Center for Strategic and International Studies

TRANSCRIPT

Event

"Summit on Resilient U.S. Medical Supply Chains"

DATE

Monday, June 16, 2025 at 2:00 p.m. ET

FEATURING

Andy Boyer
EVP and Chief Commercial Officer, Amneal Pharmaceuticals

Stephen Colvill
Assistant Research Director, Duke-Margolis Institute for Health Policy, Duke University

Joseph Grogan
Former Director, White House Domestic Policy Council; Chairman of the Board, Paragon Health Institute; and Nonresident Senior Scholar, USC Schaeffer Institute

Erez Israeli
Chief Executive Officer, Dr. Reddy's Laboratories

Janine Pallone
President, Strategic Global Sourcing, Cencora

Heather Zenk
President, U.S. Supply Chain, Cencora

Senator Todd Young (R-IN)
U.S. Senator for Indiana

CSIS EXPERTS

Richard Burr
Co-Chair, CSIS Bipartisan Alliance for Global Health Security; Former U.S. Senator (R-NC); and Principal Policy Advisor and Chair, Health Policy Strategic Consulting Practice, DLA Piper

Enoh T. Ebong
President, Global Development Department, CSIS

Navin Girishankar
President, Economic Security and Technology Department, CSIS

Philip Luck
Director, Economics Program and Scholl Chair in International Business, CSIS

J. Stephen Morrison
Senior Vice President and Director, Global Health Policy Center, CSIS

Transcript By
Superior Transcriptions LLC
www.superiortranscriptions.com

Enoh T. Ebong: Hello and good afternoon. A very, very warm welcome to you all. Thank you for joining us here in the room and online for our Summit on Resilient U.S. Medical Supply Chains, with a particular focus on generic medicines.

My name is Enoh Ebong, and I recently joined CSIS as president for the Global Development Department. I am delighted to be here today to open our discussion on how national, economic, and health security intersect around the issue of delivering medicines to Americans.

Our summit today is hosted by the CSIS Bipartisan Alliance for Global Health Security, co-chaired by former Senator Richard Burr and Dr. Julie Gerberding, who is right here, in partnership, of course, with Cencora.

I actually would like to start with thank-yous because we wouldn't be here at all without the people that I am about to name. I want to start out, of course, through our partnership with Cencora. We are so proud to bring together the wealth of expertise represented on our panels today. We are especially grateful to David Senior, Beth Mitchell, Gabe Weissman, Lauren Esposito, and many others from Cencora who have collaborated with us to put on this program along with our partners Joe Grogan and Eric Miranda.

I also have to thank Steve. Steve, thank you for your extraordinary leadership.

And I'd also like to particularly mention Michaela Simoneau, who has, I think, taken the laboring of bringing us all together; Sophia Hirshfield; and Caitlin Noe, among others from the Global Health Policy Center.

And our production team, thank you. You know who you are.

And our conferencing staff, without whom we couldn't gather and convene so successfully.

So grateful thanks to our panelists for joining us in particular.

I do want to mention that we are very pleased to be joined by Navin Girishankar and Phil Luck from our Economic Security and Technology Department. At CSIS, we are committed to leveraging the expertise across our departments to host discussions like this focusing on how human well-being, economic prosperity, and technology all tie back to our core U.S. national security interests and contribute to global stability.

So just a little digression – I have the podium, so I'll take advantage of it – to say that in my prior role leading the U.S. Trade and Development Agency, also known as USTDA, I worked with the U.S. private sector and partners in emerging economies to develop projects that strengthened infrastructure

and expanded economic opportunity both here at home and in our partner markets. In that work, I saw the challenges and the significant opportunities in aligning public- and private-sector partners to craft innovative solutions to complex problems. Such partnerships are, of course, a critical part of our efforts to ensure resilient U.S. medical supply chains.

In addition to partnerships between the public and private sector, I suspect that partnerships with likeminded friends and allies, and with emerging economies, can play an important role in these developments. From my perspective looking at global development, I would just say that as an example to the extent that nearshoring or manufacturing in friendly geographies is something under consideration, we should think about mutually beneficial frameworks that build capacity in developing and middle-income countries that may not currently have full regulatory or manufacturing capability, but with the right technical assistance and investment could be trusted partners. At USTDA, we worked on health infrastructure efforts in Africa along these lines that could be instructive.

That brings me to the only other point I'm going to use my privilege at the podium to make, and that is that we should be mindful to understand the full government toolkit that is available. Agencies like USTDA and the U.S. International Development Finance Corporation, or DFC, can and do play a useful role when it comes to planning complex activities and financing them, respectively, in overseas markets.

So, OK, that's enough of my – of my contributions there. But to just move to the panel discussions we have in store for you this afternoon, the first will cover the landscape of supply chain innovation, and really what has been learned over the past decade to stabilize the generic market and reduce the risk of disruptions. At 3:10, we will have a video message from Senator Todd Young about his work chairing the National Security Commission on Emerging Biotechnology and the strategic imperative of making life science and pharmaceutical considerations squarely part of our national security debate. Our second panel will look ahead to how we can craft a strategy for the next five years that stabilizes the global generic medicine supply chain while moving ahead on policy priorities to on- and nearshore manufacturing capabilities.

With that, I will thank you all again online and in the room for attending and participating in these discussions. And I would now like to call on the president of CSIS's Economic Security and Technology Department, Navin Girishankar, to frame our discussion. (Applause.)

Navin Girishankar: Good afternoon, everyone in the room and online. I'm Navin Girishankar. I head up the Economic Security and Technology Department here. Can you hear me? Yeah?

First of all, thank you so much Enoh. I'm delighted. We served together in government, and delighted that we're working together at CSIS and we could do our first event together on a very, very important topic. And also, really, congratulations to Steve and Michaela for putting together this phenomenal event, and bringing together leaders like yourselves and those who are listening online.

For you, you may not be aware of the internal organizational setup of CSIS. The essence of it, when you bring all these departments together, is you can't possibly deal with issues as complex as the one you're talking about today without bringing many different perspectives to the table and bringing them together. And that's really at the essence of what we're trying to do.

And it's really timely that we're having this conversation today on the generic medications sector and the complex challenges of ensuring resilient and stable supply chains. The panelists today will consider lessons over the last 15 years, how they can be applied, how they can help address growing economic security concerns especially with regard to dependence on manufacturing capabilities that sit far away from our shores. I don't need to tell you all this, but I'll say it nevertheless: 90 percent of American prescriptions are generic, and yet generics account for only 20 percent of the revenue in the pharmaceutical market. These products have exceedingly small profit margins, and there is a great deal of variability and supply chain vulnerabilities across these generic subsectors.

And so you can't ignore the economic security considerations, ones that we confronted frontally during the COVID pandemic, in particular excessive dependence on generics and APIs emanating from the PRC. Indeed, I would say this is emblematic of the supply chain dependencies and potential chokepoints that we see in a number of sectors. And that's why today's convening is timely, urgently needed, particularly as a new economic order begins to take shape.

In every sector where there are economic security issues, we must assess vulnerabilities; the robustness of our strategies/policies/instruments, maybe innovate new ones; and see whether the are fit for purpose and whether they can help us navigate the complexities of fragile supply chains around the world, how we can manage potential cost disruptions that can damage the health and well-being of Americans, and how we can lower our dependence particularly on adversarial nations where our well-being is at stake and at risk.

So devising orderly and rational strategies to transition the medical supply chain and the generic supply chain specifically is really the order of the day. It's not simple, not easy, but it is essential that we work through it. It's the

work of many hands. And it can probably start well – start with coordinated leadership at the White House and the executive branch, including active diplomacy with trusted allies. I note the G-7 summit that's happening today. The administration should develop a strategy with industry that defines the problems, the goals, and the potential bad outcomes that we can't tolerate. So, for example, is the chief goal lowering dependence on China, or it is reshoring and rebuilding manufacturing capabilities? Or is it both? And how do you do both of those things?

Secondly, someone's going to have to pay for the transition in the supply chain, including both government and industry, and we'll need to closely assess the true cost of lowering dependence/encouraging onshoring. We should consider what the split of responsibilities will be. It's ultimately a shared activity, but how do you share the risks and the cost?

Given the urgency of these economic security issues, I think the question is how the transition can be affected with deliberate speed but not destabilizing speed. And so the need for a vision in the next several years is paramount.

The administration is actively exploring a number of instruments to seek to creatively deploy public resources and instruments. A former colleague of mine at Bridgewater Associates says that we are now all mercantilists, and I think what he meant was that the role of the state in productive activities is now being rethought in fundamental ways. That doesn't mean all those ideas are good ones, but when you think about what's on the table – discussions about a new national sovereign wealth fund, the reauthorization of DFC that's coming up, the reauthorization of Ex-Im which now has new domestic capabilities – all of these things are on the table, and we should think carefully about how they can be crafted and coherently into a menu of options and instruments that we can use. How do we play all the keys on the keyboard? And these are important opportunities that I hope panelists today will weigh in on.

There's also a need for industry to convene and brainstorm about what it can do, including potentially financing. Any solution that does not – that simply builds on government handing over public resources to industry I don't think hits the mark, and so there's a need for genuine partnership.

And so, finally, let me make a final comment about tariffs. Of course, that's on everyone's mind. I take some comfort in the fact that there's been something like a momentary détente between the U.S. and China. We can discuss what the underlying implications of that are. There are anticipated announcements, including potentially with some allies, even at the summit that's ongoing in Canada today.

I think the issue, however, is if you're talking about supply chain resilience, we have to be exceedingly careful about the – what tariffs imply. There is a kind of a short shrift that you hear sometimes now that slapping on tariffs would automatically lead to reindustrialization. And just – I may be preaching to the choir, but to be clear tariffs are a tax on importers and, therefore, likely on consumers. On again/off again tariffs – and some of us have even seen intra-day tariff rates these days – can create the kind of uncertainty that really cuts against the types of investments that are needed to build supply chain resilience. And so I think one has to think very carefully about this and the role of trade in global supply chains, even if those supply chains are realigning. And in fact, trade can be a useful tool.

And so I hope these topics and others are things that we will talk about today and that we'll hear from our panelists and our leaders.

I just want to thank you all for coming and for participating in advance. The goal here is pragmatic, bipartisan solutions that can last the test of time, and I believe that we will get there. So thank you very much. (Applause.)

(Break.)

Joseph Grogan: Is the microphone working now? I guess so. OK, good.

So thank you all for being here. We're the first panel, so it leaves it to me to kick off the discussion and get the energy level up.

So I want to talk a little bit about the – you know, the Trump administration is pursuing onshoring American production in a number of different areas for two reasons. One is economic growth. The other is national security. We've seen this pattern in the United States a number of times where the United States establishes dominance in a particular industry – say, automobiles – and then over time we lose that dominance. Solar power and photovoltaics is an example. There are plenty of other ones, including microchips, too.

The pharmaceutical supply chain is, by my estimation – my limited window – the most complicated thing I've ever tried to understand ever. And whenever I get into a conversation with somebody – an expert like those on this panel – I learn something. We could be up here for hours and we would not run out of topics.

