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BUILDING RESILIENCE: ENHANNCING BIOSAFETY, BIOSECURITY, AND PANDEMIC PREPAREDNESS

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WELCOME:

SANJAY PATNAIK
Bernard L. Schwartz Chair in Economic Policy Development, Senior Fellow, and Director, Center on Regulation and Markets, The Brookings Institution

KEYNOTE AND FIRESIDE CHAT:

THE HONORABLE GARY PETERS (D-MICH)

MODERATOR: SANJAY PATNAIK
Bernard L. Schwartz Chair in Economic Policy Development, Senior Fellow, and Director, Center on Regulation and Markets, The Brookings Institution

CONVERSATION:

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Vice-Chair, National Security Commission on Emerging Biotechnology

MODERATOR: AURELIA ATTAL-JUNCQUA
Policy Researcher, RAND

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Former FBI Senior Scientist

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MODERATOR: SANJAY PATNAIK
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PATNAIK: All right, good afternoon everyone. I hope you can hear me. My name is Sanjay Patnaik. I lead the Center for Regulation of Markets here at Brookings. We are in the Economic Studies program. It's a real pleasure to welcome you all here in person and virtually, we have a big audience virtually, to this event that is in a policy area which I think is one of the most important of our lifetimes. We just lived through a horrible pandemic, one of worst in modern human history, with millions of lives lost, one million in the United States alone, and significant economic devastation. And I think what is important to keep in mind, even though the pandemic has shown us that we have the cost expressed in human lives, in societal disruption and in damage to our social fabric, it also was a real black swan event in terms of economics.

If you look at the economic damage that this pandemic brought around the world. To this day, economies around the word are feeling the aftermath with inflation, higher prices and the instability that it brings. Although my center does work on AI and climate, I've worked on climate for almost 20 years, what really keeps me up at night is the possibility of another pandemic. Maybe with a pathogen that is more deadly than SARS-CoV-2. And I think that the risks from biological threats are actually one of the largest that we're facing right now. There are three main ways, as we know, that a next pandemic could emerge. One is a natural spillover. Which we might be witnessing soon with a bird flu as it is spreading through the cattle herds in California and other parts of the country, a lab accident which multiple institutions, including the FBI, think was the most likely cause for the COVID pandemic, and intentional misuse of bioterrorism. As these threats persist, it is becoming clear that we need better ways to prepare and to deal with the pandemic. And our event today is a first step in a work stream that we are launching on biosafety and bio resilience. And really looking at how can we prepare our country, our economy, for the next pandemic.

With this, it is a real pleasure to welcome Senator Gary Peters from Michigan. In the current Congress, Senator Peters serves as the ranking member of the Senate Homeland Security and Governmental Affairs Committee, which oversees the Department of Homeland Security and is also the Senate's top oversight committee. He also serves on the Senate Appropriations Committee, the Armed Services Committee, and the Commerce, Science, and Transportation Committee. And he's recognized as one of the most effective and bipartisan senators and biosafety is one of his big areas

of passion where he has done some really incredible work in the senate. Please, can I ask you up on stage? A big round of applause. Thank you so much for being here. I know you're very busy.

PETERS: Good to be here. Yeah, thank you.

PATNAIK: So, what got you interested in biosafety and biosecurity as a legislator? It's not a topic that a lot of people are working on, but it's incredibly important.

PETERS: Everybody's not working on it? Well, there isn't a lot. We need more, though. That's part of it, is to have a whole lot more. Actually, I've been thinking about this for a long time. My first work in biosecurity and with biological agents that could be used for nefarious purposes was back when I was in the State Senate, which was a while ago. In fact, I passed the first legislation in the state of Michigan. This is in 1998. To actually make it a crime, which I was struck that wasn't, but a crime to use biological agents, or the threat of biological agents or chemical, radiological, and made it and put it into state law that if you did a hoax even, if you threatened that there might be a biological agent, particularly in a vulnerable place, like a school or daycare centers or enhanced penalties, but you could actually be prosecuted for that. That did not exist. And then, of course, later we had things like the anthrax scare and everything else that came up afterwards.

So, I'd like to say I was focused on biosecurity before it was cool, and passed that legislation. So, I've been thinking about it since then, but right now I just think it is absolutely essential that we think about this. And if I just kind of step back and think about where we are as a country, at least that's how I view it, I think we're living in the most exciting time in human history to be alive when you think about the emerging technologies that have come out and are continuing to come out, from artificial intelligence to synthetic biology, nanotechnology, we just go down the list. All of these things are gonna transform our society in ways that we can't really fully imagine now as much as we try to imagine it. And there's wonderful, all of everybody in the audience don't see me, there's a wonderful opportunity for us to cure diseases we thought we couldn't cure and have new applications that we didn't think were possible. But unfortunately, like all technologies, there's, it's dual risk.
And so, we also have to worry about how it can be used. And unfortunately, in the biospace, it can be used in your introduction, you know, can be used as weapons and weaponized. But even those who

are not weaponizing it, we understand after the pandemic, how catastrophic it is to have one of these kinds of events. The unfortunate thing is we look at that this won't be that we won't that wasn't the last pandemic, there's going to be more. I hope it's at least 100 years like the last one, but there's no guarantee that that's going happen. We better be prepared. That's why my committee when I was chair for the last two cycles, and it's better to be chair than ranking member. But when I was chair for those two cycles that we did a number of investigations. So, one was to look at COVID, particularly in the response. But it was interesting because it started actually before the pandemic. We did an investigation into drug shortages that occur all throughout the country prior to the pandemic, you know, we have hospitals, as many of you know hospitals that actually meet on a weekly basis because they can't get a particular drug, there's a shortage, but they still have got to figure out how they take care of their patients, and the solution, they always find a solution, but it usually costs more money and is less effective. Not a good solution.

And so, we investigated that and looked into the fact that basically we're overly dependent on foreign sources for these critical drugs and sometimes just generic, plain old, nothing really exciting, but are all produced overseas and most of the precursors are Chinese or Indian. A long story in the report, we came out with our conclusion at that time was if there be given on what we found, if there, or when I should say, we said when there is a pandemic, we're going to find ourselves in a very precarious situation. Six months later, my academic study about when unfortunately became real, and we were in the middle of a pandemic and we saw exactly what happened. We couldn't get the medicines. You couldn't things like swabs and masks and, you know, ventilators. Because it took a lot of worked to help them. In my area in Michigan, we had auto companies that suddenly started making ventilators, and we all had to come together. But it showed that we weren't prepared. And I'll just say, this is a long answer to your question, but unfortunately, I still think we're not prepared.

And that came out of our later study afterwards, to look at what happened, what are the lessons learned. I know many of those lessons you're looking at right now, and I want to hear from all of you over the course of your meetings here. But that we still have more work to do to protect the American people and people around the world from these kinds of events. And so that's why I've been interested in it and will continue to work on it. I have a partner, the chair, Rand Paul, is now the chair of the committee. He's very interested in these topics as well, particularly when it comes to risky

research, and I think we'll probably talk about that here. So, I think there's ways that we can come together on a bipartisan way. Uh... It's not easy getting things done and Washington right now I'm sure it's a surprise to all of you here uh... But it's uh... Very difficult uh... But I I'm hopeful that we're going to be able to do some good work uh... And look forward to working uh... With you Brookings and all the folks here in the audience I'm here uh... Want to learn from I if know you're asking questions here but after I leave here I want to learned from all of your to give us ideas how do we take these ideas and put them into tangible public policy and actually if it that requires legislation. How do we get that passed, or how we work with the administration if it's some other avenue.

PATNAIK: That's actually really encouraging. You mentioned a couple of other technologies in your introductory remarks. What other technologies are you tracking? And kind of like what legislation have you worked on?

PETERS: Well, the one-.

PATNAIK: Because I think there's a nexus between a lot of those, right?

PETERS: Yeah, and as you know, and everyone knows, I mean, there's all of the emerging technologies, all kind of intertwined right now. And when you're talking about AI and biology, those things are together so much, for example. But some of the areas that I've focused on, one, I think from a from Senator from Michigan, of course, is with automobiles. And the big technology is self-driving vehicles, so autonomous vehicles. I've done a lot of work on that to get to that which requires AI systems to be able to process massive amounts of data that we get from our automobiles and to drive, eventually, drive a car through New York City or Washington, D.C., or right out here on our way into the traffic, to do that safely. Many people think that's a moonshot for AI, when AI can do that and process that data and move it safely to make that a reality.

So, we've been working on legislation to allow that to move forward, which is, when you're talking about regulation, there's probably very few places as regulated as highway traffic safety and automobiles, and how do you allow a car that's going to go down the city streets safely? When you think about all of our regulations are designed for humans in control of a car, but now you're going to have a machine. So, for example, under the federal laws, you have to have the steering wheel in your

car, which is really a good idea. If you've got a human, you should have a steering wheel. But if it's a machine, you're not. You have to have brake pedals, but to change that can take years, and we're trying to accelerate the emerging technology in a safe way to allow it to be put out on the streets, and I'll just end quickly on this part, but is that when you think about it, every year we have close to 40,000 people who die on our highways, so over 100 people are going to die today on our highway, and many more are going have debilitating injuries, and our engineers believe they can eliminate most of that. It's a really big deal. But how do we get there? How do we pull all that together and also have people have confidence in that?

The other area that is all aligned with that, as well as with Bio, is cybersecurity. So, we're the top cybersecurity committee, Homeland Security overseeing CISA. And if you don't have security, an autonomous vehicle, for example, if someone hacks your car. That could be, it's not just someone stealing some money from you. It could be existential to drive you into a wall, which would be really bad. So, you need to have a very robust cyber systems in order to do that. Obviously in biosecurity, the most significant legislation that we passed that I wrote, that we did in the previous Congress, was an incident reporting bill that requires companies of critical infrastructure to actually report that they have had a cyber-attack. That wasn't easy. A lot of companies don't want to report that for a variety of reasons. But as we talk to the FBI and talk to others, I mean, they are saying we only have about 40 percent visibility of the cyber-attacks in our country. And if you're going to war, you better have situational awareness, know where the bad guys are, what they're using, how they're doing it. We don't have that. So now that report comes into CISA in the Homeland Security. We have a better idea of situational awareness to go forward and I'm happy to say the Washington Post actually said it's the most significant cyber-legislation ever passed in history. So, I said take that George Washington and Abraham Lincoln, I mean we did the most significant. But now with that we will have an opportunity to strengthen that which as you mentioned it touches bio as well in a big way.

