.

ALCORN: Yeah, I mean, imagine in a world that a lot of the manufacturing, pharmaceutical manufacturing, you know, the world that we live in today is, that we have, you know, every country, you know, has a lot of their own regulatory hurdles and regulatory requirements and regulatory standards. So in the U.S., we have to meet FDA standards, which are similar but a little different than EMA standards. And then, you know, you have every country kind of has their board of health and, you know, perhaps sometimes different regulatory requirements. So it gets complicated for a manufacturer, and actually slows us down and it doesn't make it easy for us to move material around when every country is coming up with their own regulatory approval requirements. So the idea of just having, like, an international standard would simplify and improve the resiliency, right, and speed, it would improve the speed in which we can get products approved. Because you would have, then, one global standard that every company would need to meet for a vaccine or a sterile injectable or a tablet or whatever it may be, versus each country kind of coming up with it on their own and then we need to kind of have different filing requirements. So I think that is such an important need to simplify and create, you know, a smoother supply chain.

WOSIŃSKA: And we're talking about somewhat different players. So on the trade side, it would be U.S. trade representative, but what you're describing is really the FDA and the counterparts for the FDA. Okay. One other question is, "what is the best approach for investment in an ecosystem to ensure both private participation and innovation, but also affordability"? So.

JURINKA: It's another panel that [inaudible]. No, and I think it's an interesting question, right? So there has to be a need, we are not, it's, I mean, my mind goes to so many places because in some ways, this speaks to again, I'm thinking through what happened in COVID and the response that many members of Congress had based on an expectation of what the Defense Production Act allowed, you know, government to do, right, versus, potentially what it does. And so there was this idea, and I think that there was, in not from an ideological place necessarily, although maybe in some cases, but this interest of saying, well, if a manufacturer can't do this fast enough, we can just go in and do it ourselves. Well, that doesn't happen, you know, the United States does not have, the NIH does not have NIH branded manufacturing, you know, owned and operated facilities, that's not, that's not really how it works, and so as we're not compelling, you don't have like compulsory licensing, if you will, within our own domestic ecosystem, that that partnership has to exist. The tension with that, going back full circle. I'll just, as a statement of fact, write that the

committee, the health committee in the Senate is going to have the CEO of Moderna come up and testify about the pricing of the vaccine. I believe it's next week, I think. And whether that is a good hearing or not, is not, I'm not here to comment on that, but I think it's more of a reflection of what happens when federal funding does go in and facilitate investment or invest in the possibility of a response for the public. And then eventually we know the public health emergency is going away and there is an additional dollars of the feds to go in and purchase more vaccine. Eventually these products go commercial and then what happens? And so we're going to see that. Tune in to that hearing. I believe it's next week to see what that tension actually looks like played out, I think, on C-SPAN, as you, as, I hope you all do. But, I mean, it's a good question, I think it's one that's not going to be answered in full today or probably for a while. But again, there are, I think, members and policymakers and folks such as Tanya and Tom and others that are tuning in here, to the extent that this is important and this investment over time is important and there are domestic manufacturing facilities that are being used, those workers, right, or those companies should be telling their members of Congress, this is, clearly I'm a former staffer. Tell your member of Congress this is important to you to actually fund through an appropriations process, because those companies and those buildings and facilities are already here. The other part about this is that building a new facility is not easy, right? So even if we were to start today having all of these facilities such that everything we've talked about up until now is ignored, that doesn't happen overnight. We wouldn't necessarily see the benefit of that investment immediately, right? Having said that, we could probably do a better job using the facilities that we already have, right? And not, and you know, be, again, more efficient with the resources that we currently have control over.

WOSIŃSKA You know, I'm listening to you. I'm a policy person, so when I see a question like this, I want to propose a set of policies to answer this. And this is why it's great to have Liz here, because Liz is like, okay, and then there's politics. [Inaudible].

JURINKA: After this, we could have Schoolhouse Rock.

WOSIŃSKA: So we are about to wrap up maybe with just really like 30 seconds from each one of you. What would you like to leave the audience with? Tanya. That's good. Let's start this way, Tanya. 30 seconds.

ALCORN: 30 seconds. Listen, first of all, thank you for having me here. It was great, great discussion with this great panel. Yeah, I mean, maybe just to conclude with, you know, again, Pfizer as representing the industry, we are all about getting access to as many patients to our medicines, whether it's essential medicines, generic medicines or innovative vaccines. And the way that we do that is through trust, partnership and through scale. Not one country can do it alone. You need many countries, many partners. We need private sector and politics and governments all playing nicely together. So thank you.

WOSIŃSKA: Tom.

BOLLYKY: Great. I'll just use my 30 seconds first to thank Brookings for hosting this, but also to float something we haven't really talked about before, which is transparency. A big issue around government interventions to address supply shortages in a crisis is having increased transparency into those and then the supply chain. So we saw companies and suppliers sitting on critical inputs in this crisis because it wasn't clear where the needs were and how to address them. We also saw a lot of lack of transparency around how the DPA was used, so that other governments blame the US for supply shortages that weren't actually related to what we were reading because we weren't very clear about where and how we're using the DPA. So one thing we need to establish out of this crisis is this coordination and transparency around how we intervene and ensuring well-functioning supply chains.

JURINKA: And I guess I'll say again, thank you. Thank you, Marta, thank you to the foreign minister. I think the lessons learned from the last few years I think are going to continue. We're going to continue to learn about them and hopefully improve upon them. I think to end on a positive note, you know, a remark, it was remarkable that I think the United States did as well as it did,

right? And that we have come out on this other side. It's very, very difficult. This is very, very hard. It takes people working together. And I also think that, again, I'll, I will come back to this notion of politics is local. People are very, very interested in having a solution when they need it as fast as possible. People are very, very, and we understand why, right? No one wants to be told that something that is so obviously, that should be so obviously available to them is not, and so to get ahead of that does take planning and it does take transparent efforts. And unfortunately, those long term projects are sometimes the least interesting to people when there is, when there are other crises that kind of intervene in the meantime. So I think that coordination and partnership, both with the private sector and with government and with international governments, is going to continue to be incredibly important moving forward. And until then, you know, we'll see what this conversation looks like a few years from now. Marta, when you have everyone back. Did it work or did it not?

WOSIŃSKA: Yeah we'll have to do a redo. So with that, I would like to thank our esteemed panelists for participating for this rich discussion and Minister Lahbib for her opening remarks. I also wanted to express my gratitude to the Brookings event staff, to Megan and Caitlin, the facility staff, the AV staff, for all of their work on this event. A recording of this event will be available on the events page and on YouTube, and you can stay engaged with our ongoing work on pharmaceutical supply chains and subscribe to the Schaeffer Initiative newsletter at Brookings.edu. So with that, thank you very much.