So offshoring products in the pharmaceutical supply chain has definitely made these products cheaper and freed up resources for research and development, but it has also made supply chains longer and more prone to breakage. There are currently 270 drugs on the FDA shortage list. And while

that is not a record, it is markedly higher than the 174 drugs that were on the shortage list in 2017. Additionally, we have geopolitical tensions, regulatory differences across continents and national borders, logistical bottlenecks, and low profit margins on generic drugs. All these discourage manufacturers from expanding production capacity and making these pharmaceutical supply chains less adaptable to sudden increases in demand or supply chain failures.

We have three excellent panelists to have this discussion today.

To my left is Heather Zenk. She is the president of U.S. supply chain at Cencora, formerly AmerisourceBergen. And I apologize if I refer to it as AmerisourceBergen during this discussion; it's still a challenge for me to think of it in any other term. She's had over 20 years of experience in pharmacy procurement, distribution, and supply chain, and the overseas and U.S. distribution networks. I won't go into her full bio, but she played a key role for Cencora in the COVID-19 epidemic as well.

Stephen Colvill, at the end, is the assistant research director at the Duke-Margolis Institute for Health Policy at Duke University. And he is a former official at the Domestic Policy Council in the Biden administration, he's worked at Pfizer, and he's worked at Hospira.

Erez Israeli is the CEO of Dr. Reddy's Laboratories, based in India. It is among the first in India to export API at scale. He also had a number of senior roles at Teva Pharmaceuticals, at Enzymotec. Excuse me. He holds an MBA from Bar-Ilan University in Israel.

So, Heather and Erez, I want to start with you to understand a little bit of what we're dealing with the supply chain. The first conversations I had with Cencora many years ago were illuminating to me about how complicated your work is. So, Heather, maybe we can talk just a little bit about you in a day, in a week, in a month running U.S. distribution. What are you looking at as far as managing your supply chain? How many products are you moving around the country? And follow up to that is, when you see something – say, a hurricane headed to Puerto Rico, or a national security event or disruption somewhere in the world – how do you start thinking about preparing for that?

Heather Zenk: So thank you. And easy-peasy, right? (Laughter.) There we go. No, thank you for having me.

So what does a day look like? No day is the same. I will say here in the United States – I'm going to put some numbers out there. If we can't understand

what those numbers are, we'll try to connect them to something else in the marketplace.

We have 28 distribution locations that are servicing about a third of the United States pharmaceutical market today. We do that with about 5,000-ish team members here in the United States. I have about $17 billion – with a capital B – in inventory positioned throughout the United States, which is twice the amount that our colleagues at Amazon potentially store on a daily basis. We receive on average today about 1,500 different manufacturers' products, all FDA-approved, into our network. I service every night about 30(,000) to 60,000 locations. And by a location that could be one large academic medical center, but we may shift to or have 18 to 20 different locations inside that medical academic center that we're putting products into the marketplace. Last night alone, we shipped 4.7 million units out to the United States citizens.

Also, what a day looks like is our sites of care that we deliver into, they could be a retail setting. It could be a dental office. It could be a large academic health center. It could be a specialty physician. So think of the places where, again, none of us wish to ever have to go to, but many of our family members may rely on it: an oncology office, a retinology office. Those types of products, too, they're ordering from us till about seven p.m. local standard time. We are fulfilling those orders in the evening time and getting 98 percent of those orders to them by noon the next day. So how we really take living the purpose of all health care is local in a community, but we really take seriously how short our operating clock is, how high of service we provide for a third of the United States citizens, and also what it means to be a patient of our customers.

We know that also health care is all local. Many do not go outside of a local ZIP code or two ZIP codes away to receive care in the United States, but it's very complex how you receive that care. And we take it seriously that we have to have that pharmaceutical – which usually hopes to keep someone out of a health-care setting, helps to keep someone out of a long-term care setting, or potentially out of a setting where you may have to receive surgery – that's really what we're doing every and how we're doing it.

And then we are looking at what is going to disrupt. So, again, fire of the urgent. Last night, some citizens in West Virginia were impacted by severe floods. We had 18 customers that we couldn't get shipments to today. I knew those numbers by one a.m. this morning. That's how we're dealing with the situations of the day, and also then alerting colleagues, you know, like my colleague here on my left of are we going to be able to receive inventory in, should we have inventory diverted to a different location to fulfill orders, what does that look like on a daily basis.

So that's kind of what we're dealing with every day, but I'm sure we'll get into more details throughout the course of the next 30 minutes or so.

Mr. Grogan: Erez, talk a little bit about the generic industry worldwide. You've worked at Teva. You run Dr. Reddy's now. So what are we talking about when Cencora wants to do an order for a generic drug, or let's say 20 generic drugs? What's going into that? Where does that drug start and how does it end up in Cencora's warehouse?

Erez Israeli: Thank you for having me.

So just at when we get an order from Cencora – we anticipate whether we'll get an order from Cencora. The work actually start 18 months before that, buying the first intermediate for an API. Some of us are making the API and the finished good. Some are doing only the finished good. The finished good is the pharmaceutical itself.

So when you make the first intermediate, just like you have a flavor, every SKU – and you buy how many SKUs?

Ms. Zenk: Twenty-five thousand.

Mr. Israeli: Twenty-first thousand. Every SKU has one hundred different SKUs enter into that. You need to buy the excipients in one place, and the API in a different place, and the market in a different place. And most of this stuff is done in Asia. So, for example, most of the API is done today in India, China, and Italy. Between these three countries, actually, 90 percent of the API in the world exists. And then you have, of course, Qatar and other places.

To make the long story short, Heather needs to take care of something, she gets it one a.m. in the morning, seven a.m. in the morning, we are supposed to anticipate it and prepare for it 18 months before that. And just to add to the people who have the complexity, there are about 200 generics players today serving Cencora, give or take; about 400 to 500 API supplier that serves those 200, some of them with captive use**.** Each one of them moved and basically build on the paradigm that of, you know, loss of exclusivity, patent expiration that allow the product to go. This is normally what drive the companies to know whether they can actually make the product.

So you have that many players. And in the United States, about seven customers: three retailers and four distributors. So it's very, very narrow. Most of the products have between eight to 10, on average, competitors. Some of them have 30 or 40. So you don't know whether you'll get or you don't. Most of this market is working on transactional basis; there are no contracts or long-term contracts. You work per order. And you normally plan

for what you know, which is what happened to you in the past, but you don't know what will happen next.

So that's the paradigm that we're working on. Normally, the margins are very low because it's a competition in which, you know, 10 guys needs to get something from three guys, so eventually seven on average will not sell. That's the reality of the business. And you fight for market share.

Which means one of the key things that is not taking into account, for example, issues like national securities or something like that. It's not in the discussion because it's mostly about private people that are buying from private people, and whether it's available or not. I think it's part of the issue that we'll have to take, how do you take other consideration into account.

But in general – and this is the last thing I do – when there is an issue in supply chain – I'll give two examples. You know, there was a war now in the Middle East. I am from Israel, so, obviously, I am also personally heavily emotionally involved. We in India could not use the Suez Canal. In order to supply to Qatar on a timely basis, we normally use the time that of shipping because normally most of it is heavy and you are not doing it by air; you are doing it by sea in order to save money. In the last now almost two years, we have to bypass it to go to Africa. That's the reality. And most of this stuff that's coming to India, most of the SKUs are coming from Asia and has to do this route. That's made it three weeks longer and, obviously, more expensive.

A different example was during COVID. During COVID, obviously, everybody had their challenges. In our case, how can you distribute goods from India to the United States when there are no planes, there are no ships, at least for a certain period of time? And when they started to come, it was in much less, obviously, capacity than it used to be. So these kind of the challenges that you are dealing with when you are in the outside in order to give a good service here.

Mr. Grogan: Stephen, let's go to you for a second. So you worked in the Biden administration at the Domestic Policy Council, and now you work at the Duke-Margolis Center. President Trump recently signed an executive order on regulatory relief to promote domestic manufacturing of critical medicines. How does this approach differ from what the Biden administration was trying to pursue? And when you look at the levers available to the federal government, we – I mean, we heard in the intro that this shouldn't be about taking money from the Treasury and giving it to the private sector. I'd also suggest the opposite, right, that maybe the private sector shouldn't be shipping more money off to the government and we need to balance this. But how do you think, when you look at the different levers at the federal level, we can alleviate the supply chain shortage issue?

Stephen Colvill: Yeah, absolutely. Well, first of all, thanks for having me, CSIS and Cencora, and for – thanks for hosting this event.

I think on the domestic manufacturing executive order there are some important pieces in there that were being worked on before as well in terms of streamlining regulatory review and enabling domestic manufacturers to be successful. But I think before we get into specific policy levers, it's important to think about the very distinct problems that we're talking about here, which are – which are different.

So, you know, you have drug shortages, when a patient has a drug and can't get it. You have questions around pharmaceutical quality assurance. You have geopolitical risks and national health security risks. And then you have a need for economic growth and job creation. And those are all really important, but all very different, and different policy solutions are needed for each of those.

So, in terms of what are those right policy solutions, I'd highlight two things that are also bipartisan and have been, you know, worked – there's been progress made over time on these two issues, but we need to do more.

One is on strategic planning. We need to get a lot better about identifying what success looks like for supply chains. You know, what are some measurable objectives that we should be working towards? From a domestic manufacturing perspective, can we identify some specific products and then identify a target? Should 25 percent of volume be coming from the U.S., 50 percent? What's the right amount? It's not going to be a hundred percent, but maybe for critical products it probably should be higher than what it is today. But not just around domestic manufacturing targets; we also need targets around drug shortages. Can we reduce the duration of drug shortages? Can we reduce the number of new drug shortages by, you know, say, 50 percent by 2030, or something along those lines? If we can set those tangible targets, then that starts to catalyze action and gets people thinking about, OK, what do we need to do to actually change the system to get there rather than being more so crisis-driven, which I think has been the approach frequently in the past to this issue?

And actually, at the Duke-Margolis Institute we just released a white paper a couple weeks ago explaining more details about how a strategic planning initiative could be established to bring together all the agencies within the federal government that are needed to set these targets and to put a strategic plan together, because no one agency can really own this on their own; it needs to be multiple people working together, including with the private

sector and including with Congress as well. So that's number one, strategic planning.

Then the second policy step, I think, is around competition on resilience. If there was something I could put on my business card or, like, on my email signature – I need to start doing this – it would be competition on resilience. Right now there's too much competition on who can be the cheapest – which is important, you know, saving costs, of course, but we need to factor in resilience and reliability to that more as well, and enable health-care providers and others to shop based on resilience, not just shop based on who can be the cheapest, and select more reliable suppliers.

So what can we do to get there? I think there have been some innovations recently that are working towards resilience, like new committed-contracting models. I'd highlight Civica Rx, their model. Cencora has a sure supply program. Other wholesalers and group-purchasing organizations have programs that have a real commitment between a manufacturer and a purchaser where there's actually a contract. Like Erez was saying those are not prevalent right now, but can we move towards increasing the strength of those committed-contracting models?