PATNAIK: Yeah, for sure. And so maybe we can stay a little bit on the threat of external actors on China, right? Like you co-sponsored legislation on protecting Americans' privacy and health data by cutting off taxpayer funding to Chinese biotech firms like BGI. Can you talk a little about that effort and what prompted you to go in this direction?

PETERS: Yeah, a prompt to that is that we know that the most important thing when you're looking at, as I see it, advancements in biotech is you've got to have massive compute power, but you also have to have a massive amount of data. Data is power. AI systems, the more data, the better, as long as you can work the data and it works. If that's the power, and you think about where the world is today, it used to be land was wealth, it use to be oil was wealth. Now it's data. And the more data you have, the more power you have if you're able to then use your compute power with your algorithms and systems to go forward. And so, we know that the Chinese get that, and that's a major competitor for us. They understand that power and they're collecting that data. They now have the largest database of genetic information in the world. They collect it from all of their citizens. In fact, my understanding is if you were born in China today. You have the gene sequencing done that goes into the system for the Chinese government. So, they know every single person.

They acquire other genetic data on open sources that are available, and they're continually collecting that. But then with – based on our intelligence community, they also collect it in other ways, including having sequencers in the United States that are working for a physical entity of some sort here in the country. But then that data ends up in Beijing as well. And so, as that information's coming, you are now collecting information on U.S. Citizens. And our genetic data is particularly valuable. It's very diverse. It's a really great data set you should have, but you shouldn't steal it from folks who are not providing that to you. And so that's where the Biosecure Act comes together. Bipartisan legislation, I'm working with Senator Hagerty in the Senate that basically says if you have a system from one of the companies that are identified as a risk, BGI is probably the top of that list for that, you can't get any federal funds for that. You'll be cut off so that you'll have to find another provider for that, and there are other companies as well that would be in that category.

So, we introduced it. We passed it out of the Senate. There's a House companion. The House made some changes and we've been working closely with them. Changes as to kind of making sure there was a runway that people could react to the law, particularly to make sure that people on Medicare and Medicaid and other kinds of services were not being impacted. We want to make it's not hurting people. We wanted to give a runway for that change to occur, was part of it. The other tricky thing too is that company, if you're just naming a company we all know a company can go out of business and another one can start up and it's the same company, but it's just, you know, then you're playing whack-a-mole basically all the time with these as well. How do we have a mechanism then to protect

folks to go forward? So that's in the House. It didn't pass in the last Congress. We are continuing to work on that bill, and it is my intent to reintroduce it. It will look a little different, but we're working in a bicameral, bipartisan way. It's also possible that the administration could do it without legislation, and so we're talking to the administration, but I think this is an important bill that I think we have a path to get it passed, and we will hopefully be reintroducing something in the near future.

PATNAIK: And I think it's going to get very relevant with a bankruptcy of 23 and me, right? Like we're going to see where all that data ends up. So, when we look at the biotech sector that we currently have, what other biotechnologies do you see where people should be really mindful of the risks? The genetic data I think is a big one that people underestimate, especially if it ends up in the hands of China. What other technologies do you in that space that are risky?

PETERS: Well, you just mentioned a great one, the example of 23andMe is certainly an example of that. People don't, I think it's kind of new with some of these, or not unusual rather, with new technologies. They're really kind of exciting and fun, but people don't realize what they're giving up to do it. So, you had 23andME and you could have this scan and know your ancestry and know all sorts of things about their genetics, which is really pretty cool. Great. But now you've given a lot of information to a company that is, and that information, as I mentioned in my opening comments and everyone here knows, is incredibly valuable. Incredibly valuable for that data and what are kind of the safeguards there. And now, as you mentioned, the company's going under. What's going to happen to that data? Who's going get it? That should be a real concern. That's why I'm working actually on legislation right now with Senator Cassidy from Louisiana, Republican colleague of mine. Uh... To uh... Have protections that someone if you have given your data you can get it back you can have it destroyed uh... You can safeguard because you have no idea where it's going I think we got to go more this is kind of uh... Response to the 23andMe, but we should probably thinking about putting safeguards up front for people before they get into other companies that are going to be like 23 in the and others that to collect information. And how do we institute kind of consumer protection when it comes to genetic data, and not just rely on disclosures and waivers that you sign. You know, when you take out that, people sign things on 23andMe, like I understand I don't have control, all that kind of stuff.

That doesn't protect people. We have to have consumer protection, I believe, and we'll be looking at other legislation to prevent that from actually occurring, where people unknowingly are giving pretty valuable information away to get a service that is. Valuable to them, but not as valuable as the information they're giving away. And I just say, you know, I have an example of consumer protection of how those laws work and how that can apply to bio, and I'll just use the example of a toaster. You know, we have consumer protection regulations that protect you from being electrocuted by your toaster, we don't say, as long as you give a copy of the schematic to a customer and you're okay with it, that matters, so it's like after the toaster electrocutes you, you'll say. You should have looked at the schematic and seen that after five uses it was going to electrocute you. No. There's consumer protection that doesn't allow that to happen to begin with. How do we do that in the biospace as well? Because these are technologies that are valuable and can be used for nefarious purposes and the consumer has the right to know.

PATNAIK: No, I totally agree. And so, let's kind of move into the biosafety space. And you co-led a report in 2022 that made a lot of recommendations how we can improve biosafety in the United States, including like cross-government preparedness, clarifying the agency roles, et cetera. Where have we made progress since then? How many of those recommendations have we actually started implementing? If at all.

PETERS: Yeah, so it's we had I'm gonna get my memory. I think there were 17 recommendations. My staff is nodding. So that's good. 17 17 recommendations we made in the report. And I think six to seven are in some phase of that. You know, we had the Pandemic Preparedness Act, which took some of those recommendations, although none of them have been fully implemented. And I think, you know, if I look at that act, it was a good first step. An important step. We have to go further. Probably the biggest issue with it is we got to have funding, so there's got to be more resources put in. But there's still a lot of work to do. And if I were to kind of characterize what we really need to work on when it comes to biosecurity and with COVID, what happened under COVID is we have to have more robust surveillance systems to be able to really know what is out there and act much quicker than we saw happened in COVID. It was too slow.

How do you do the sequencing? How do you get through it quickly to understand the scope of the problem, and we know all the problems that have occurred there. I think your folks have talked about that previously about that. And we're not doing, and aren't doing the better job in surveillance. We're seeing that in the bird flu, if we talk about that, it's just there's not enough surveillance aggressively happening I'm also worried about it globally, because, you know, a lot of these pandemics will start somewhere other than the United States, and they get here, could start here in the United States, but they'll come from – you've got to look at this. Surveillance has to be global. It can't just be within our own country. I just got back from Kenya, a little jet lag right now, but got back from Kenya. And I will tell you, folks were concerned, because there's quite a bit of surveillance that goes on in Kenya. Uh... And right now, there's no MPox that is uh... breaking out uh... In Kenya, uh... And yet because of the cuts that we're seeing from the current administration with USAID and others but they're really worried that that surveillance will not be there absolutely crazy to think that we are not putting in that kind of surveillance not just in Kenyan but around the world including here in our country.

It's because the cost of not catching something early is as we know, we've lived it and we've lived that nightmare. That could happen again, so that's critically important. The other element that is important is that it was when I mentioned earlier about having the ability to have supplies on hand and to have them local is to have a very robust manufacturing ability to create the what is necessary if we go into a pandemic. We didn't have that in the COVID. And we were relying on foreign sources and foreign sources are gonna use their material for their own country first as we would use it for our country first. Don't begrudge them for doing that but that's why we have to make sure we have that capacity here for all sorts of essential supplies, whether they're pharmaceuticals, but even things when we think about in the pandemic, we didn't have like syringes and just really common stuff, that that has to happen here and we still have not made progress in that. And then to the bird flu example, the same thing is happening. We're seeing that in my state. This has been spreading. We actually now have, I think we have one fatality already. Other people are sick. We have some in Michigan as well. It's a pretty scary thing. We're familiar with bird flu. It's not the first time it's been out there. It's still there. But I was just in Michigan with folks who raise pheasants for pheasant hunting and he was saying that it was how scary it was that they basically lost, I think, a thousand birds in like three days that were all killed. And then they went through and they cleaned the facility.

They thought they did just a thorough job of cleaning that and put in new birds and it got infected again. They lost another thousand birds. So, this is pretty scary stuff. We have one of the largest egg producers in the country, is Michigan. They provide, when you're eating an egg McMuffin, that's those are probably from Michigan, with this particular farm. And they've laid off half their people as a result of that over part of this because of the impact of it. And now, as you know, bird flu is a little different in that it's crossing over into cattle. And when you have, we have to be thinking of this differently. And the surveillance isn't there. You see this administration not putting that. They're not sharing information like they should. We've got a health secretary that's saying, why don't we just see how many birds have natural immunity? You know, like what? Like, 90 to 100 percent of them die. That's not a whole lot of natural immunity. That's a crazy, that's not strategy. It's crazy. We have an Ag secretary who says, maybe people should raise chickens in their backyard, which is not really a solution, and you worry about raising chickens in your backyard and the potential for wild birds infecting them. That is, those are not plans. And so, we have not learned anything from the pandemic and thinking upfront, if you look at what's happening now with this avian bird flu.

PATNAIK: That's quite disturbing actually. Let me also-.

PETERS: It's very disturbing.

PATNAIK: Let me talk about a second aspect of that, which is risky research. So, we've seen, I think it has come out over the last couple of years, that there is risky research going on in different labs around the country, around the world. Does this need more oversight? And what are some of the gaps, especially in the oversight, for instance, private labs, right? There's not much regulation, much oversight there. And so, I'm really curious to see how you think about that, because this is another source for a really potential pandemic for the next one.

PETERS: Yeah, absolutely. And I think I mentioned in my opening, that's an area where I'll be working with our current chair, Rand Paul, who's very interested in this as well, and he's right to be interested, and so am I. We're working on legislation right now to deal with that. There's no question, and he's particularly focused, and I am, on gain of function research, is that when you're doing gain of function, you're really, as all of you know, you are playing with fire. You're going to be making viruses

even more virulent. I understand the reasons for that, and there are really good reasons for some people to do that. But I still think you're playing with fire, and you probably shouldn't be doing that, because it's an incredibly dangerous thing. But if there are good reasons, then there should be some sort of oversight before you are engaged in that. So, what this legislation does is still a work in progress, but require we have an independent board that you have to bring your research forward, to have them evaluate and to determine whether or not to go forward to get federal money. Otherwise, you're not going to get federal money to do that research. But if they say no, you can't do it. And every agency has to abide by how this board has ruled on that.

There's also a pretty strict oversight of the people who are on that board to make sure there isn't a conflict of interest. There's always concerns that the people who are making these decisions also have some sort of other interest in that research, which is simply unacceptable. So, to make sure that it's truly independent and then they can make determinations as to whether or not that risky research or that gain-of-function research should be done. But it's got to be an incredibly, incredibly high standard. But we also want to look at labs generally. There are a lot of labs out there that are doing very high-risk research. So, what are the protocols they're using in safety? My understanding, and folks can correct me, but my understanding is most of the biosecurity protocols used in these labs were designed back in the 1950s and 60s. Now, I think the 60s was a great decade, but I think we could probably should look at it again now. Now there were where we are to see whether or not some of that stuff should be changed. But there are probably roughly 70 plus labs that are doing high risk research right now and 25% are private. So, it's a little more difficult to be able to oversee that. And what I'm really concerned about some of these high-res labs, there's a lot of pressure, a lot a pressure for advancements in bio products and biotechnology. Biotechnology is for all the things I said at the beginning and all the promise for this tremendous rewards for folks. So, there's lot of a pressure to be first and to be get the product out there. It's not just in the United States, it's China and other countries that are doing that. And so, when there's a big incentive... To produce uh... biotechnologies, there's also an incentive to take shortcuts and if you take shortcuts it could be absolutely catastrophic and so we've got a tighten that up.

PATNAIK: And how do you do that for private labs and for private funding? Would that be an independent agency, again, overseeing that, if you do any type of that kind of research, almost like a nuclear oversight?

PETERS: We may. So, I think that's, you know, that's where we've got to figure out how to do that. And that's why we'd love to have folks, you know, help us try to think that through exactly how we get that to happen.

PATNAIK: That's super important, and I'm glad you're working on this. We're almost at the end of time, so one last question. You've been a senator for 10 years now. You have two years left, and so can you talk a little bit about what you try to accomplish on biosecurity, which is related to biodefense and national security, which an aspect that we haven't covered yet so much?

PETERS: Yeah, well, I think in the time that I have left here, I've got a couple things. One, first off, we've got to make sure we fund it. As I mentioned, funding isn't there to do the kind of biosecurity stuff. I will tell you, it's an incredibly challenging environment right now when it tries to come for funding. We have to make the case that this is an absolutely essential investment to make, because if you don't make the investments, the costs far outweigh anything that we're going through. But we've got to put in the surveillance, we've gotta build the manufacturing capacity, we've gonna be able to surge all of those things that came out in our report that needs to be done. We actually have to start implementing. We actually to make that go forward. And I think we also wanna make broader investments in biotechnology as well. We just passed the Chips and Science Act through Congress, understanding that the chips and semiconductors are absolutely essential in the modern age and whoever is able to produce those domestically will have a tremendous economic power. It's the same with biotech. We should be viewing this in the same way and maybe a chip sack for biotech is something to take a look at where we're investing in the capacity for bio foundries. We have the capacity to make sure we're developing the talent in this country locally to be able to be in this industry going forward. I think those are important.

And then one last thing that I think about, and I'll just say it briefly, is that we have to think a whole lot more about ethics, the ethics of biotech, and what does this mean for humanity? I mean, you think

about how it changes the essence in some ways of who we are as humans, potentially. What does that mean for us as a society, as a culture? What does it mean for the future? And if you have genetic engineering and you're creating people who are smarter and faster and stronger, uh... How does that work and if we don't believe we should be doing it here what if our competitors and other countries are doing it think of super soldiers uh... Uh... You know all the kind of ways that people could think about that uh... It's down the road but we it's a mistake not to start thinking about it today for what are likely scenarios in the future.

PATNAIK: I totally agree, and I really am glad that you're doing this important work. Thank you so much, and thank you for sharing your insights today. Thank you.

PETERS: Thank you.

PETERS: I'm going to ask our next speaker, Dr. Rozo, please, and our moderator up. And then we're going to have a break, and then I'm gonna go into the panels.

ATTAL-JUNCQUA: Good afternoon. Please have a welcome Dr. Rozo, who is currently serving as the vice chair for the National Security Commission on Emerging Biotech. Dr. Rozo is also the vice president of technical capabilities at In-Q-Tel, and previously she was the director of technology and national security at the NSC at the White House, as well as the principal director for biotech within the office of the undersecretary of Defense for Research and Engineering at DOT. So, you have a wealth experience and expertise on this topic. So, we're very happy to have you here with us.

ROZO: Thank you so much for having me.

ATTAL-JUNCQUA: Of course. So, my first question to you, first of all, congratulations on the reports that just came out. Very exciting. And the report highlights both opportunities and challenges in the biotech landscape. At a high level, we'd love to hear about how you worked towards understanding how biotechnology can help us with pandemic prevention and biosecurity, as well as the security of sensitive bio-data.

ROZO: Well, first of all, again, thank you so much for having me. Really nice to be with you today. As you said, I'm Vice Chair of the National Security Commission on Emerging Biotechnology. Maybe I'll step back just a moment and explain who we are for everyone. So, you can think of us like a legislative advisory board. We were created by Congress for Congress to advise them about the state of play of emerging biotechnology and national security. So, there's 11 of us serving as commissioners on this legislative advisory board. We're a group of subject matter experts. Of former senior government officials and four elected bipartisan members of Congress. And we've just finished, as you mentioned, two years of work reviewing the state of play of emerging biotechnology both here and abroad. We spoke with over 1,800 stakeholders spanning 30 different countries to come up with, what is frankly a very sobering conclusion, which is that without U.S. action, China will become the global leader in biotechnology.

So, we lay out a series of recommendations to prevent that from happening. And this is split between running faster and slowing China down. And ultimately, we recommend spending $15 billion over five years to ensure that the U.S. Can remain the leader in biotechnology and in some areas regain it. And so, you know, this is really important that the U. S. remains in the lead for of the things that you described, because biotechnology can be used for immense good, but also for immense harm.

ATTAL-JUNCQUA: That's right.

ROZO: And so, it's why we feel so strongly that the United States needs to remain in the lead of this technology. And part of that is leading with our values at the forefront and leading with a commitment to safety and security and responsibility to prevent against misuse. But I will say we took a look at our existing policies and found that there were gaps in our ability to do that. And so, we lay out a major recommendation to address that issue that we found.

ATTAL-JUNCQUA: Yeah, in section 4.4 of the report, you actually mentioned that the current oversight tools in the US are blunt and reactive. We'd love to hear more about what specific tools you looked at to come to the conclusion, and as well, what are your recommendations to make them more adaptable and flexible so that they can keep pace with the advancement in technology. And...

ROZO: Exactly, I'm just going to show the report. Please take this out, it's at biotech.senate.gov for the full version. I'll put that to the side now. Thank you for mentioning that we did describe that the existing policies are blunt and reactive. I think it's helpful here to walk through an example. This is really the approach we took throughout all of our process was to identify problems that we saw, come to a consensus around how to describe that problem and then work towards bipartisan solutions for how to address it. So, let's take gene synthesis security as an example because it's been talked about a lot recently. We recently made some great progress in moving forward with oversight around this area. But I think industry, academia, government, and the national security community would agree together that we're not yet where we need to be.

The existing policy that's in place, it can in some ways hinder innovation, it's difficult in some way to implement, and at the same time it's not going far enough to mitigate the risks that we see, and so there's an opportunity to continue to evolve in this area. So, let me walk through this in a couple gaps that we found as we looked at this area, so gene synthesis screening and gene synthesis broadly, even stepping back one more layer, is a pivotal point in the bioengineering workflow. And as we all know, researchers dream up exciting things that they could do with biology. New capabilities, new functions that they want to put into living organisms, into test tubes in order to create new products and capabilities. And when they're designing this, they're doing this at the level of DNA. So, they're writing A, C, Ts, and Gs, new code that will create that functionality. And gene synthesis is this part where that design goes from virtual to physical, right? It's the actual writing of that DNA using machinery. And many times, today, while this could be done in the lab, it's done using big commercial service providers who get sent these sequences from researchers and then print this physically on machines and then send that back, right? And because it is this digital to physical transition, it's seen as a really optimal time to put in security measures because the design by itself can't cause harm, but the physical thing could, right.

So again, a policy is put in place that took a great step forward here. And now if you are a researcher that receives federal funding for life sciences, you have to use a provider, a DNA synthesis provider that attests to screening against sequences that we know could cause harm. And there's some other components of that as well. So again, a really good step forward. But what are the gaps that we still see? So first, who's in the lead? Well, there are a number of federal agencies that are responsible for

this policy. You have HHS, Department of Commerce. Department of Justice, FBI, Elements of the White House, did I mention DHS? If not, I should. So, there's a number of them, which means that there is no one entity that has this as their full primary responsibility. Okay, is it going far enough to address the risks in the technology we see today?

Well, no, because right now we're only screening against things that we know could cause harm. But we also know that with the convergence of AI and bio, we can design things that have similar functionality. But have completely different DNA sequences, right? And while there is the process in this policy to eventually move to screen for things that could cause harm, we don't really know how to do that yet. Okay, so how do we test is it working? We can't do that right now. There's not a good way to test for any of the issues we might see. Another gap we found. What happens if something goes wrong? Who's liable? Unclear?

ATTAL-JUNCQUA: That's a good question too.

ROZO: And then finally, how does this keep pace with evolving technology? We'd have to redo another policy, we'd have to legislate something new, this creates a lot of political will to get that done. And it doesn't even begin to address any other of the areas that we might want to talk about. Gene drives, mirror life. And you could ask these same questions about each of those things and come up with very similar gaps in our ability to oversee it. So that was sort of the process we went through one by one and realized we can't do this one by. We have to come up a better way to really solve this problem in totality.

ATTAL-JUNCQUA: So, I guess my next question is, what is the solution here?