And also, supply chain assessment programs. How do we collaboratively evaluate manufacturers and determine who is more resilient relative to their competition? There are a few recent examples like the Healthcare Industry Resilience Collaborative and U.S. Pharmacopeia, which both have recently either launched or announced new benchmarking programs to enable purchasers, again, to better shop for more resilient, more reliable suppliers. And I think those innovations have started, but they're not really prevalent in the market yet. And to get them to be more prevalent, I think we need to have additional incentives put into place. For example, one thing – one type of incentive we're working on at Duke-Margolis is around CMS payment mechanisms that could support health-care providers in participating in these kinds of programs more frequently, you know, providing the additional incentive payments if providers are engaging in committed contracts or purchasing from suppliers that are more resilient or more reliable. Especially when you think about drugs that are in shortage, you know, oftentimes they're injectable products frequently used in the hospital setting. Medicare accounts for 50 percent of inpatient days in the U.S. Medicaid accounts for another 25 percent. So I mean, that's – to really move the needle, that's the lever that needs to be pulled to make that happen for resilience and also for domestic manufacturing.

Ms. Zenk: Can I add one thing too? One of the really foundational things that helps support what Stephen's talking about is, again, a crisis came about – don't let a good crisis pass you by – and the Supply Chain Control Tower was set up by our colleagues at ASPR. And what that entailed is we were all submitting –

the pharmaceutical wholesaling space in the United States was submitting data on where products were in the United States. So there was a lens where an entity – ASPR was at the time leading that effort – could look and see if they were seeing an outbreak in Kansas City where maybe a steroid wasn't available for use for a patient. They could look across and see. So some data visibility as a foundation is needed for some of the things that Stephen's saying so you can see end-to-end supply chain.

Because, as Joe alluded to, this is a very complex supply chain with high-quality needs. And we sometimes, you know, say this isn't duct tape and toothpicks; these are, you know, pharmaceuticals that all of our families are taking, all of the – you know, many in the marketplace. How do we help enable that? And really, a foundational dataset where we can exchange information.

Also foundational for that was the same definition. You lean into a space – we heard, you know, the FDA drug shortage list. We have visibility to that many months sooner to when that gets posted by our colleagues and friends at the FDA and our colleagues at ASHP, which is the American Pharmaceutical Association's health society, they take – we see it months earlier, signals of potential disruption in the marketplace, and it takes quite some time for that to get initiated. And realistically, what do we go from as what's a shortage? If we have a customer that wants to order a product that we don't have available on the market. Again, many different reasons for that – high demand, disruption, sometimes it's weather, sometimes if there's other regulatory issues that are driving – but there are many reasons why those come about. But realistically, we need a foundational way to talk about the same things in the same way to help our policy partners understand more effectively and efficiently to engage versus the marketplace talking about the definition, which happens a lot in this space.

Mr. Grogan: We're going to go to a couple questions in a – in a minute or two, so think of what you want to ask.

But, Erez, you made reference to Israel. That's a country that, obviously, takes national security seriously. How do they ensure that they have an adequate pharmaceutical supply chain internally for their citizens? Are they manufacturing it all for themselves, or do they take a different approach?

Mr. Israeli: No, it's a different approach. Obviously, Israel is a very small country and it doesn't have the capability of, obviously, United States or any other big country. So the approach is inventory. If you need atorvastatin, you just buy atorvastatin for five years and replenish it. By the way, I think it might be a good idea also here, you know. Obviously – (laughs) –

Mr. Grogan: It's a – it's a supply – it's a five-year supply or it's a five-year contract?

Mr. Israeli: It's five years of inventory sitting with the – with the right expiration date that can be supplied anytime. It's a matter of national security. So there is a body in the government that decide how much inventory to keep and for which product. And accordingly, they are buying it with a certain replenishment mechanism. It might be a good idea here, at least for those items that it will take really a long time before it can be onshored again.

I'll just give an example. If we asked to make – and we will do it gladly – to build API plant in the United States that make, let's say, product like atorvastatin – Lipitor – if we start today, the first kilo will be available maybe in 2030. It's not – it takes time to take land, to build. These are – these are not digital facility; these are kind of what you call the low-tech type of facilities. So if there is an urgent need, this is a methodology that, I mean, I'm sure people can look at.

Mr. Grogan: You said that India, China, and Italy dominate the market. Why – how did the U.S. lose this capability, if we ever had it? And why does Italy continue to have a role in this market?

Mr. Israeli: No, so it's a kind of interesting history. The API industry actually started in Italy, primarily leveraging two things that they had in the past, and this goes back to the history. One, they had amazing universities that educate, department for chemistry. And actually, to make API you need chemists and you need chemical engineers. And they were really, really good at it. These were private companies, normally relative to today small factories, and they did it for years. And they actually lost that. I remember when I started to work in the United States – this is more than 25 years ago, when I actually lived here and worked with the API – 90 percent of the API actually came from Italy. We at Teva, my previous company, had six plants in Italy that made some of this product.

Then they put a patent law that did not allow them to make new products, and in China and India at that time there was no such patent. So, obviously, the industry migrated to a place that you could work before that. And then, obviously, the cost advantage and the availability of talent in both countries – China with the incentive of the government, India as a result of private people; in India, they call them promoters, those private people – actually created that. And also, the ecology laws were very, very different. And so, if you wish, the basis of low cost – which is the main driver, like you said, for this industry – low cost, good quality, high level of service, that's the main principle of this industry – were created over there, and they leveraged the fact that if you want to make something in India or in China for sure in the

past it's one-twenty percent of the cost that we'll have to do it in the Western world. Even today, it's in this magnitude, give or take. That's why – I'm sorry, I may be preempting – 10 percent or 20 percent tariff will not change that, because we are talking about magnitude of scale of cost.

But to address these questions, so historically it moved because of patent law, ecology, access to talent, motivation of people. And then it was very, very hard to get it back – very, very hard.

Mr. Grogan: Yeah. Yeah.

Do we have any questions? In the back.

Q: Hi. I'm Bautistav Ivankov from the Cato Institute.

I was wondering if you would be able to explain what a resilient supply chain looks like versus a non-resilient supply chain looks like, just to give us an example of where are the areas or issues in particular that companies and manufacturers should be focusing on, you know, whenever they are designing these supply chains. Thank you.

Ms. Zenk: Or Stephen? Yeah.

Mr. Colvill: I could jump in and start, and then you would be great to speak to that too.

But I think we have a lot of examples of what really, really resilient supply chains look like when you look at branded drugs that have high profit margins. I mean, they have dashboards that the CEOs are looking at around, you know, every little risk in the supply chain that could happen that could threaten the supply of that – of that drug because it has a major financial – it's a major financial driver for the company. So I think we're fortunate in that we can look to some examples of supply chains that have redundancy and inventory strategies and strong investments in quality culture. And there are generic manufacturers that are good at those things as well – maybe not to the level of one of your blockbuster branded drugs, but we do have generic manufacturers that are good at this too. So we just need to get better at measuring and then communicating out the relative levels of resilience that exist, and get people competing over each other, jumping over each other to see who can be more resilient.

Ms. Zenk: We look at it similarly, resiliency, but also redundancy across the board, but in every step of this – of supply chain channel. So, again, when I get a finished good from Erez, what do I have? Do I have strong technology where we can place orders for customers in different locations? Do I use different transportation assets? Do we have team members that if we need to, do we

migrate team members to different locations to work? So we look at each step in the supply chain as a way to make sure we have redundancy, and quality always leads that. So do we have the right cold-chain assets? Do we have the right storage temperature? Do we have the right locations? All of that looks into what we think is, again, a redundant supply chain and resilient supply chain.

But it's not easy. You know, you're talking an 18-month cycle, if not longer. It's very difficult. And then if we need to change a manufacturer if there is a disruption, the rest of the market doesn't have limitless inventory to pick up and manage. So then we look at what other supply chain tools do we have.

We tend to talk a little bit about the word "allocation." I know for us it's a supply chain stabilizer. For some in the market I think it feels as if, you know, I want more inventory to care for patients. We really look at it as how do we make sure all sites of care could have viable inventory to support – maybe not every single unit they want, but enough to be able to manage the care of the patients that they have. So there's also using technology and tools and indicators and demand that also drives some resiliency on our side.

Mr. Grogan: Can I ask you a question? Sorry to interrupt, but you mentioned in your first answer about the – was it 18 billion that you're moving every – so what's –

Ms. Zenk: No, we have 18 billion in inventory.

Mr. Grogan: In inventory.

Ms. Zenk: We put about a billion in transit every day as large of an organization as we are at this point in time.

Mr. Grogan: So what's the breakdown in that of branded versus generics?

Ms. Zenk: About 90/10. So we heard about, you know, 90 percent of my inventory numbers is in the – in the innovation space, and about 10 to 15 percent is in our generic colleagues.

Mr. Grogan: That's in value, but not in – not in, like, weight or unit numbers, correct?

Ms. Zenk: Correct. It's inverted the other way for units. So we ship 90 percent generic molecules and generic bottles every day, and about 10 percent of our volume that gets shipped is in the innovation space.

Mr. Grogan: And is the – dumb question, but I just want to go back to Steve's point.

Ms. Zenk: No.

Mr. Grogan: Is this – you see the same thing as far as resilience in the supply chain. Obviously, the branded manufacturers are going to have a stronger supply chain than the generics. It's going to be thinner and more easily –

Ms. Zenk: You see the – we see exactly how Stephen said it, yes.

Mr. Grogan: Yeah.

Mr. Israeli: Just to add two more points to that, one is it will be great to have more commitment. You know, when we ship inventory United States – and we are holding about three months in the United States. We have, of course, inventory in the relevant supply chain place outside of the U.S. But let's say in the U.S. So when Cencora is ordering from us, we are naturally giving it from the warehouse we have in New Jersey. In order to have these three months – three months based on the past; it's not three months with committed orders. The orders are coming sometimes a week before, sometimes two weeks before. So you have to match the one or two weeks of ordering time to 18 months. So at least for those SKUs that it's important to have resilience, it's important to create some commitment to it because then people can work on it and put emphasis on it and make sure that it's happening, it will be in the CEO dashboard to your point, et cetera. This is one.

The second one – and there is a different one than 90/10 – when a product is going off patent, the price is going down up to 99.5 percent. Not all of them, but let's say it's normally more than 90 percent. So there is a reason for that value. And after this – after this erosion, normally people are fighting on the nickels and the dimes to get the market share. So, obviously, in this environment you have less of an incentive to keep inventory or to do this kind of stuff. Again, that's the nature of the business. That's the – that's the reality of the business. We are living that. But naturally, the part that is related to national security or resilience of supplies was not a parameter that we used to talk. I believe that it's great that we are doing it, but we need now to think about then how do we weight it and how we are actually coming together, at least in those areas that are very important to the people in America.

Mr. Grogan: When you – Heather, when you think about that transfer of data and opportunity for transparency at the assistant secretary for preparedness and response, is that – how broad is that? And what are you tracking at Cencora? Are you looking at not just natural disasters and potential supply; are you looking at the economic data? I remember when I was at the Food and Drug Administration we had a terrible problem with tainted heparin coming out of China, and after the fact we realized, oh, we should have figured this out because the price of heparin was skyrocketing because there had been a supply chain disruption there. And we kept on thinking, oh, you know, in the future we should – we should get economic intelligence for this to prevent

adulteration, but not much was done over time. But what are you looking about in the private sector to figure out – to anticipate these shortages before they – before they become critical?