ROZO: And I'm happy to share our recommendation. So, we recommend consolidation, a deduplication, and a streamlining of existing federal authorities for biosafety and biosecurity into one entity, which for the purposes of today's discussion, we can call Biostar. And Biostar would have three primary functions. First, it would have the ability and the authority to innovate in biosafety and biosecurity to fund leading research in the capabilities around this technology with industry and academia. And I should note that we recommend that Biostar be funded at a level of a billion dollars

over five years. The second function that this entity would have, that Biostar would have would be to evaluate vulnerabilities on an ongoing basis and where gaps in our governance exist.

And then the third function would be a couple of those two things together with regular iterative responses and updates to our existing guidance and regulation, work with industry to do those periodically, and in doing so, take what is now seen as a compliance burden into an economic driver, really ensure that biosafety and biosecurity is at the forefront and push forward this technology, but do so in a way, again, that aligns with our values and our commitment to responsible use. So, I can walk through this in a little bit more detail, maybe back with the gene synthesis example and go back through those questions again. Now with Biostar in place. So, who's the lead? Easy, that's done, it's Biostar, right? We've consolidated and we've de-duplicated the existing components all across government into one entity.
So, this is a streamlining of existing functionality at the government. Is it working to address existing technology, the risk that we see with technology today? This is where function one comes in. We would have Biostar fund leading edge research on the sequence to function problem when it comes to gene synthesis. So, the ability to understand how you predict if a sequence could cause harm, which again is a gap today that we don't know how to solve. And so, for the gene synthesis problem, we need to be able to solve that fundamental research problem in order to effectively do synthesis screening with the technology.

ATTAL-JUNCQUA: Yeah, we've heard in the past from providers that there are a pretty large percentage of sequences that come in in orders that they don't know what they code for. That's right. So that's a big issue.

ROZO: That's correct. And in order to solve that, we need to do – we need research around it, right? And this has to come from government. There is no incentive for the private sector to solve this alone. The third question we asked is, you know, how is this working? How do we test if it's working or not? And that comes to the second function of Biostar, which is the ability to stress test the system. So Biostar would have a governance sandbox. It would carry the liability and the ability stress test the systems. For DNA synthesis screening, think of sending in a controlled fashion sequences that we know could cause harm to customer, to commercial entities, and then again being able to walk

through in a control fashion how far along that process those sequences would get. Do companies make them or can they detect them and stop that process and work with those companies to be able to mitigate again and ensure that if there are gaps that those are being addressed.

There would also be a no-fault reporting system similar to the aviation national aviation system. So, a systemic way to understand where things are going wrong with the goal again of addressing them until thing before things spin out of control and then what happens if something goes wrong? We recommend that Biostar have the ability and the authority and the mandate I should say to create an independent advisory board similar to The National Transportation Safety Board and this bio-incident response entity, would have the ability to respond after a biological event, would be mobilized, be able to go to the incident, have the authority to understand what's going wrong, and be able bring those learnings back into the system to ensure that we're not making the same mistakes again. And then finally, what happens as technology develops, and this is really the third function of Biostar, which is the integration of all of those things with those. Iterative updates to the process. And so, you don't need to create a new Biostar for gene synthesis and mirror life and, you know, gene drives.

This entity would work on all of these topics, would do so with the resources that the federal government entities like the national labs, NIST Commerce, the technical expertise and integrate that with industry and academia. And again, I just want to stop and thank, you know, many of the folks in this room across, you know, who have worked in biosafety and biosecurity for a long time, who helped our team craft these concepts and worked with us over the last two years to shape this into something that, you, know, is ideally meant to be an evergreen entity that can evolve as technology evolves.

ATTAL-JUNCQUA: Great. And where would this new entity sit and how would it connect and work with the broader federal government?

ATTAL-JUNCQUA: So, we recommend that it's placed inside the Department of Commerce, but look forward to working with Congress on that. We also have recently introduced legislation – one of our main recommendations in the report was finding that at a broader level, the U.S. Government is not prioritizing biotechnology and doesn't have effective means to coordinate for it. So, our congressional commissioners introduced a bill that would create a national biotechnology Coordination Office at the

White House. And this office would be able to look across departments and agencies, and Biostar would work through that, again, to be able do that coordination with all of the entities that have a stake in this issue set.

ATTAL-JUNCQUA: And to be fully effective, would it require certain, like, legal authorities or actions?

ATTAL-JUNCQUA: Definitely. So as our audience, as I mentioned before, was Congress, we specifically oriented our recommendations towards things that require legal and congressional action. And so, we have 18 months left on our statute as a commission. So, we've released our report a few weeks ago. We don't just drop dead. We continue to exist and are now hard at work with and with members to get these legislation ideas shaped into bill text. Introduced into Congress and ideally passed into law. And I should say that our team has been amazing at this. We have connected with over 250-member offices at both the House and Senate and committee staff across all of our ideas. One of the reasons Biotech is difficult to legislate is that it touched so many committees. But...

ATTAL-JUNCQUA: It spans different sectors, healthcare, agriculture, environment, energy manufacturing, everything.

ROZO: I think that we conclude that our recommendations are across 19 different committees, I believe, so basically almost all of them, and which makes it really challenging to legislate on. But we have done the groundwork. There's a lot of champions on the Hill for this. Really appreciated Senator Peters' comments just before mine on biosafety and biosecurity and the need to fund biotech. That aligns very strongly with the recommendations that we come out with in the report. And again. To accomplish what we just described for Biostar would require new authorities. It would require the ability to execute on all of these functions we talked about, and it would critically require the resources to be able to go out and do this. And we're shaping that legislative text right now and we'll spend the next 18 months working to get it introduced and passed.

ATTAL-JUNCQUA: What sort of actions would be the most important from the legislation perspective?

ROZO: So, it is – we're really writing out the entire – the authorities to do all of what I described. And it is sort of the combination of the authorities, to do the oversight functions, to have the liability for that sandbox concept we talked about, to have that independent board, but also the resources to be able to fund the technology, do so in this ARPA-like fashion. And I should mention that DARPA and IARPA and elements of the federal government have had really great research efforts around biosafety and biosecurity, but they've been bespoke and one-off and we really need a dedicated effort to pull this forward. And so, it's that combination of the authorities and the resources and the consolidation of that existing functionality across the government that gives Biostar the ability to do what we lay out that it could do.

ATTAL-JUNCQUA: So, you mentioned DARPA and IARPA that have historically worked on sandboxes as well and new technology for virus safety and virus security. How would the new entity work with them or fund them? And do you have any other examples about other technologies that you're excited about that we should be working on to strengthen virus security and virus safety?

ROZO: There's so much that we could be doing here. We talked, again, I was grateful to listen to Senator Peters' remarks, some of the, how we haven't innovated in biosafety and biosecurity for so long. How much of a spill is too much of the spill, right? How much causes an infection? How, what, from a biosecurity perspective, what are the actual mitigations that can put in place that are effective for what types of threats? So, there's things that are very basic that we could be funding around the science and implementation around biosafety and biosecurity. All the way to sort of the leading edge and it's been talked about a lot about the intersection of AI and bio.

What are the threats associated with that? What is the benchmarking of existing capabilities? And to do that work, you really need the intersection of industry of the leading edge of where this technology is being developed. But I also think you need the capabilities to test this securely, right? And to so in a way that allows that rent teaming to happen. And that's again, I'll mention the national labs and the system we have in house and so this entity would have the ability to work with our existing expertise across the federal government and with that mandate and the resources to be able to do that and execute on this mission.

ATTAL-JUNCQUA: That's incredible. That sounds very exciting. So, you mentioned earlier in your earlier remarks that the US is falling behind China in the biotech landscape broadly. I'd love to hear your thoughts on like the role of international partnerships and how that would be important in strengthening our ability to prepare and respond to pandemics. What is the role in the US in this international partnership ecosystem? And how can the U.S. Lead by example going forward?

ROZO: It's a critical question. We can't do this alone. We need to work with our partners and allies. And in the case of biosafety and biosecurity, we're prudent that should include China. We laid that out in the report of promulgating our best practices for these standards and working with the international community to do so. We call on, in the report on Biostar, to lead this when it comes to biosafety, and responsibility, and we envision a role for this entity as it is innovating in the science behind biosafety and biosecurity in the governance approaches to be able to promulgate those standards internationally, to work with NIST and the Department of State, international standards organizations, our partners and allies, you know, that share our values, and those that don't, to try to – you know that's too critical – it means too much to get this wrong, and so it is an opportunity for us to lead with our values at the forefront.

And we have the innovation ecosystem ready to go, you know, industry that I've talked to, they want something like this to exist, right, to be able to work with them. And again, we had amazing stakeholder consultations over the course of this work to include the international community. And this is something that there's great alignment around the need to work in an international community, because as we all know, biology doesn't respect borders. We could do something here, but if it's not repeated abroad, they will still create issues. And so, again, we lay out a role for Biostar in promulgating these norms and standards abroad.

ATTAL-JUNCQUA: Is there any particular organizations that you would look forward to collaborating with?

ROZO: I think that there are a number of international entities, everyone from technical standards bodies to UN organizations that work more on the norms aspect and deal with governments. I mean, there's really a lot of opportunity here. And we have a number of key international partnerships that

could be leveraged. It's just having those standards ready to go, things that meet the risk we're seeing today to be able to shape in those venues.

ATTAL-JUNCQUA: We see today, I think we mentioned in the previous panel, the cuts in R&D and innovation and research in general happening currently in the government. How do you see that playing out with your current recommendations and is there a way forward to make them meet in the middle?

ROZO: We lay out in the report how the importance of federal funding and how the history of strong R&D support from the federal government has shaped the biotech ecosystem we enjoy today, how critical it has been, and how that's been a historic strength for the United States. We also lay out a series of areas that we think need additional funding and additional support. We call these grand research challenges. We're not yet at this leading edge of biotechnology. It's still a field of discovery, but almost a field of design, as we like to say. And so, we lay out a series of areas that we believe the government needs to fund now, and that includes making biology predictably engineerable and scalable. And so, we detail that in, again, great detail in the report and online of what those areas are, and the critical role in the federal government in supporting that type of research and development.

ATTAL-JUNCQUA: Is there any areas that you think are currently underfunded or could benefit from more attention from the USG?

ROZO: Yeah, we lay out, again, a series of areas that we prioritize in this area. I think, again it's around these sort of hard problems that this sort of basic tool development that we need to do in order to get engineering biology to the next phase of development, the metrology around that, the tools around that. And we have in great detail online what all of those elements are and look forward for folks to check those out.

ATTAL-JUNCQUA: We have a few minutes left, so I have one kind of final question for you. Looking forward, what steps should Congress take to implement the recommendations, and especially that the creation of this dedicated entity that you've championed here?