Ms. Zenk: So we're looking at a few factors. One of them is to – how many competitors are in a space. So we still have generic products that might only have one or two manufacturers in the space. Those tend to, of course – if one of those gets disrupted, it's a likelihood that you will have a longer duration or a drug shortage at that point if they're difficult to manufacture. So there are certain types of formulations – which, by the way, full disclosure, chemists, for all the pharmacists in the room – yeah, a little chemistry, which didn't know if I'd get through third year but got there – (laughter) – so also are difficult to manufacture because those also tend to have disruption or quality concerns that usually the manufacturer will self-identify ahead of time. So there are formulations that are more difficult to manufacture.

We also see new players to market. So if a new manufacturer enters a market, does that do something to the marketplace? Does the price drive down significantly? What will that do to the market stability and marketplace?

And also, we look at the – we try to get as much information as we can from our manufacturer partners to see, do we have single-threaded locations of active pharmaceutical ingredients, key starting materials? I know we talk about those two a lot, but one of the things that put heparin on the shortage list too is rubber stoppers, the little rubber stopper that went in the glass vial. They struggled to get those consistently and at a sterility level that would make it viable in a therapeutic environment. So something as simple as – had nothing to do with the active ingredients.

All of those things the manufacturers are looking at, and it becomes every single product has a journey. Every single product has a hundred things that make it the finished good. It could be any one of those hundred that drive it. So we talk a lot about the active pharmaceutical ingredient and key starting material, but it can be something as simple as the rubber stopper or the glass vial or the label. So those things are also things we try to say, do we know if it's single-threaded through one location? And that elevates it also in the marketplace.

Mr. Grogan: OK. Any other questions? Yes.

Q: Hi. David Senior from Cencora.

Question for Erez. How do you – how do you assess the U.S. as – from a market attractiveness standpoint versus other markets in how you think about prioritizing markets around the world?

Mr. Israeli: Yeah, no, thank you for that. It's a great question.

For most organization outside of the U.S., the U.S. is their number-one market. Obviously, being the number one, very, very important in many of the products, if you are – because you are trying to reach global scale. For example, when we are selecting a generic to develop, we are normally doing it globally.

I'll just give you an example. And if it's OK, I'll even use what Heather example just did on the stoppers. To give an example, we decided to do all the GLP-1 products, and the first product that we are going to launch actually very soon is a product called, you know, generic version of Ozempic, obviously being very popular as we speak. In order to – Ozempic will be generic – the first market to be open, actually, will be Canada, in January '26, while the United States is somewhere in 2033. So, first off, the consideration is where you can actually clearly want to be in this kind of a product or products, a family. For example, the GLP-1 family will be, like, 26 products over the course of a decade with different – lots of exclusivity dates between 2026 and 2036. This is where the Eli Lily product will become off patent as well. So you select those products and going accordingly, we will launch – and this is going to be manyfold – the Ozempic in 87 markets, but not in the United States. Therefore, there will be less of a consideration for this kind of – that because of that together.

The second is, obviously, the price point. If we are – we have places in which we can sell let's call it more easily, whatever "easily" means, because we see less competition – in some of the SKUs in the United States, we see 20, 25 different players competing with us, and the prices in the United States can be lower than what we can achieve even in markets like Turkey, believe it or not in Africa, believe it or not in India. So it's just the nature of the competition and the commitment of the people to buy.

Going back to the Ozempic example, in order to make Ozempic you need to achieve three things at the same time. You need to have a device with all the stoppers and all the stuff. It's pretty interesting stuff; I will not go into too many details. You need to have a cartridge that you can fill in an antiseptic way, what we call sterile manufacturing, sterile fill and finish. And you need to have an API which is 39 amino acid peptide. All of that needs to take into account the supply chain of that is three different sites, that you need to assemble at one go, and you need only one stopper, one stuff that is not there that you will not have Ozempic. And I know Ozempic is not yet on the essential list that we are discussing, but likely that it will come with the evolution of this GLP-1.

So, just to make sure that I answer it properly, you take into account loss of exclusivity, take size of the market, the prices that you take, the competition that you have, the commitment that the customers will have, and obviously the importance of the customers. This is eventually the most important one, how important it is to have a long-term relationship with these partner. All of that taken into account.

I can tell you that for us the U.S. is by far number one and likely to stay number one, and I want it to be number one. At this time, like in the United States like everywhere, you have challenges that we have to overcome. And we need to build the right coalition to do that. The two factors that came recently, tariff and national security and that stuff, are adding to that complexity, and we need to take care of that.

Mr. Grogan: Anyone else? Yes. You, yeah.

Q: Allan Coukell with Civica.

I have a question for Dr. Israeli.

Mr. Israeli: Erez. No, I'm Dr. yet. (Laughter.)

Q: A question for Erez. You talked about a five-year timeline if you started to make atorvastatin until the first kilos came available. The president has signed an executive order aiming to get regulators out of the way and streamline permitting. What's the potential gain there, both for API and for finished drug?

Mr. Israeli: So we need to decide whether we make it for national security or we make it because it's commercially the right thing to do. There is enough capacity of – from if we look at it – and I'm ignoring presidential orders and, like, taking it as a normal course of business – there is enough capacity for atorvastatin in the world, but not in the United States. In the United States there is none. My understanding is that atorvastatin is an important product for national security. And then, of course, it's up to the United States what to do with that, either to build a site or to buy inventory. Both are possible to do.

The question is, OK, if we need to build a plant in the United States for atorvastatin, it will cost tens of millions of dollars. Who is going to pay for it? We don't need it. Cencora will not order atorvastatin because of that. So who is going to pay for it? And we can do it. And likely that this will be maybe ten times more expensive than a kilo that will be made today in India. It is absolutely possible to do.

Mr. Covill: And as another question on top of who's going to pay for the – for the new plant, how are you going to ensure ongoing sustainability of that plant, you

know, after it's been constructed and once you have products on the market? Is there going to be an ongoing market that enables that plant to be successful?

Mr. Grogan: Steve, let me ask you that. I mean, the U.S. federal government does buy a fair amount of drugs, PEPFAR being a great example. Would that solve this if you – for those – say, for antivirals, could you say five-year commitment from this manufacturer, product this generic, could you do it for the pharmaceutical stockpile? You know, we use that for countermeasures. And should that be built in? Have you explored, either at Margolis or when you were at DPC, building this in in any of the other payment programs – Medicare and Medicaid?

Mr. Covill: Yeah. So in terms of direct federal procurement, I think that's an important lever. In many cases it's already in place where there's buy-American preference that has enabled some base of production. You know, it's helped in some instances for a base of production to stay in the U.S. But it could certainly be improved. There's steps that could be taken to make it more, you know – defining the product, American-made products, better and that sort of thing. But the real lever is Medicare and CMS payment preference that could be provided to domestic or reliable manufacturers.

Mr. Grogan: But in the – in the stockpile and PEPFAR, are there multiyear contracts when the federal government chooses to buy them? I didn't mean to put you on the spot, but I – Erez mentioned a five-year commitment in Israel, so I was – I was trying to figure out of that's –

Ms. Zenk: There is.

Mr. Grogan: Is it?

Ms. Zenk: There is, yes.

Mr. Grogan: OK.

Ms. Zenk: Yeah. I think it's two to three years – correct me on this – for the stockpile.

I will say I do think, too, we have different stockpiles, too. Many of the states have taken actions also, which is I think where good private-public partnerships – so we don't have redundancy. And there is some support so the manufacturer isn't potentially creating multiple scenarios. It would be – it would be great to have some public-private partnerships. And then, again, you can use the supply chain channel, such as ourselves, to move that inventory through so it doesn't expire – through the commercial channel, but hold some aside, which, again, we have some policies out there that can help

do that. But how would we – how would we do that in a public-private partnership? I believe it's a three-year contract, if I'm not mistaken.

Mr. Covill: I'm not sure about the details of that, but I think for a lot of products federal procurement represents maybe 1, 3, 5 percent, you know, somewhere in that range. So, helpful, yes, but how much does it move the needle is the question.

Mr. Grogan: Question?

Q: Yeah, thanks. Paul Friedrichs, senior – (comes on mic) – sorry, didn't mean to have you have to hustle over here. Paul Friedrichs, senior advisor here at CSIS and formerly at the White House and then in DOD.

So this concept of public-private partnerships is one that you guys have referenced several times. In Europe, they've picked 11 drugs, focused on those, and then identified what public-private partnerships were needed in order to mitigate those specific drugs. Japan's done something similar with antibiotics. Korea's done some really interesting public-private investments to maintain manufacturing capacity. Could I ask each of the three of you: If you were advising this administration on what the most beneficial public-private partnerships could be, what would that advice be?

Ms. Zenk: I would say what has been started. We have to start somewhere. I think this is a great forum to start and I think it's a great forum to have, but to start and look at 10, 12, 15 pharmaceuticals that we deem as, you know, essential in the United States, and let's target those, and let's get going. I think that we have – we don't want to let perfect be the enemy of better or good, and at times we get there. And I think it would be very exciting to have that type of public-private partnership for an entire supply chain to be able to have some stability around pharmaceuticals that particularly we feel would be targeted to drug shortages or in critical short supply frequently.

Mr. Israeli: Yeah. I want to join that. I would start with the inventory, assuming that it's on top, because it at least address it relatively fast with certain replacement, which is easy because you can use the private movement to change and to sell stuff that way before it will expire, so you don't need to, you know, throw it away.

The second is if it's indeed essential to make stuff in the United States, and you actually want the manufacturing capability, it's more of a coalition of the entire supply chain. Like I mentioned, we make the API. We make the pharmaceutical. But we buy many of the stuff before we do. It's not that it start with us. The intermediates we need to buy, the stoppers we need to buy, the device we need to buy, et cetera. So it's – so even for those operation, they will need to buy somewhere. So it's more about creating a coalition for those

essential products to make sure that all the parties are fully engaged and fully, you know, support the program on a long-term basis.

And number three is to create a coalition. I am very much advocating for coalitions. So naturally, Cencora being a very important player in the market, they will have their priority to suppliers that they can rely on. Obviously, if we are chosen to be one, then we have certain responsibility. And if it means that we need to do something for the United States, including to make stuff here or to bring the inventory here or to do anything else, this is part of our job to do that. In return, we know that we are valued by the United States and can do business for many, many years here. This is the kind of relationship.

So I am very much about let's see what are the priorities, obviously dictate by the relevant parties in the United States. And let's see how we can help.

Mr. Grogan: Steve?

Mr. Covill: Thanks for the question, Paul.

I would start with, within the government, creating the strategic planning initiative that I mentioned earlier at the HHS level to bring all the agencies together to work on setting the future direction. And then in the process of doing that work I would leverage public-private partnerships, or maybe private industry consortiums that already exist like the End Drug Shortages Alliance, like the Healthcare Industry Resilience Collaborative, or like U.S. Pharmacopeia that I've mentioned previously where industry has banded together in coalitions working on this topic, just could benefit from some additional, you know, collaboration with the government, I think.

Mr. Grogan: And we're a few minutes over. Unless there's a pressing question, I'll try and get us back on track. This was a great kickoff with a tremendous amount of expertise. We talked about public-private partnership. We set the stage about some of the dynamics of the supply chain.

And I realized about halfway through that I was so focused on getting this kicked off and introducing the experts that I forgot to say who I was. (Laughter.) So I'm a fellow here at CSIS, Joe Grogan, and a scholar at the University of Southern California Public Policy School, the Schaeffer Institute, and former Trump administration domestic policy and OMB, as well as the Bush administration.

But we were dealing with this in Bush, dealt with this again in Trump. I'm sure we'll be dealing with this again in this term and for many times. But to your point, Heather, we have to get started somewhere. So thank you very much. (Applause.)

Ms. Zenk: Thank you. (Applause.)

(Break.)

J. Stephen Morrison: Thanks to our first group of panelists. I do think we got off to a great start, a number of ideas around what a five-year strategic plan might look like and how to get it moving, and the essential factor of needing leadership coming from high levels within the government with empowered leadership, and with resources, and with the ability to pull not only the executive agencies together but to devise these way(s) forward with industry.

As we heard from Enoh and Navin in the opening, the issues we are wrestling with today focused on medical supply chains for generics. These are part of a much wider geopolitical debate over the U.S. bioeconomy. This has led to an increasingly common premise that we're hearing in our own political discussions that the United States needs to prioritize on a national security ground strengthening U.S. industrial policy in the life sciences to ensure continued competitive advantage in biomedical technology, especially with regard to China. That premise alone does not tell us much on how to operationalize such a logic, and in which sectors, and with what strategy, investments, targeted outcomes, and metrics to judge success.

Before we begin our second panel, we want to take just a minute to hear from Senator Young – Senator Todd Young, Republican from Indiana – who has shared a short message about the recently completed work of the National Security Commission on Emerging Biotechnology. Congress insisted upon the creation of such an exercise over a two-year period to generate a strategy and concrete answers, including draft legislation. The commission suggested a three-year timeline to invest 15 billion (dollars) in biotechnology capabilities or risk ceding the ground to China and other U.S. competitors. It's an ambitious effort. It remains to be seen how much of this moves forward. There's a multitude of recommendations. But it's a model for action that may feed into related, evolving debates over the degree to which global supply chains for U.S. medical products are a national security matter and deserve the sort of dedicated long-term U.S. government-led strategy with industry that we've just heard of here and we're going to hear more of in the second panel.

So please join me during our break in listening to Senator Young's very brief remarks. Thank you.

Senator Todd Young (From Video): Hello. I'm Senator Todd Young.

For decades, the United States has been the global leader in biotechnology. Now we are dangerously close to falling behind China. Given this reality, Congress created the National Security Commission on Emerging Biotechnology in 2022 to help America keep ahead. As chairman of the commission, I helped lead a two-year national effort engaging with experts and stakeholders to produce a major report for Congress in April of 2025.

Our commission reached one major conclusion: Urgent action is needed to fully harness U.S. innovation and investment in biotech. We also found that America's growing dependence on China for numerous critical supply chain elements is a national security vulnerability.

In the years ahead, biotechnology can be the key to increasing supply chain security, resilience, and scalability by allowing the U.S. to control its own access to critical components. Biotech can revolutionize health, food security, defense, and deterrence. It's a national security asset. But it's also a risk. China is rapidly integrating biotech into its military and industrial plants, guided by its values, not ours. I believe strong American leadership is vital in this area. To stay ahead, we must unleash America's full innovation potential.

I encourage you to take a few minutes and read our commission's report and action plan for Congress at biotech.senate.gov. I appreciate your collaboration on these issues, and thank you for allowing me to share a few words.

Dr. Morrison: Thank you. I want to invite Senator Burr and our second panel to come forward to the stage and we'll get started right away. Thank you.

(Pause.)

Richard Burr: Well, Steve, thank you. And thank you to all who are here today, and I thank you to this esteemed panel.

And I want to publicly thank Todd Young for his commitment to serve on that commission for two years and to bring a word, even though it couldn't be in person. We hard pressed him to try to get him here, Steve, and thank goodness we weren't counting on that because the Hill is sort of locked down this afternoon as members scatter for meetings as text of the reconciliation bill are beginning to be introduced as of last night and throughout the day.

Joe Grogan is a lot better-looking in person. I'm glad – (laughter) – I'm glad we got him away from London and got him here. But the first panel was fascinating. I'm sorry I got here late. More focused on current conditions. And you know, my takeaway from it was really in the last comments: coordination, collaboration. Well, you know, I got to tell you as a – as a

product of Capitol Hill for 28 years this is a very difficult thing to accomplish in Washington, much less on Capitol Hill, collaboration and coordination, and in this case between government and the private sector.

But the next panel I'm here to say is here to talk about the future. The last panel, today. This panel, tomorrow and thereafter. And it will bring up a number of different challenges that will become apparent. But this panel's here to really talk about the nuts and bolts, the operational realities analyzed by the first panel, and share some thoughts on the essential elements of really a pragmatic five-year approach that will lower dependency on China and other countries, and create greater nearshoring and onshoring capabilities hopefully in an orderly and predictable way.

Now, it's not an easy and simple task, I will say that. We're going to hear a lot about leadership. We're going to hear a lot about the time that's needed. We're going to hear a lot about the money that's needed. Those things really aren't normal conversations on Capitol Hill, let me assure you. But the United States has to lead. It's absolutely a priority, and it's a challenge. And to accomplish this, we can't do it unless somebody's put in charge.

As we will hear, any strategy requires funds. It requires active and deft U.S. diplomacy and a new creative partnership with industry. It requires a very clear idea of exactly what investments are to be made in what specific areas and what specific desired outcomes.

So, as you've heard, it's possible to invest a lot of money and not achieve the intended mission. So the industry will need to change its thinking, its behaviors. It will be called upon to invest some of its own resources. It'll be called upon to expand sharing critical data with the United States government, which has not always been the case. As a matter of fact, Paul, I think it's safe to say government doesn't share with government a lot of the crucial data.

Audience Member: Amen. (Laughter.)

Mr. Burr: Let me say this is a – this is a balancing act. And it prioritizes as a national security and a market stability issue.

And there is a certain urgency to act based upon what we've learned during COVID, based upon what Senator Young found from his two-year study, and that we continue to observe daily in the fraught and at times unstable relationships between the United States and China. And I might say that the international landscape of the geopolitical map continues to change now minute by minute, hour by hour.

So I'm delighted to be here today, and lucky to have three exceptional leaders to talk. But first, let me do introductions.

Andy Boyer is executive vice president and chief commercial officer for generics and biosciences at Amneal Pharmaceuticals, where he brings extensive expertise across the generic industry to his work on marketing and distribution. Amneal is an exceptional – is exceptional in having created significant onshore production capacity for generics.

Jan Pallone is president of strategic global sourcing at Cencora, where her expertise as a pharmacist and in pharma connecting – helped her to lead the company's work on manufacturing partnerships and product distribution. And by the way, we are grateful to Cencora for partnering with CSIS to make today's convening possible.

Last but not least, Phil Luck is director of CSIS Economic Program and Scholl chair in international business. He served as deputy chief economist at the State Department during the Biden administration, where he led work to strengthen global supply chain resilience. Many thanks to all of you for your attendance today.

Let me start, if I can. What strategies balance the risk of a shortage and the real risk of a market collapse if you do it wrong? Phil, I'm going to start with you.

Philip Luck: (Laughs.) Well, that's – well, you start with a good one. Thank you. (Laughter.)

Well, I think I will kind of punt on that question, but answer a different one also. Which is, I mean, that's exactly the problem, right? That's exactly the challenge that we have to make. You know, I was thinking all through the first panel – I have certainly heard people say, this is going to cost money, this is going to cost money. And there's no way to get around that. Resilience is kind of the opposite of efficiency in most ways. And that means it costs money. So you can build more and more resilience if you want, but that's going to come at a dollar value. The question really is, how much do you need? How much do you want? And what's the marginal cost there?

That's a super hard question. But even before we get to that question, we have to figure out what level of resilience we have. And that's basically a data exercise, right? We don't have the necessary information that we need to even get to that really, really hard question. So I would say, I mean, there was a lot of talk about this in the first panel, which is, you know, you really can't manage what you can't see. And right now, there's huge parts of the supply chain that we just can't see. And, you know, we talked – you know, in the last administration, we, of course, were coming out of COVID, supply chain

shortages. We were laser-focused on supply chains. You know, probably too much, in some ways.

We made the least progress on this one, because – not out of a lack of effort, but a lack of just not being able to see the problem in order to find the solutions. So that's just – you know, I kind of punted on your question, but the answer – the thing we have to answered before that is, what do we need to see, and how do we need to get the data to see it?

Mr. Burr: You'll find, I don't forget that you didn't answer it.

Dr. Luck: OK, great. (Laughter.)

Mr. Burr: Jan.

Janine Pallone: OK, I'm really under a lot of pressure to answer this then. (Laughter.) Yeah, I think that the things that are really needed – so, panel one, thank you very much for kind of setting us up for this discussion. A lot of the themes are going to resonate. Really, when we're looking holistically at the full supply chain – so with key starting materials, API, all the way down to the site of care that's actually dispensing the prescription to the patient, or administering the prescription, or the therapy, we really have to look at all of those pieces and bring them together. Because if you only work in one pocket, there'll be a lot of disruption shocks to the system.

And I think that there's kind of three parallel areas that we should be looking at to bring us through this long-term plan – kind of a short-term solution, a mid-term, and a long-term. The short-term being the resiliency of manufacturing. And I'm sure Andy will talk a lot about that. But it's really about getting manufacturers to the point where they have predictability. And there was a lot of conversation around that in panel one.

The other piece to that is, how do we ensure that when we come to this collaborative list of essential medications, which is a recommendation that panel one had and we have as well, how can we ensure that the manufacturers are incentivized on those products? Because sometimes some of these products are hard to make. There is no margin. How do we ensure that the manufacturers are incentivized, and that there's enough manufacturers in the market? So it's not just one or two, it's multiple, to kind of decrease that potential for risk? And then ultimately incentivizing manufacturers, but also incentivizing purchasers. So how do we incentivize purchasers to actually be aligned with the additional costs that this is likely going to take, to get through that resiliency?

And then kind of the mid-term is more about reserves. And we talked a little bit about supply reserves and things like that. But I think that there's really

an important thing that we need to look at with, how do we look at, like, an HHS or federal government reserve, but also in the states? How can we make sure that each of the states are kind of looking at their supplies, ensuring that they're aligned with these critical medication lists, and creating a reserve that works for their state? And then also creating something that's cohesive across all states, so that they're not competing with each other. Because we do see that in times of crisis, you know, states trying to outdo another state, or doing what they – doing what they should be doing for their own citizens, but also potentially disrupting other states.

And then, from a long-term perspective, certainly we have to look at tax incentives and other types of incentives to incentivize manufacturers to bring manufacturing to the U.S. or near shore. And that's all the way from KSMs and APIs to finished goods. But also gets back to those sites of care, and what does their reimbursement look like? How do we ensure that there's fair reimbursement to those sites of care, so that they're aligned, again, with the cost structure that the generic manufacturers have to enter into, in order to kind of close this gap that we continue to see decades and decades.