ROZO: So I touched on this a little bit before, but critically, we need Congress to move forward and to act and legislate on this, not just authorizing, but also appropriations, which is so difficult to do. We need folks like you, those that are passionate about biosafety and biosecurity, but also those who may not have been in this community for a long period of time, but care about the future of biotechnology, about S&T in this country, to advocate for this recommendation, help us shape this as it moves into legislative text. If there are things that you think could be improved, we want to hear about it. Please tell your members of Congress you agree with it, that you like it, and that you think it's important, because we need. All hands-on deck, really. We need the advocacy to make this become a reality, to be able to prioritize what we think is so critical now, amidst everything else that is happening. And it really takes everyone in this room and folks like you to be to be able to make that happen.

ATTAL-JUNCQUA: Great. And then the final question for you, as you were working on this for the last couple of years, what were the biggest challenges that you've encountered and any big surprises as you dig the research and work on all these issues and biggest opportunities that you think are ahead of us?

ROZO: Well, I'll end with the opportunities, because I like to end on a positive. I think from the challenges perspective, I was surprised just how much changed in the two years that we were doing our work. We came out with our interim report, and we said the US was ahead, but we need to act to remain so. And by the time a year had passed, and we came out the final report, we said, you know what, we're actually behind. And we're behind in key areas. It's no longer a comfortable lead. We're now falling behind in areas that we thought we would never give up. And that is a sobering reality, as I said up top. But in terms of the opportunities, I get every day to intersect with companies that are working at the leading edge of this technology. I get to see firsthand what real exciting capabilities there are in the United States and abroad, and to move forward by our technology to solve many of the problems that we're facing as a world today. And that is just so exciting for that potential. And just to be able to also watch how quickly the technology is evolving. This isn't science fiction anymore. These are things that are ready to go and deployable. And could be within months to a year in our hands in the commercial marketplace and really making a difference for the way that we live our lives today.

ATTAL-JUNCQUA: Well, thank you so much, Dr. Rozo, for your time. We're very excited about the report. And I encourage everyone to go and read it online or in person if you have a copy. It's a really great report. So big round of applause for Dr. Rozo.

ATTAL-JUNCQUA: Thank you.

PATNAIK: All right, everyone, we're gonna have a 50-minute break until 3:15 before we're going to dive into our first panel on risky and potential pandemic risks. And then we're go to have a second panel on future pandemic risks, okay? All right. There's some coffee, pastries, and water outside, so please try to mingle, and then at 3:15, we'll be back here. Thank you.

PATNAIK: ...into the COVID origin pandemic, and then Jesse Bloom is a professor at Fred Hutchinson Cancer Center. Hi, Jesse. Good to see you. Thanks for being here, all of you. I want to start with a question for all three of you, and maybe we can start with Gerry. The COVID-19 pandemic exposed significant vulnerabilities, I think, in global response and preparedness, and so what are some of the critical lessons policymakers should have learned about managing biological risks and pandemic prevention, and do you think we have heeded some of those lessons?

EPSTEIN: Thank you very much, Sanjay and Brookings, for being a part of this, and I really hope everybody out there has heard the opening speakers, Senator Peters and Dr. Rozo, particularly because Senator Peters answered your question. One of the things that we really learned we needed is surveillance. You want to track a pandemic, you have to know where it is and where it's going, and there's two aspects to that. One is having the data systems and the analysis to figure out what's happening and where. Another is something that we did make an effort to address, which is how do you modeling to figure out where it's going to go. We had set up at the CDC, a Center for Epidemic, not sure I'll get the name of it, Epidemic-Modeling and Outbreak Analysis. And frankly, I don't know what the status of that center is, but that's something that one needs to be able to track where a pandemic is going.

I would just start with, we were fortunate to have a wealth of academic experts doing pandemic modeling. It's fantastic, it allowed innovation, it allowed people to come up with new ways of approach, in fact, new systems that beat the previous ones, a good example of how the United States innovation system works. The problem is we shouldn't really depend on people kind of volunteering their time to do something so nationally important. So, I think Senator Peters was right on when he said we need surveillance, and to that I would add not only modeling and analysis, but some sort of federal ownership of that mission so we're not just relying on people working 22-hour days using their own university resources.

PATNAIK: Jason same question to you. What lessons and you were in the thick of it when it happened. So what lessons should we have learned and did we learn them.

BANNAN: Yeah, I think one of the great things that we learned was uh... There's a need to keep government going and uh... That was very stressful for the throughout the entire government uh... During the shutdown and everything how do we keep things going I think senator Peters also touched on the preparedness uh... In terms of all the other things that you need uh... The PPE, the medical equipment the respirators, even right down to mask shortages and Tyvek shortages. Uh... Those things were very important and I think we had learned a little bit about that during the ball outbreak when we had a lot of uh... A big U.S. footprint in East Africa during the Ebola outbreak and um... We were running into the same issues for our personal broad uh... So, you would think that we would have learned that but uh... We were facing and I think it was because it was a much larger scale than the Ebola outbreak was. But we ran into that and we realized that we had lost manufacturing capacity uh... That the that the pandemic was causing a supply chain crisis there are a lot of economic consequences that were interfering with our ability to uh... To get supplies and stuff so uh... Those are the things that we have to prepare for the senator said we really need to prepare that for the future. Make sure that we are ahead of the game, not behind the eight ball.

PATNAIK: What about you, Jesse? You commented from a virologist perspective. What are some of the lessons that you think we should have learned?

BLOOM: Yeah, I mean, I think the biggest lesson from the COVID pandemic is once a novel virus that has the ability to efficiently transmit from person to person has spread to more than a handful of people. It's honestly very difficult for any strategy to really do anything to stop that, you know, so, so that's one of the difficult, one of the things we've learned that, you know pandemics of transmissible agents are just. Hard to stop, and they're really only going to stop when most of the global population has acquired immunity. And that can happen either through most people having gotten infected, or hopefully if it's a pathogen that causes substantial disease, through most people having gotten vaccinated. I think one of the major successes from the COVID pandemic is it really highlighted the potential of new approaches. Like mRNA vaccines that can be used to potentially create vaccines to new pathogens much more rapidly than is possible with some of the older vaccine technologies. And with technologies like mRNA vaccine, it's a real barrier to rolling out a vaccine quickly once a new pandemic agent emerges is really in large part probably, you know, matters of regulatory and scaling up. But with that said, I think, you know, I'd think one of the things pandemic really emphasized is that pandemics are hard to combat and the best strategy is just to sort of avoid having outbreaks of transmissible agents start in the first place. That's obviously a difficult challenge as well and there's no magic bullet there, but I think that's the biggest lesson.

PATNAIK: So how do you view the current emergence of bird flu in other species, like in cattle, for instance, and our response to it? Do you think we are responding correctly to it? Do you think we're applying lessons from COVID or are you worried about it?

BLOOM: I'm certainly worried about the bird flu outbreak. I mean, it's a very different situation. So, there's COVID-2 by the time the first human cases were identified, or certainly at least by the first time the human cases were acknowledged in China and probably by the time they were first identified, even there, the virus was already quite transmissible from person to person. And there was probably a very limited window where anything could have been done to stop it. Bird flu or avian H5N1 influenza, although it's caused a large number of human cases, at this point it is not very transmissible human to human. Perhaps in a few limited cases of human to human transmission, but most humans have acquired it from animals, but we're obviously worried it might acquire the ability to transmit from human to human. So, I think we should do everything we can to reduce the interface that that could allow for continued human infections. It could eventually lead to evolution of human transmission

while also doing everything in our means to be in a place where we could respond with countermeasures like vaccines and other countermeasures if we should be unfortunate enough that the virus acquires the ability to transmit from human to human.

PATNAIK: Jerry, like billing on that, how do you think we could build a surveillance system that is better, that could like monitor for that kind of potential spillover? Because I don't think we're currently doing it very well, are we?

EPSTEIN: I was just thinking about that as Jesse was speaking, and unfortunately, I wasn't thinking about how to do it better, I was thinking about why it's difficult. And particularly in bird flu, it's difficulty because there are a number of incentives for people not to want to know answers. And I'm always chagrined to find out when the answer to a question involves collecting and analyzing data, to find that there's reasons why that's hard. You know, this isn't pejorative, but... There are huge economic interests at stake. A false call about infection of veterinary animals could have put billions of dollars at risk. On the other hand, missing the call can potentially have equally serious pandemic consequences.

Additional factors may be some of the people who are most vulnerable in these situations are people who may not be documented in the United States. And when they have an incentive to stay away from hospitals and from medical care, we will not have the ability to catch them before they have the chance to spread the pandemic further. Surveillance is hard, as I mentioned, as Senator Peters mentioned, in the human case. In the agriculture case, you've got industrial values and industrial interests and personal interests, which make it more complicated. Again, I'm not accusing industry of malfeasance. I'm just recognizing that there are other factors that policy has to take into account and makes a hard problem even harder.

PATNAIK: I think that's a really good point. I think we saw during the pandemic that oftentimes we have so many different policy areas intersecting, oftentimes not working well together, and the economic impact oftentimes drives a lot of decisions, right?

EPSTEIN: I understand that because you're an economic center.

PATNAIK: I'm glad to hear that. Jason, initially, like when I talked to Senator Peters, we briefly touched upon it. Kind of like there are three different risks that we can see where a pandemic could come from, we have a natural spillover that bird flu could emerge into. We have our lab accident if you do risky research, and then the lab worker gets infected and spreads it out. And we have a bioterrorism where people really try to develop something like this. Do you think in our current system, we address these different risks equally through our regulatory and policymaking system? And how do intelligence agencies assess the relative likelihood of these things happening?

BANNAN: Well, that's a complex question. I'll start with the bioterrorism aspect, I mean, going back the last two decades, when I went, when I made a switch from clinical research to get into government and address these bioterrorism threats, there was very little legislation on the books. But there was a lot of money. One of the reasons I switched in my research, it was still infectious disease research, but it was bioterrorism, and that's where the government was putting a lot of money, that was around, that actually was before 9/11 before the anthrax letters uh... The government was putting a lot of money into bioterrorism and uh... But one of the things that happens and I think the senator mention this is that often as technology moves uh... Of the laws and legislation are behind it I think we recently in biotechnology we recently saw that with uh... genealogy being used to solve unsolved crimes, and going into, you know, the genealogy databases that people are submitting their family searches to and using that to do searches among people who are going to be innocent.