Mr. Burr: Could you – and I'm going to warn you, I'm going to come back to you after we go to Andy, because I want you to address what role did states play before COVID in these reserves. Andy.

Andy Boyer: Listen, I think panel one did a great job of setting us up.

It starts with commitment, right? And I think everyone's told you, it's 18 months for API. It's all the stoppers and everything else, the hundred different items that go into a finished good. So I think if you're going to look at essential medicines, and you're going to look at a way to stabilize and do that, you've got to come up with that list first. You cannot boil the ocean. It's never going to happen. So you've got to start someplace. We don't do any API in the U.S. We really don't do any KSMs in the U.S. So if you don't start with those essential medicines and look for that opportunity, it's never going to happen. That's number one.

Number two, I think as you look at generic margins, you've made mention of it this now, reimbursement. There's an issue with reimbursement in the U.S. And that's whether it be from the government or that be from the private insurance and the PBMs. They've driven down – they did their job. They've driven down prices in the U.S. to the point where they're no longer sustainable. And that non-sustainability is what's leading to a lot of these issues with shortage of supply. You've got a finite amount of capacity in your facilities, whether it be for KSMs or APIs, for our down shore – downstream folks, or for the manufacturers of the finished goods.

You've got to take and utilize that as efficiently as possible. And what I would say is, is that unless you get commitments at every level of the health care system, starts with reimbursement and it goes all the way back to the KSMs. If you don't get a commitment of volume and dollars associated with that volume, it is going to be very, very difficult for us to change this paradigm going forward. So we've seen what not-so-good looks like here over the last five years. The future has to be a commitment to change. And that change has to be at every level of the supply chain, and ensuring that everybody has value to do what you're saying we should do.

Which is, should we build more inventory? We need to invest more in quality. We need to invest more in technology. Those things cost money. When you're working off thin margins to begin with, those investments that are so forward-looking, without any kind of a commitment of something getting a return on investment, for the private sector they're just not going to invest in it, because they can't afford to. So as I look at you're trying to take national risk and the balance of it, that has got to be fixed. The government has to be fixed from the standpoint of reimbursement. We have got to address the insurance and the PBM piece. And then, more importantly, figuring out those targeted items.

Doesn't matter whether it's 10, 20 – it can't be 200. But you've got to have those targeted items, and understand all the different data pieces that you're speaking about, Philip. Yeah, you need to know all those data pieces. Where is that KSM made? How many different suppliers are there? How many different API suppliers are there? Are they of quality? Can they get it into U.S. in a timely manner? Are they keeping six months of inventory on hand? How many – how much inventory do you want, of the KSMs, or the API, or the finished goods? All those things, like you said, cost money. Those are the data – that's the data that we need. And it starts with those products.

Mr. Burr: And I'll stay with you before I go back to Jan for our last question. So your assessment as to whether the strategic national stockpile is a successful tool, and if your answer is it's not, then how would it need to be changed? And how can it be an example of the architecture we need for others?

Mr. Boyer: Great question. So the strategic national stockpile will be successful if the product and the company they pick is being used in the commercial marketplace on the third of the Cencora business, just as an example. The reason being is, you've got to rotate that inventory constantly in order to keep it from expiring. If the only strategic national stockpile is by one manufacturer, but the rest of the market is using another manufacturer, it is not going to be a success, longer-term. So to me, again, it goes back to commitment – commitment from the public sector, commitment from the private sector, marrying those two together. And then you have a successful strategic national stockpile.

Mr. Burr: I'm going to dig deeper on that, but I'm going to – I'm going to dig deeper with Phil. I'm going to go to Jan first, and Phil, where I'm going to come to on this is that at least in the COVID example – and it certainly was not predominantly pharmaceuticals. It was more PPE, where you had a lot of options but the marketplace players, those – the consumer of it, as soon as COVID was over, the cheapest dollar won out and it eliminated a lot of congressional options about warm basing and things like this.

But, Jan, let me go back to states for just a second. Did states assume a role before COVID on stockpiling of key things? And if they didn't, is this just as tough of a sell to the states as this is going to be to Congress?

Ms. Pallone: So I'll caveat that I'm from the great state of Missouri. And I did serve on the Missouri Board of Pharmacy. So I'm more familiar with the state of Missouri. I think that each state in and of itself is trying to do the right thing and understand where they can play in that national security, and take care of their citizens. I think where the breakdown is, is what we were talking about earlier, is this lack of transparency and data. Where is the inventory? Where does it sit? How do you have one set of information and data, and trending, so that each state can make decisions holistically for itself, but also looking at the full supply chain, so as not to create these unintended disruptions? So I think that each state prior to COVID was doing some things individually, but certainly not holistically across the board and in a common set of information.

Mr. Burr: You raised something in your answer, though, that's challenging. And I think you implied that a state had to coordinate with what the national strategy was. And coordination has not necessarily existed between state and federal health care policymakers and administrators. How do – how do we achieve that level of coordination that you're talking about, because our system was really designed – and I say this with Julie Gerberding in the room – that CDC was reliant, and part of the system required states to report things. Yet we still were deficient from a standpoint of how much robust data we had to make decisions. So it can't be forced. There's got to be – there's got to be a different relationship, isn't it?

Ms. Pallone Yes, I agree. And I think that does go back to this public-private innovation. Because, to Andy's point, we have to be able to utilize both kind of sets of product inventory in order to stockpile, reserve, rotate. And it's very difficult, if not impossible, to do that without creating disruptions and shocks, if you don't have a collective, common set of information that everybody is working from. So it does certainly help to have coordination across states and federal.

Mr. Burr: OK, Phil. Geez, if you look back at post-COVID, with people like Paul Friedrichs saying, here's the direction we've got to go, and this is what we have to make sure we've got access to. And, quite frankly, the commercial market flipped immediately to, where's the least-expensive gown? Where's the least-expensive set of gloves? Where is this or that? It made it very difficult to say to a domestic or near-shore manufacturer not only are we going to buy, but the marketplace is going to buy from you. And the marketplace will sending the exactly opposite signal. How do we address that?

Ms. Pallone: Yeah. I mean, I think that's obviously the challenge, right? Markets are not – markets are very, very good at certain things. Building incredibly high resilience at higher cost is not something that it normally does, right? You know, I think this is where we need to have – we need to, again, map out the supply chain, so we understand where we have these vulnerabilities, and then we need to keep – we need to put, you know, robust and consistent market signals out there, right? If there's a – if there's a supply chain that we decide needs to be more robust, we have to be willing to pay for it. We have to – somebody's got to pay for that. And that signal has to be clear. You know, this is just going to have to be through some sort of resilience, right? As an economist, I think about this as, look, there's just an externality here, right? You know, no one's willing to pay for this extra resilience unless we just sort of do it societally. So that has to happen.

But to the earlier point, we cannot do this on everything all at once. We have to start narrow. Basically, we haven't done it on anything yet, really. (Laughs.) So let's start somewhere. Let's start somewhere. We map it out. We identify how much is necessary to pay. We agree that it has to be done. And then we do it. The other thing I would say is, this is – you know, as you noted, this is hard enough to do within just the United States. This really should be sort of a coalition doing this, right? If you look at – so, I think, based on the OECD estimates, 70 percent of APIs used by G-7 countries are produced outside of the G-7, right? This is a huge market. You know, we need – if you want to map out any of these supply chains, they the whole problem is that they're global. So we need to be able to have sort of a global solution. And so we need to invest in these larger, multilateral solutions. Again, that's really hard to do, but that's what we have to do.

The last thing I want to say too is, you know, I think, similar to COVID, you know, I think there's this idea that, oh my God, these supply chains are not resilient because they're – because we don't know where they are, and they're far away. Just also want to note that, like, across all supply chains, like, domestic, doesn't mean secure. You can have a very domestic supply chain that's very not secure, right? Just look at sort of baby formula a few years back, right? The only reason we're able to get some baby formula is because we were able to buy it from New Zealand, right? So, you know, I

think we do need to – sort of, we can't just say as a sort of catch-all, or sort of, you know, a heuristic for security is domestic. That's not the right way to think about it. You actually have to do the hard work to identify how a supply chain is or is not resilient, and not rely on sort of these domestic or foreign heuristics.

Mr. Boyer: Just one – I mean, Stephen made a comment on the previous panel, where he said, you know, look at the brand companies, how resilient their supply chains are. Well, yeah, there's a reason why. Their utilization is like this. It's slowly going up, slowly going down. So if they keep six months of inventory on hand, it's an exclusive. It's a lot easier to forecast that, and plan for that, and manufacture for that. But, you know, you're the economist in all of this. Look at the regular marketplace. It's inflation everywhere. How is it that the generic industry is deflationary, and you expect it to, long term, be sustainable? It's not feasible.

And to the point where you're paying more money, yeah, you're going to have to pay more money for it. There's a reason why we're making chips out in Silicon Valley right now to protect ourselves. We're going to pay more money for them, but we're going to protect our own citizens. So, you know, you got to look at all the different pieces of it.

Mr. Burr: Is there consensus on the stage that we're currently in a total redesign of the supply chain for the United States and for the West?

Mr. Boyer: I would say we're pretty close.

Ms. Pallone: I don't think so.

Mr. Boyer: I mean, the fact that this bottle of water costs more than your medication for atorvastatin for the month, that you made mention of, or your antibiotic, or your diabetes medication – the fundamental mindset of the U.S. consumer that wants it at a lower price, and not recognizing what that lower price is. You're paying $1 a bottle for your lifesaving medications, the same as you're paying for a bottle of water. Your Starbucks coffee could be more than – your one Starbucks coffee could be more than what you pay for your entire diabetes drug for a year or more. So it's a fundamental mind shift that we have to have, in addition to everything else.

Mr. Burr: Clearly, you haven't been through an airport lately. There's not a dollar bottle of water. (Laughter.)

Ms. Pallone: Inflation! A perfect example of inflation.

Mr. Boyer: I was talking about – I was talking about Costco. (Laughter.)

Ms. Pallone: I think – well, my caveat is we need to be in a reset. I don't believe that we're there yet. So I keep going back to this collective holistic plan, which isn't easy to get to, right? There's so many different pieces that come with that. But I think we're getting close to – closer to realizing that it's not sustainable. We've been saying it's not sustainable for years, though. And so action is really what we need. And I think Stephen talked about that as well. All the panelists have. We really need to take action. And whether that starts with a small number of essential medicines, we have to start somewhere and learn from it. And we have to go from beginning to end in order to understand what's working, what isn't working, to adjust and shift. But to continue to talk and take no action is going to continue to be problematic and cause more issues.

Mr. Burr: Did you have something that you wanted to?

Dr. Luck: Yeah, no, I think starting small, but top – front to end, is exactly the right way to do it. But one reason I'd say that is because, you know, this is not the only supply chain we have to sort of make more resilient. To your point, I mean, you know, whether it be critical minerals, or a million other things, right? And we only have finite capacity in the United States, right? We only have so much money to throw around for the federal government. Doesn't seem that way sometimes, but I assure you it's true. And we only have so many people to do work here, right? So we have to do – we have make hard choices about this, right? Medical supply chain seems like an obvious place to prioritize, but, again, we need to be very clear about what is and is not necessary to be the most resilient, and at what cost.

Mr. Boyer: Well, I think, to your point, what has to be done in the U.S., versus not? So to me, if the government makes a commitment for product X, well, the next line down is, there's got to be a commitment out of the API supplier for product X. There's got to be a commitment out of the KSM supplier for product X. Otherwise, the U.S. government has decided they're not going to utilize that entire supply chain. And at that point, then you get to the private sector, and maybe they do the same thing. We need to see all the different pieces, and we need to see all those commitments, or we're not going to procure that product for patients and for our pharmacies and for our institutions to purchase.

Mr. Burr: Andy, would you be more comfortable if the president started talking about nearshoring versus onshoring?

Mr. Boyer: Depends on the product. Antibiotics? Onshoring. I wouldn't go –

Mr. Burr: Let's say for a minute he doesn't have the capacity to separate the two. I mean, I'm looking for the overall message of what's said. Because what I heard in the first panel, and I think what I've heard from you guys, onshoring

the medical supply business for the future, that's not in the cards. Pieces of it, yes. Reliance on access to API marketplaces that there's trust and confidence and established relationships for manufacturing, yes. But we're not going to onshore everything. And I think to some degree, that's what you hear in the message. I'm not sure that's what the White House means. If you separated the two, or you just went with nearshoring, does that begin to bring a level of clarity to it?

Mr. Boyer: If your nearshoring is somebody you really trust long term because, to Erez's point, it's five years to make an atorvastatin API. So if you decide that somebody today is going to be very strategic for us today, and you don't recognize whether they're going to be strategic for us 10 or 15 years from now, then you got to make a different decision. So nearshoring is fine, as long as you've vetted those nearshoring entities to the point where you know that it's never going to change, or you've got some kind of reciprocity that makes it so that they need you as much as you need them, to make sure that that doesn't change.

Mr. Burr: Jan, this is right in your wheelhouse. So how do you comment on that?

Ms. Pallone: So I agree with what Andy's saying. So Cencora, as a global organization, we have relationships in multiple countries. We know the EU. And I think someone brought it up, maybe it was Paul, earlier about the 11 products that they've been looking at. I think that there's a lot of commonality across allied nations, whether it's nearshore or across the water, that have these common themes. And if we can come together with those allies nearshore, I think that we can, to Andy's point, find a solution that works for not just the U.S., but for them as well. And it is that reciprocity.

But I do agree, to some extent, that there's certain products, like antibiotics, that might deserve a little bit more scrutiny about where those products should be, all the way from KSMs to finished dose, because of the criticality of those particular products and the clinical need for patients who need them, and to not have that access. Because if you can't get the KSMs or the API, you can't make the antibiotic, at the end of the day.

Mr. Boyer: China's making all of our KSMs and API right now. That's the bottom line. So unless you're going to find some other – some other place to make that, and quickly, and know that they're going to be with you for a long period of time to sustain that, you better bring it onshore.

Mr. Burr: Well, I go to a congressional report of a two-year study, and would paraphrase their report. There's national security problem with not changing the reliance that we have on China relative to those items. So, Phil, let me ask this, because allied partners have been mentioned multiple times. Can you talk about the importance of allied partners?

Dr. Luck: In this, and many other supply chains, it's hugely important, right? I mean, we – you know, we are a very large country, but, you know, our power is really expanded by sort of the network of partners we have, whether that be Europe, or Asia, or other areas. Hugely important. Hugely valuable. And there's just returns to scale that you just can't get around that, like, there's value to having larger markets, and more certainty. And not only for, you know, pharmaceutical generics, but for the research and development necessary to do the stuff that's, you know, under patent this is true. And for pharmaceuticals, AI, critical minerals, you name the sector that we decide as being critical, like, this is always important.

This is another reason why, I think, you know, look, if you want the certainty about the department, whoever you choose as your trusted partners, you want to provide them with the certainty that the trading relationship will stay somewhat stable, right? That's a problem when you think about 232 tariffs, or 301, or IEEPA tariffs, right? That's a reason – one of the main reasons, you know, that's really great to have trade agreements go through Congress, is that gives a level of certainty that the trade relationship will be relatively stable. So this administration's, you know, inclination to not want to go through those sort of more traditional, stable arrangements creates problems. It creates a lack of certainty that makes it really hard for industry to make investments because of these timelines.

So, you know, again, I think – and I think one thing that's been helpful is that, I think, you know, of course, we can talk about the sort of shocks that come from things like COVID, which are sort of just, you know, out of the blue and no one can really predict. But we have a separate problem, which we're sort of talking about a lot, which is China, right? And that's not a random shock. They can turn this off or turn it on, right? This is a foreign policy instrument. A lot of our partners, especially in Europe, are waking up to that, right? They really have changed their views over the last four or five years. So I think we have willing partners to address these problems in ways that I don't think we did a few years ago. But we need to, sort of, you know, I think put some of the manufacturer tensions aside, in order to solve these sort of underlying problems.

Mr. Burr: So, Jan, you and Andy both are reliant on action by Congress, that'd be a safe? What do you see that needs to be changed, relative to Congress's involvement in, education of the challenge that's in front of the industry, and ultimately, the American people? And I might say, a large slice, probably two-thirds slice, of the global population.

Mr. Boyer: I mean, I would say it's a commitment – I'll go back to the same word. Congress has to figure out how there's going to be a commitment to

companies that can supply the U.S. market consistently and reliably. And that may be onshoring, that may be nearshoring, whatever it may be, and there's got to be a commitment.

What happens most of the time when dealing with the government is we'd like you to do this but the other arm of the government hasn't chosen to procure that product even though they've asked you to develop it over here.

So there's got to be some connectivity within the government and there's got to be that connectivity that says when you do this, regardless of what the incentives are – you can figure that out down the road – we're going to commit to this, and that is the single biggest problem that you get with the government.

Because other than the strategic national stockpile which, to be fair, only works if you've got commercial businesses well, there's very little commitment out of the government from a procurement standpoint. Actual volumes and actual timelines it just doesn't exist.

Mr. Burr: I agree.

Jan?

Ms. Pallone: So I want to go back to some of the statistics that we were talking about earlier. We have two – maybe 250 generic manufacturers that are producing 90 percent of the units of the prescriptions and 10 percent of the cost.

So I think what we need to do is create – and ask Congress to create incentives cost structures that give these 250 or a smaller group of manufacturers who are willing to enter into producing some of these essential medicines in a reliable manufacturing perspective the incentive and the long-term commitment to produce, because that's one of the things that's missing in the generic market today is this – I think Erez talked about it – you know what the demand was yesterday but you may not necessarily know what the demand is tomorrow.

So it's very hard in these low margin environments to produce enough product and be willing to keep the product on hand beyond what you know you're going to be able to sell.

So I think if we can get some incentives in place and also get the private and public sectors to agree that they're willing to take on that additional cost – so incentives, reimbursement, fairly reimbursing so that gives the purchaser enough financial motivation to select these essential medicines from these manufacturers that are creating a reliable supply chain.

Mr. Boyer: The largest purchasers of product in the United States is the United States. VA, DOD, Medicaid, Medicare – that's where Congress could help. Making a commitment for those establishments to buy certain supply chains that they know are going to be consistently available.

Forget whether it's nearshore or onshore, but vetting that out and saying that that's where that product is going to be procured.

Mr. Burr: I'll come to you, too. But let me just present you a reality and if you will offer your suggestions as to how we deal with it.

Certainty and predictability is the subject of both panels. Two-year term in the House, four-year term in the White House, six-year term in the Senate.

Mr. Boyer: Hundred percent.

Mr. Burr: We can have all the stars and the moon aligned for 24 months and all of a sudden the next day it changes. How do we actually get an industry to coalesce and feel comfortable and supportive and invest with a system that's so time limited, potentially?

Can you?

Mr. Boyer: The system needs to fix itself. (Laughter.) Let's be honest.

Ms. Pallone: I mean, today's market is highly competitive in a race to the bottom, specifically in the generic market. So I think without having purchasers aligned, right, because they're competing against whoever their competition is and so they're looking for their best financial situation and so on and so on, right – this cascading effect.

So I think it has to be a holistic approach.

Mr. Burr: I'm going to let Phil comment on this but I'm also going to throw you, Phil, and then to Jan and Andy we tend to look at things like the world is static and we're certainly not static.

So I'd like you to share with us how you see technology and specifically AI changing the landscape – let's go for the next five years, and I'll trust that we can get through two sets of congressional elections.

Phil?

Dr. Luck: You know, does that mean – as I was saying earlier, this is a problem we have in a bunch of different supply chains and this is a huge problem, and, again,

whether it's critical minerals and making decade-long investments or pharmaceuticals this is – we just – our system is not well set up for this.

You know, I think – you know, longer term I think that does make me less confident that sort of a subsidy-based approach is going to work because the timelines aren't there. Maybe you do need some sort of more regulatory approach. You know, but then again, that requires data, right? Because you can – I can subsidize and industry and they get no more secure, to your point. They can – we can spend money and not solve the problem. We're very good at that.

So I would say, you know, maybe we need an update to do appropriate stress-testing, right? Maybe you want to think about part of like the same thing as like a financial industry stress test, right? So I don't know exactly what the solution is, but we need to think about ways in which we can build institutions that – you know, again, maybe they aren't requiring the sort of upfront money from the government but they create the market structure that's necessary to get the industry and able to get the investment back on further finances.

But we do need to solve this. And again, I do think we need to – whether it's this industry or others, we need to find ways to sort of solve that problem.

Mr. Burr: I'm going to turn to the audience in just a second for questions, so I put you on notice.

But address technology and specifically AI and whether it has an impact on generic business going forward.

Ms. Pallone: Certainly Andy has more expertise in manufacturing, but I would definitely say that anytime that we have a complex situation like this, there has to be innovation. And technology and efficiency is critical here because that's one of the things that is bringing down cost and one of the reasons why we've ended up in the situation we're in, right, going to other countries where the cost is lower. If we can harness some of that cost savings through technology and AI, then we can reduce the cost to produce in the U.S., and that helps solve some of this issue – not all of it. Again, you need a holistic approach, but certainly it's needed.

Mr. Boyer: AI and technology absolutely can create value, but creating value comes at a cost. So again, I think it goes back to commitment. If you want companies to invest and become more efficient and become more robust, there's got to be something at the end of that rainbow. And right now bigger companies like Amneal, Dr. Reddy, yeah, they can probably absorb some of that. They're doing it worldwide; we're doing – we're a U.S.-domiciled country – U.S.-

domiciled country in most of our businesses here in the U.S. We can absorb it, but most companies can't.

Mr. Burr: So Andy, is there a public-private partnership that you can point to that would be the example of what we need to replicate across the marketplace.

Mr. Boyer: Today? I can't think of it off the top of my head. I don't know. Can you? I can't think of anything.

Mr. Burr: OK.

Ms. Pallone: (Laughs.) I will – I did want to – I know that Alan's here from Civica. Civica's model – it's not necessarily public-private, but the way that they have created this partnership with their purchasers to create product and have a committed purchasing agreement – you don't see that in very many areas of the generic pharmaceutical world. If we could harness that in some way – now, Civica's nonprofit, so how do you take kind of some of those learnings –

Mr. Burr: You basically told me the generic business is nonprofit. (Laughter).