You're building a family tree and then you're going back through that family tree until you get to somebody who meets the suspect's criteria and then questions arise like, well, did I violate anybody's privacy in my search up to that point and if I see this person and that person how do I now conduct surreptitious searches for their DNA without warrant? So, we realized that legislation often is behind the technology. And that's something I think that the senator and the other legislators have to keep pace with. And then as far as the natural outbreak scenarios, we have surveillance networks throughout the world. I mean, we mentioned yesterday in some of our talks that.

You know there are agriculture databases for surveillance of agricultural disease in animals there are even those for uh... Plant diseases worldwide there's a lot of sharing of that data uh... We have

human surveillance uh... disease, you know how do we effectively communicate that when we see something that's going on that suspicious if like as somebody who worked for the FBI when we say something suspicious uh... Will open an investigation in the intelligence community can open their investigation and stuff but what does the public health community do with that information you know they're busy trying to keep us all healthy uh... Uh... Among while we're all sick and everything do they have the sufficient resources to be gathering that data analyzing that data and being prepared to head something off at the pass You know, that's a tough job.

PATNAIK: So, what about like... Accidents and like risky research that could lead to something.

BANNAN: Lab accidents are actually more common than people uh... Think and um... That's something that we have to think about one when I was on the fees at committee for President Obama uh... One of the things we looked at was do we have sufficient guidelines uh... Rules regulations guidelines uh... On biosafety and biosecurity in the united states uh... And kind of found out that we did but the enforcement of that. Is rather poor. And some of that comes right down to just, I'll say, ignorance, but not in a pejorative sense, ignorance that many of the researchers out there who are working are not aware of a lot of this stuff. You'd be surprised how many people have never read the BNBL from the CDC or know about OSHA biosafety regulations. Of the, what is it?

EPSTEIN: It's the, Biosafety, the manual for biosafety... A safety manual.

BANNAN: It's a biosafety manual from CDC, and they may have even changed the name now, I'm not sure, but, you know, ignorance is part of it, is that scientists often, they don't get this in their education, and we're educated to do science, but we're not educated in the rules, regulations, and biosafety and biosecurity. You'd be surprised with the select agent legislation. People don't know what the select agents list is, how many agents are on there, and can I even work with it? Without going through all the hoops and all that. So, it's just, it's a question of education.

PATNAIK: That's really interesting that like gap between scientists and policy experts. And I think we see that in other areas, too, like AI, for instance. Gerry, I want to come to you. You've done so much work on this. When you look at the current policy frameworks that govern biosafety in the United

States, can you talk a little bit about how the U.S. Regulates biosafety and how they've changed over time? Things like the FSAP, NIH guidelines, et cetera.

EPSTEIN: Sure, I'd love to do that. Let me first tack on something that Jason just said about lab accidents. I think first, it's a very important topic and I'm glad we're looking at it. First and foremost, the primary victim of a lab accident is the researcher. So, I think we have to understand that the researchers have as much interest in avoiding lab accidents as anybody else. Where it becomes a concern to the rest of us is if a lab accident can lead to something that affects the community. That's unlikely in lots of reasons. The agent may not be appropriate or may not escape from the lab in a way that's actually going to get into the community. So again, lab accidents mostly affect the researcher. The problem is there can be lab accidents with agents that have the potential to create pandemics, and I think we'll get back to that. So, I think it's a very small in number and percentage, but very high in consequence. But I do want to avoid the impression that researchers don't care about lab safety. Their own health and their own lives are the ones that are being protected. As to the framework in which we address biosafety, first and foremost, safety is by and large under the U.S. Constitution a state and local responsibility.

So, most biosafety's not actually a federal concern. Federal government gets involved when there are security aspects. And you mentioned the select agent program. It's laws passed by Congress that give the Secretary of HHS and Agriculture the ability to enforce regulations over the use and possession of agents that pose threats to public health and safety. And the institutions, the listed agents, some 60 or so agents that fall into this program, one has to have permission from USDA or HHS to possess the agents. Individuals working with them have to be vetted by the FBI, and there's a fairly set of procedures in terms of reporting leaks, and reporting theft and misuse. Safety is covered in this program, but it's basically, you need to have a plan, you need the exercise. It doesn't get into the prescriptive type of regulations we see in other areas. That's the select agent program, which by law regulates anybody that uses these agents. Another part of the federal by safety infrastructure is providing resources.

The BNBO manual that Jason mentioned, that CDC and NIH work together on, lays out how one does safe laboratory procedures using agents that range from barely pathogenic to deadly with no cure.

And so, it's a very detailed manual. Another manual the federal government has put on is a handbook on use of recombinant and synthetic nucleic acids. And this originally started with the famous Asilomar conference in the 1970s in California when scientists were realizing that things they were doing in the lab could actually have quite significant consequences that they didn't understand. That led to a whole series of guidelines that NIH put out, which is not only useful information for anybody working in the field, but is required by people who accept federal money that they must, and it has to do with creating institutional biosafety committees. The third set is there are a number of policies the federal government has in place which are attached to federal dollars. And here, one has recognized starting sort of 2000 or so, that there are basic science experiments that one could do in biology that could have significant consequences if misused for harm. And it led to a concept of research called dual use research of concern. Dual use research has a legitimate use and it had an adverse use like a knife. You can cut your dinner or you can stab someone.

Almost everything is dual use at some level. Dual use of research of concerned rises to a significant threshold that this is not only potential use for harm It might be something that we really need to pay some attention to and think about before we go down that road. And you know, as government establishes a policy on such dual use research which says for a certain number of agents, if you're doing one of certain types of experimental activities that have great potential to be misused, like you're teaching a pathogen to jump from a guinea pig to a human or a Guinea pig to a monkey, then there's a set of procedures that institutions are supposed to go through in terms of assessing the risks, coming up with mitigation plans, and giving the funding agency the it and say, okay, we think that you've sufficiently understood the problem and you can go ahead with the work. So that structure is in place. That's only for federal funding.

PATNAIK: I see.

EPSTEIN: And on the far end of type of experiments that could cause outside consequences is where we started with about research that might somehow lead to a pandemic. There's a separate federal policy, or it was separate, it's now been unified with the first policy, on experiments which have the potential to enhance an agent and either giving it or adding to its pandemic potential. This has the same sort of requirements in terms of understanding possible risks, understanding mitigation plans.

But it has an additional set of requirements in that there are principles listed in a policy that these experiments must satisfy. It's not just to sort of just look at the analysis and make a decision. They must satisfy this. And they also have to undergo review within the Federal Funding Department by an agency or entity independent of the one sponsoring the research. So, if NIH is proposing work, it has to be reviewed by an office at the secretary This is called – the policy now is called a policy on pathogens with enhanced pandemic potential, and that covers that high-end risk. Significantly, again, it only covers research that is federally funded.

PATNAIK: So not privately funded research.

EPSTEIN: Privately funded research would not be affected at all. One might say there isn't a lot of privately funded research underway. I'm not sure about that. That might be right. But my interest in having this regulation extended to everybody else is if there is that type of research on a private sector, and maybe it's not at a pharmaceutical firm, maybe it is in somebody's garage. I want them to go through the same kind of review, and if they don't, I want that to be a crime.

PATNAIK: I agree. I mean, you can start your own nuclear reactor in the basement, right? Like, there's a reason for that.

EPSTEIN: Having something on a regulation or a law like that not only allows it to be a crime and a lot of people that don't do it but more importantly with my FBI colleague here the FBI cannot investigate things that are not crimes and if somebody's doing research with a pandemic pathogen as a hobby and we have a legal structure in place where you needed to get permission to do that and they didn't get permission do that. And I call the FBI and say I think somebody's working on a pandemic how do I know? He told me over a beer. If that's not a crime the FBI has to tell me I'm sorry sir that's a crime we can't do anything about it. If it is a crime They can investigate, and if they find out that it's a problem, then it goes through the law enforcement. So, there's a lot of reasons why things need to be regulated, not only because you're actually concerned about the activity itself. There's a lot of things that flow from the fact that there is a regulation or a law in place that are also important in biosecurity.

PATNAIK: Great. Let me turn to you, Jesse. The Senator mentioned it already, the term gain of function research that is often colloquially being used. Why is that risky, and especially when we talk about viruses that could cause a pandemic? Can you talk a little bit about what it is, and what's the benefit risk calculus of even doing this kind of research? When I hear stories about like NEPA virus and other things that are being manipulated in the lab, I always get quite queasy when I think about the potential for something going wrong.

BLOOM: Yeah. So, first of all, you know, gain of function is not a good term for describing, I think, what we're trying to talk about here, because it's really neither necessary nor sufficient for research to oppose the types of risks we're talking about. So, gain of function, in its most general terms, just means adding some new property to some biological entity. So, this could be, you now, using some virus to deliver a gene for some benign purpose or help treat cancer as an oncogenic virus or something like that. So, much of what could be called gain of function, I think, is not actually particularly risky. And then furthermore, work with potential pandemic viruses does not have to involve gain of functions to be risky. So, for instance, obviously the origins of the COVID pandemic are still debated, but the one pandemic that we know had a non-natural cause, which was the 1977 H1N1 influenza pandemic, was caused by reintroduction, possibly via a vaccine trial of an old strain of H1N1 influenza.

And there's no indication that that strain had been modified by anything we would call gain-of-function research, but the fact of the matter is it was an old human pathogen and there wasn't sufficient immunity, so it caused a pandemic once it got going in the human population. And some of the most alarming types of accidents I could imagine, for instance, if someone were to be experimenting on smallpox, which fortunately there's very rigorous regulation of them were to have an accident, that would be devastating at a global level, given the transmissibility and virulence of smallpox, and there wouldn't have to be any gain of function involved at all because smallpox is already that way. So, I really think what we need to do is refer to research on potential pandemic pathogens, which are pathogens where if there's an accident, they could spread widely and cause great global harm. I very much agree with what Gerald Epstein was saying in that I think we need to distinguish between biosafety and sort of the occupational safety aspect of like, is the researcher safe enough from an accident that would harm them and the larger consequences? You know, my view is that although

biosafety certainly isn't perfect, from an occupational safety standpoint, I think in general biosafety in the U.S. Is adequate.