Ms. Pallone: Yes. I think they would agree with that. But how do you – how do you take a model like that and kind of grow it into something that's bigger, but in a for-profit environment.

Mr. Burr: Let me turn to the audience. Questions for the panelists? It's a free shot at them; I'd take it if I were you. (Laughter.)

Over here? Yes, sir?

Q: Thank you. I'm Bautista Vivanco for the Cato Institute.

I was wondering if you think that allowing compounding pharmacies to create the copies of already commercially available products serve to increase the resilience on the supply chains of America, even as an alternative perhaps. Thank you.

Mr. Boyer: I'll speak to it. What I would say is if we've got an FDA approved product, then the 503B compounders open the organizations, open the country, open up our health care system to exposure. So the 503B compounders are great where there isn't any alternative. If there's an alternative, we should – that should be the gold standard. It's been approved by the FDA. And that doesn't mean there can't be one; there could be several. But the bottom line is 503B compounders are great when there's no other alternatives, in my opinion

Mr. Burr: Other questions?

Q: It's Paul Friedrichs again.

So, first, thanks to the panel. These are some great insights that you all have laid out. And you've talked extensively on the manufacturing side and on the economic side about the need for collaboration. Hopefully this will not surprise you, to hear that the Department of Defense has had a critical medication list for years. FDA has had a list, CDC has had a list, NIH has had a list, and then ASPR had a list. And when we've tried to reconcile those lists, everyone has agreed that their list was right. (Laughter.). As we look at – and I say that somewhat tongue-in-cheek. I'm not being completely fair, but that's the reality.

As we look at how to move forward with the strategic plan, can you say a few words – more granular words about what the federal government needs to do? I mean, you know, it's easy to say we need to collaborate and, you know, we need to coordinate. Those are all true statements. But what are the specific tasks that are unique to the federal government in your opinion that would help us move from platitudes and admiring the problem to actually doing something?

Mr. Burr: Who'd like to take that first? Jan?

Ms. Pallone: I'll take a shot.

Mr. Burr: Thank you.

Ms. Pallone: I think it comes down to common definition. So the FDA, government – they have the majority of these pieces of information. How can we collectively – public-private – come up with one definition that we all agree to that is a critical medicine and/or a product in shortage, so that we can all be concentrating on working together kind of on the same list?

I think the other piece is – I think Heather mentioned this – at Cencora, because we're distributing to these sites of care, we're working specifically with our manufacturer partners on a daily basis, we're – we may be seeing some of that information more real-time, right? It's not as lagged. And so how can we be working together to pull some of that through to bring these situations earlier so that we can react to them faster and potentially mitigate these issues?

Mr. Burr: Phil?

Dr. Luck: I'll – just a few words. I mean, I totally agree we need to get beyond the admiring the problem phase of this, which unfortunately it feels like – we certainly were in the last administration still there.

I'm going to go back to my sort of data point, which is there is just a criminal lack of understanding of these challenges within the federal government, and that's also across partners as well. That needs to be solved.

I'll give you one just sort of small anecdotal example. When I was the deputy chief economist at the State Department, we spent a lot of time thinking about or helping partners think about their vulnerabilities to the PRC economically, helping them understand those. We had one partner who, not surprisingly, had a very high reliance on certain APIs. You know, we could see that in the trade data, by the, you know, harmonized tariff schedule codes, which is what the tariff – that's what the trade data is in. We would then say, OK, we see this problem; now we need to understand what those harmonized tariff schedule codes are in terms of the actual, honest to God, what that API is used for. So let's go to the FDA and do this and figure this out. Months later, couldn't figure it out, right? That is a fundamental problem. You can't go from looking at the global trade data to understanding what needs to be done, right? Until you solve that problem, I'm not sure how you solve these problems more fundamentally.

Mr. Boyer: But even from a procurement standpoint, what we know right now with the data that we have – should the federal government buy anything from China that's considered an antibiotic or an anti-infective? The answer is no. But I can tell you real-time that the decision was made about two years ago, for price, to buy an antibiotic from China instead of from the U.S. So if you want to ask what changes can be made immediately, I guarantee it's on every single one of their essential lists.

So I think there's certain things that we could do. We could block procurement, at least from the federal government, for certain entities that we don't consider to be safe for us long term from a national security standpoint or from an effective standpoint. Because who's to say that that product wouldn't be tainted when they send it over from China? It's a whole host of things that you need to consider.

Mr. Burr: We're going to wrap up to keep everybody on the same timeframe. I'm going to let Andy go and work in reverse for any final comments. But I – just with your last comment, I want to say that – this sort of gives away how long I've been around here – I remember when we – Congress initiated legislation to harmonize with the EU our drug regulatory system, and it took about half a visit before the regulators here said, there's no way that we can harmonize with European countries. (Laughter.) Now, these are our closest allies, yet the belief that we could accept the Italian standard for drug approval in replacement of FDA was unheard of. So we're now 20-some years later and very little progress towards agreement.

We've got to accept the fact that the world is different, but that if there's a common goal that's established that over some period of time we can work to a level of confidence between two systems, that it could be interchangeable.

So, finally, comments – wrap up. Andy?

Mr. Boyer: Yeah. Well, I would go back to what Erez said earlier – you know, the U.S. is by far and away from an innovation standpoint the number one country in the world from a pharmaceutical standpoint of bringing products to market. That's great. That's important. Finding a pathway for the generic industry to be sustainable longer term as well, for biosimilars, for generic institutional, generic retail, is going to be critical to our long-term success. I think you've got players in this room. We know our partners, day in and day out, are willing to work on it. We've just got to get the right people in the room to do so.

Mr. Burr: Great.

Jan?

Ms. Pallone: I made a comment to Andy last week that we've been having this discussion for decades, and so –

Mr. Boyer: She started when she was two, by the way. (Laughter.)

Mr. Burr: I was going to say, then why haven't you solved it? (Laughter.)

Ms. Pallone: That's a really good question. (Laughter.) Because we don't have all the answers, right? We have to work together and we have to start small. But we have to have a holistic end-to-end answer. And it does take everyone. You know, if you want to say it takes a village or whatever saying you want to choose, but ultimately we have to start somewhere. And I think it was Heather that said we have to take action. So whether it's perfect – maybe it won't be, but we have to start somewhere and we do need to take action now because of the situation we're in with China, our KSMs, our APIs. We need to start strategizing on how we're going to reduce that exposure from a national security perspective.

Mr. Burr: Good.

Phil?

Dr. Luck: So I would just – three things I'll say really quickly. The first is, like, I hit the hammer home again in terms of data. We can't solve this problem if we can't see it.

We can't solve this problem without changing incentives, right? You can – we can talk all we want about sort of making more resilience, but unless we provide the right incentives to industry to actually change the way they're doing business, we're not going to solve the underlying problem. So we can make the profit margins bigger without solving the problem, too, right? (Laughs.)

And lastly, I don't think – I will tell you a narrow band of things – maybe we can solve this domestically, but I don't think we necessarily should try and solve this purely domestically outside of certain very particular things. So this needs to be sort of a broader allied solution where there's broad agreement on the basic challenge. Let's use the larger size of our markets to sort of solve this problem at lower cost. Because we've got a lot of other challenges we need to solve as well. So –

Mr. Boyer: Great final comments.

Let me suggest that the homework for not only the panelists but for everybody in the room is, if you have the opportunity to engage with Todd Young or the commission or members of Congress, the takeaway from the second panel is, pick a point to start. Identify what we think can be sort of the nucleus of something good – start there. Design it. See what grows out from that, regardless of how much time it might take. But take the initial step of making sure that we pick an area ripe for change and establish that as the beachhead of this effort.

With that, I thank the panelists today and we turn it back over to you, Steve. Thank you. (Applause.)

Dr. Morrison: I want to offer some thanks, and then some closing thoughts.

On the thanks I just want to give a special shout-out to Richard Burr and Joe Grogan for the moderation they did and the commitment that each have shown to the work of the alliance here. So thank you so much.

To Jan Pallone, Andy Boyer, Phil Luck, Heather Zenk, Steve Colvill, and Erez Israeli – wonderful to have you all here with your very valuable contributions. I want to offer special thanks obviously to Cencora for working with us over many weeks putting this program together.

My colleague Michaela Simoneau has been indefatigable in pulling all these elements together and deserves specially attention and thanks, along with our other staff, Priya Chainani, Sophia Hirshfield, Caitlin Noe.

I think Richard chose the right word in closing with ripeness. I came away from this afternoon more encouraged than I was expecting to be that there was a consensus that this is a ripe moment. This is a big moment, and this appeal, this call to action of get started – I think Heather said most vividly and everybody sort of picked that up – says something.

There is a consensus. There's – across these panels there was a consensus on what the major elements are. And I won't go through every last piece of that, but leadership, commitment – pick your spots, have a select place to start, be very realistic and humble in going about this. This appeal for realism and humility and patience – I like the appeal that Phil brought in about keep in mind this is a transatlantic issue and it should be embedded within our diplomacy on transatlantic. These are markets that are so closely tied that the solutions are going to stretch in that way.

I also wasn't expecting to hear the sense of urgency around the unsustainability today of the generic marketplace and that that is a danger and a threat, but it's a motivator. It's something that allows you to sort of say, we've got a serious immediate problem; we need to begin to push for solutions.

I liked the focus on fixing the data problem, the visibility issue, and making sure that the incentives are there as a first matter of priority.

Just a few cautionary thoughts: How do you make the case that we're talking about here outside of this room? We know that our national debate is extremely fraught and crowded at this moment, so how do you make that case? Richard said go to Congress and make that case. I think that's wise. But we've got a very crowded field. We could use I think a much greater unity and focus coming from within industry itself as a force to try and bring greater coherence and greater clarity that there is a consensus emerging within industry. That would be a very important element.

Obviously we're in a moment of fear in this moment of tariffs. There's a certain understandable reticence and caution in stepping forward and talking about the need for an industrial policy in this period in which there's a fear of tariffs and there's a fear of being targeted. There's a fear – there's a caution and reticence that's settled not just into this sector; it's in many other sectors where we have universities, law firms, media, and others.

The other political reality which Richard didn't touch on much but I'm sure he could share with us more – there's an art politically to making the case to Congress on why Congress and the American people have to subsidize industry in the pharmaceutical sector. That's a tough – that's a tough proposition politically and it's one that can be done but it has to – you have to have a pretty clever political strategy to bring that forward.

We're saying we should prioritize Congress, but that does not mean exiting or not pursuing a strategy of engagement with this administration. Ultimately it's going to be the leadership within this administration that's going to break the ice and move this forward with the urgency that we're looking for, so I think we need to focus really on both fronts.

So thank you all. This has been a terrific occasion here today. And thank you all who are here in person and those who are joining us online. The video will be posted on the CSIS website. We will add a transcript in another day to that, so you'll have access to this and it can be shared widely, as we hope it will be. And you've given us a lot to think about, and we want to stay engaged in this.

And I – so we're adjourning now. There's coffee and refreshments outside, so please – I hope many of you can stay for another half-hour or so to catch up with one another. Thank you. (Applause.)

(END.)