There are occasionally accidents, but you know. There's lots of things we do like driving cars to work and things that probably pose greater risk to the researchers themselves. However, when we're talking about this very small slice of research where if there was an accident, it would go beyond being an occupational safety issue that might affect the particular researcher themselves doing the experiment and instead. Lead to some pathogens spreading uncontrollably in the community or even globally, then you're talking about something where really any risk which isn't zero is probably unacceptable. So I think that's really the type of research we need to focus on. As far as what is the benefit-risk calculus for that type of search, I mean, first of all, I think it's important for people out there in the world thinking about scientific research to understand that scientists themselves when they're doing research typically do not really decide what to do within a risk benefit calculus. Most scientists, including myself, believe that in general, basic scientific research to understand biology and understand the natural world is sort of often valuable in its own right.

And there's a lot of research that's done without a clear benefit in mind that in some cases turns out to be very useful. So I think scientists traditionally don't perform risk benefit calculus is when they're deciding what to do. However, you know, as scientists, we've become aware that there are certain cases where research can have larger ethical implications, where society as a whole may ask for there to be risk benefit analysis. So, for instance, if you look at the history of the influenza virus field, much of what we know about human immunity or some of what we know human immunity to influenza was by studies that well-known virologists like Couch or Castle or Robert Chanak were doing in the 60s or 70s where they were infecting prisoners with influenza viruses to see what happened. And, you know, that was a very effective way to generate scientific information. But eventually a sort of larger society came to the viewpoint, you know, in my view correctly that there were ethical implications about that research because, you know, humans outside of the research themselves could be potentially adversely impacted. And now when you do specific kinds of research involving human subjects, there do have to be, you know, things that would sort of mirror risk-benefit calculus that are stuck. So we're in the same situation for potential pandemic pathogens in my view.

PATNAIK: That's really interesting, actually, and I didn't know that about the prison experiments. So when you follow the debate, especially someone that is not a scientist and is an economist, you oftentimes have got these two camps pitting against each other, and people that do that kind of work saying, oh, it's very critical for preventing pandemics, dealing with vaccine development, antiviral development. What role do these kinds of risk, if we really look at that slice that you mentioned, play in helping us prevent a pandemic? Are they really critical for developing vaccines, antivirals? Are they just being done for science sake? I'm really curious.

BLOOM: Well, so, you know, obviously, as I was discussing at the outset, preventing pandemics is a very difficult thing to do, I think, to help us combat human disease and hopefully mitigate the effects of pandemics if they emerge. So certainly, there are valid scientific reasons when you're developing vaccines or antibodies or other antivirals against rapidly evolving viruses. That in some cases, you need to understand the impacts of mutations to viruses on those countermeasures. So, for instance, at the beginning of the COVID pandemic, there were a large number of monoclonal antibodies against SARS CoV-2 to that were developed and used in humans and the virus fairly rapidly evolved to escape most of those. And in retrospect, we know that better sort of thought and understanding of how mutations affected those would have led to the design of antibodies that were more robust to viral escape. Similarly, vaccines against SARS-CoV-2 influenza need to be updated annually because the virus is changing, and there needs to be some understanding of that process.

Another great example is respiratory syncytial virus, which is the leading cause of hospitalization in the U.S. In infants. There are now monoclonal antibodies against RSV that are showing a lot of effectiveness at preventing hospitalizations, but some of the early monoclonal antibodies were developed, like the Ceptubumab antibody that was developed by Regeneron, failed in clinical trials because people didn't appreciate that there were already viral mutations out there that caused resistance. So, there's a lot need to understand sort of the impacts of viruses and how their evolution can affect vaccines and antivirals. That's certainly important. You know, as far as the best way to do that and how much that work you know, should involve direct experiments with those potentially dangerous viruses versus other computational or surrogate approaches that cause reduced risk is a question that is partly scientific, but partly a broader question. You know, again, going back to, you know things like human challenge infections with influenza. You know, we still develop vaccines, but

we now do a lot less human challenge studies with these viruses than we used to. And instead, scientists often do things like using animal models and so on, which probably actually scientifically are not quite as good at answering the question, but are much more acceptable from an ethical standpoint. And so I think it's really a broader question of, you know, how do we balance the larger concerns about the implications of research with what is the most effective way to answer the question that someone might be interested in.

PATNAIK: Great, Jason, anything to add on this before I get to the next question?

BANNAN: I would like to add on something that Jesse said. I think if you ask everybody in this room about gain of function, there is the definition of gain of functions which is if I make a change to an organism and it gives that organism a new ability, that is the generic definition of a gain of a function. And what Jesse was saying was that, you know, there are, there's, if you have, we're talking if you just in the conversations people are worried about gain-of-function research and they'll say I want to stop that what's the reason that somebody is researching what genetic changes are necessary to make this more infectious to humans or more virulent in humans, whatever. People worry about that research and they question is there a value in that. If we just look at the EcoHealth Alliance research grants they were looking at what genetic changes were necessary to jump species, virologists will tell you that most viruses, animal viruses, will require genetic changes to be successful in a new species, especially in, you know, in humans.

And so is there a need to look at what specific genetic changes were necessary to make that more infectious to humans or more communicable among humans or whatever? But there's other kinds of research as Jesse mentioned where scientists are doing legitimate research to say, hey, what, you know, the new vaccines for COVID or whatever, basically look at a very small region of a functional protein of the virus and try to protect us by inhibiting that function. But they're concerned with what genetic changes to that small region in the vaccine would be, would prevent this vaccine from being effective. That's legitimate research. They may be making those changes and say, ah, see, this change will make this vaccine ineffective. So if the virus makes this change, we're gonna run into trouble with this vaccine. But what I think people don't realize is that the majority of gains of function in research are serendipitous. Researchers are not usually planning to do gain of function to make

something that's more infectious to humans. It's a serendipitous event. Just like as Jesse explained. Yeah, we're looking at this genetic change to see if this genetic will make our vaccine ineffective.

AUDIENCE MEMBER: Unintelligible.

BANNAN: No, I'm not saying EcoHealth was, I'm saying the majority of research.

PATNAIK: Please let the panel speak.

BANNAN: The majority of research, biological research and genetic research, where we're making changes, we're make changes to find something else out. As Jesse mentioned, one example is a change to see if this vaccine becomes ineffective. But that change could also, there could be serendipitous consequences to that. That change could make it more communicable between humans. Or some other change in function. So, I'm saying that... Most gain-of-function research is not geared to make something more effective, more pathogenic in humans. It's usually just something that happens and that has to be reported. We have mechanisms to report on that.

The NIH has guidelines in federally funded research what needs to be done before any additional funding is provided for that research. There are a lot of problems that when we discuss gain-of-function research and we say we want a moratorium on this and we want to shut down research we really have to be careful in those conversations uh... Because the most of the legitimate science uh... That's out there uh... It's not being done for nefarious purposes it's not being done uh... In a reckless way and some of those results that we see that do turn out bad our serendipitous and we should be able to get a handle how to screen for, you know, make sure the researchers are reporting that and making sure that they're on top of that.

PATNAIK: Jesse, anything to add to this?

BANNAN: Uh, not really, other than obviously, you know, I agree with most of what Jason was saying, but I think we have to keep in mind that the intention of the research and the outcome of the

research, you may or may not be aligned. So, you an important question evaluating this is always not just what is the intention, the research, but what is that?

PATNAIK: Gerry, I want to turn over to you, like, who is actually in charge, I mean, Dr. Rozo mentioned it like that the new idea they have is to centralize some of the oversight because currently it's all over the government. Who is actually charge of implementing biosafety oversight, biosafety regulations, like where are the main centers across the government?

EPSTEIN: Life safety is implemented in a number of places and those different places are in charge of their piece of it. So it's like the aging program is under the CDC and the Department of Agriculture. The NIH policy, the policies attached to government funding are overseen by NIH, but typically these policies are designed and discussed through an interagency process within the federal government, and then some agency will be responsible for rolling it out. Some of the policies on screening DNA sequences that Dr. Rozo talked about, it wasn't clear. OSDP. It issued some guidance on that. I think the Department of Homeland Security was given a task. The National Security Commission on Emerging Biotechnology, that Dr. Rozo talked about, proposes that commerce be given an office. But right now, there's no single point of contact for that. It's just different policies done in different places.

PATNAIK: And how do you – Dr. Rozo tried to mention it a little bit – the technology is moving so fast. And so how do – and we face that not only in biotech, but we face it in AI and many others and we think a lot about this at our center. How do you make sure that the regulations are kind of like dynamically adjusted and keep up with the market and with the technology?

EPSTEIN: Absolutely, that is the challenge. How do you do that? I think she did a great job of explaining how important it is and what a challenge it the first thing you need is somebody whose job that is. Right now the various different aspects of our governance system are implementing those aspects of it and they're sort of looking ahead as to is this regulation still working. But there isn't really a part in the government that's trying to say here's what new technology is now making possible, here's a new biosafety concern, here we have the agency with a hammer, here the agency of the screwdriver, there we have agency with the pliers. But it's nobody's job to say, what tool do we need for this? So I very strongly support her rationale for the commission's creation of Biostar, because for

one, it creates somebody whose job it is. Part of having somebody whose job it is you give them this mission of foresight and technological anticipation.

What's coming down the road? As you said, it's very hard to keep track of things as they're happening. It's even harder to look ahead. But if nobody's looking, you're not going to find it. So that agency has to have that job. It has to also. It would be more efficient to have it centralize all the other aspects of biosecurity policy so when it finds something it says well here's the existing toolkit we can maybe adjust those as necessary and maybe we need to come up with some more but again it's hard to do that when it's dispersed throughout the government. The challenge is there's a lot of rules and regulations and procedures that determine how the federal government runs that are often called red tape which are not there just to frustrate people and make life difficult. They're there because we have values that we want to achieve as US government in transparency and fairness. So when the government issues regulations, they put them out for comment.

All potentially affected stakeholders have the right to comment on them. And this has a fair amount of inertia. And so reconciling anticipatory high-speed approach to looking at future hazards and then adaptively changing to address them, adaptive governance is something that the commission talked about as well. That's important, but you have to do it in a framework that says, we have a deliberate way of going about things. Because we have these values that we want to protect. Now maybe we don't have to protect those values through 180-day Federal Registered Comment Periods. Maybe there's different ways to get to the same goal, but that's gonna require some institutional innovation as well, and just getting rid of it all and saying, we can't afford to take the time, has a lot of potential adverse consequences in terms of protections that we now have from the way the government is structured to go through regulation. And just one point on regulation, there's a... A quote I love so much from Dr. Renee Redbrizen who is the former director of the Advanced Research Project Agency for Health on exactly this topic. She says, the reason you have brakes on a car is not because you want to drive slow. The reason you brakes on the car is because you wanted to drive fast, safe. And I think that's exactly consistent with Dr. Rozo's creation of Biostar not as a hindrance on innovation but as a promoter of innovation. And you want be able to have the ability to go do things that are safe and have the ability identify things that might be problematic and then do something about Before it gets to be too late.

PATNAIK: That's a really good point, actually. Jason, I want to turn it back to you. We have had a pandemic. It's been five years now since then. We still don't have an official assessment of where it came from. The FBI and other institutions lean towards a lab accident. Why is it even important to find out how it started? And how does it relate to current biosafety regulations? How is it important for pandemic prevention? When people say, oh, we might never find out, or we don't need to find out. I think I disagree because I think we need to find out but I'm curious to hear like, how do you see that? And what is the role in potentially preventing future pandemics from occurring?

BANNAN: Well, the simple answer to that is that if you don't know, if you don't find out, you won't know how to mitigate the next one. And so that's the simple answer. But I think it's also important that, you know, as we look ahead, people, this pandemic is, I think when we first came out with the first 90-day report, and the FBI was the only agency at the time that had assessed laboratory origin uh... There was a lot of blow back on that and a lot that was coming from scientists and I believe a lot about the blow back from scientists uh... They were worried that an agency like the FBI uh... Who is viewed as you know uh... Illegal entity and that there may be uh... Laws following that are going to prevent scientists from doing this innovation and you know, that we were going to shut down research. Uh... The government may shut down research or whatever uh... And that and that's a legitimate concern but uh... Because we have had moratoriums on research before legislation has have been passed.

This select agent legislation you know uh... Didn't exist twenty years ago uh... And so you know scientists often worry about what is the government going to do that's going to hinder our ability to effectively do science. Uh... Or and not slow us down but I still think it's important to understand uh... And to keep looking all right now we still don't have a definitive answer doesn't matter how many other agencies have come out and said lab origin or how many other governments have come down now and said they assessed lab origin uh... We need we need to keep an open mind because number one coronaviruses do most commonly emerge through zoonotic events. And that's a fact that most scientists will agree on. We know that from the SARS, first SARS epidemic.

We know it from how MERS emerged. All our cold viruses, the coronaviruses, there's genetic and phylogenetic evidence that they were through emergencies with other animal species, from other animal species. So I don't think anybody's going to argue that we still shouldn't keep an open mind to a zoonotic emergence, but five years later we still don't have any evidence. There's no epidemiological evidence. There is a lot more evidence, circumstantial, but a lot of this circumstantial evidence is telling us that this really looks like, you know, why Wuhan, you now, that this was, this could have been, and it's an assessment. We're not looking for proof. We're assessing what do we think with the data that we have is most likely. And if we don't do that, we won't be able to prevent the next pandemic.

PATNAIK: And so actually related to that, I'm curious. I think whenever we have a catastrophic event, let's say a plane crashes, right, we have an independent investigation. We don't let the pilots or the engineers developing the plane investigate themselves. So who should have led an investigation, an official, who could still lead an independent investigate into this? What kind of data sources do you need? So far, I think it's been mostly led by scientists, some of which have been working with people there at the lab, and so I'm just curious, how could an objective, trusted investigative commission look like that would be independent, that people could trust from both sides of the debate.

BANNAN: I think that's a good question. I think if you look at the 90-day report, President Biden had tasked the Director of National Intelligence to lead that. So you have intelligence entities who have different missions. As Jerry was saying, one may have the wrench, another may have a hammer, another the screwdriver. And that exists among the intel community. You know, we have some that gather signal intelligence. Some are that really good at human intelligence. Some that uh... Are more open to open source intelligence uh... That some have more scientists than others uh... So one of the things that we that I saw missing from that was uh... There was no one from HHS or the CDC involved in that ninety-day report so we didn't have public health people uh... They were looking in in on that. We had people with experience, you know, people like myself, a clinical microbiologist with a background in infectious disease, but, you know, that was 20 years ago in my career. I'm now an FBI scientist, and the other agencies also had, you know, many good scientists looking at it and stuff, but we didn't have clinicians. We didn't have epidemiologists. We really, I saw that as a missing piece.

PATNAIK: That's interesting.

BANNAN: And so I think you know that there should be and you know and we had and some of the actual intel agencies did have those people the national center for medical intelligence they were participating in this but I think we could have done a better job as a whole of government in coordinating the investigation of its origin.

PATNAIK: I actually have two audience questions to relate to some of that, one for Jerry and Jason combined, and one for Jesse.

BANNAN: He was in the middle of this.

PATNAIK: Perfect, so Jesse, you mentioned the importance of reducing transmission interfaces for zoonotic leaps from farmed animals, for instance, with more surveillance, and it's hard in farm workers, so how do you see us reducing those transmission interfaces?

BLOOM: You know, I think... Yeah, so I mean, obviously, there are two ways that a virus like H5N1 could become transmissible to humans. It could either, in the process of transmitting in some other animal, sort of pick up serendipitously the mutations that make it transmissible to humans. And then the first human that gets infected already you have a human transmissible virus and it takes off. The second one is you could have a human infection and during the course of the virus replicating in that human it acquires mutations that promote its transmissibility and to be quite honest we don't really know for any of the prior pandemics exactly which of these mechanisms happen but either could happen. I think overall you know what you want to do as much as possible is simply reduce the interface between, you know, viruses that could potentially cause a pandemic in humans, and humans and, you know, this is really, I think, a principle that applies.

Both the zoonoses and lab accidents, right? I mean, the reason that nobody does research in smallpox anymore is because we want the interface between smallpox virus and humans to be zero, right. And we decided that that was important enough that just smallpox research is largely not allowed. I mean there's at least very stringent international regulation on smallpox, research. You

know, for H5N1, there's a large interface at this point between H5N1 and people working on you know, on farms with dairy cattle, also people who are coming in contact with birds in various ways. And you know I think the more we can limit the transmission of the virus in those animals and the more can provide, you know protection to the people who were interacting with the animals, the better. But I admit that's an extremely challenging problem.

Like once the virus is widespread in an animal species it's extremely difficult to eliminate it or stop that interface without taking really draconian actions. And so I think that goes to the second point that any time that there's a virus that we think poses a plausible risk here, we also need to be taking the actions in terms of developing candidate vaccines, being prepared to ramp up those vaccines, to respond as quickly as possible if there is a human case and human transmission. And then finally, surveillance, you know, particularly of people who are working at these faces, whether that's odd. You know, people working with animals, people working in labs, you know surveillance of these interfaces. So if there are infections they can be identified as soon as possible. That's also important.

PATNAIK: Then actually, let me follow up on something. There's a second question here. If you look at Operation Warp Speed, right, like how do you assess it in terms of response time, in terms success, do you think this was how it should have been going? Could there have been something improved in terms vaccine rollout afterwards?

BLOOM: You know, I mean, that's really more of a policy question than a scientific question. And I try to stay more on the scientific than the policy questions. I will say though that the actual design of the construct that became the initial Pfizer and Moderna mRNA vaccines took only a very short amount of time. And most of the time was scaling up production of the vaccine and performing trials for safety and efficacy. And so, if there's a future pandemic, we now probably have even more knowledge, at least for many viruses on how to design those vaccines. We also have the latent capacity because there's now large-scale vaccine production to produce those vaccines at scale probably faster than was done for the COVID vaccine. And so in that case, probably the real bottleneck with the speed of, let's say, the rollout of a H5N1 mRNA vaccine, if H5M1 should start to transmit from human to human, may really be at the regulatory steps of safety and efficacy testing. And so I think that that probably needs to be a real focus.

PATNAIK: Gerry, anything to add to this?

EPSTEIN: Yeah, you brought up Operation Warp Speed. I'm really intrigued by something I've seen, General Paul Frederick, who is the White House head of the Office of Pandemic Preparedness, has said on a number of occasions, and that one of the dangers is drawing the wrong lesson from something like Operation Warps Speed. It was a terrific..

PATNAIK: Interesting.

EPSTEIN: ...program and showing that we could get solve a logistical manufacturing hurdles and get vaccines within a year when previously they'd taken five years or 10 years. That has given people, he said he's, I think he's attributed to conversations he's had with Hill staff and with members, that's contributed to a feeling that well all we need to do next pandemic is put 10 billion dollars in a vaccine machine and out pops a new vaccine because we pulled it off in Operation Warp Speed and what he always emphasizes is the reason that was I think Dr. Liu mentioned that we actually had the sequence of the MNRA. I believe it was within eight days of getting, it was very soon after getting the actual-.

PATNAIK: It was faster.

EPSTEIN: And as Jesse had just said, it was the testing and the clinical trials and the manufacturing that took so long. That was because we had done decades of research on MNRA vaccines or on coronaviruses. You cannot have a vending machine that gives you 30 years of research on the spur of the moment. And so even though that was a masterstroke in terms of actually applying what we knew to get that outcome, we can't assume we're going to be able to do that again if we don't have the research base that lets us spring with the short-term discovery of the actual sequence and then getting towards the trials. That's not going to happen unless you have the resource base that lets you build on.

PATNAIK: That's a great point. Let me stay on that. You brought up a really interesting point earlier, and we have an audience question on this, which is the lack of a legal framework, right? Like that you say like the FBI can only investigate if there's a crime. And so do you think the lack of an illegal framework for a lab accident or for kind of like a bio event led to like a hindrance in like investigating COVID origins? And the question is for both of you.

EPSTEIN: And I think that's an important point. I don't think that there are certainly, if one had done, well, I'm sputtering here. There are lots of ways one can break the law with biology. So the fact that one didn't have a legal framework in the case of pandemic pathogen research doesn't mean that anything you want, you're scot-free. So there probably are grounds, particularly after an event that has that kind of consequence. I also think that even though I have argued, I just said we need some kind of legal framework, I don't think regulation actually is very effective if it's a very adversarial system. One can always pass a law and force researchers to comply because the government has the power to have that kind of action, and if they don't comply they lose their funding and they go to jail. You have a power to do that, but you're not going to make the regulation work unless the people who are regulated have some sense of buy-in. We actually understand why you're doing this and have the ability to contribute what they know.

And say, well, if you're worried about X, here's the way to do that. The law you've passed or the regulation you passed is pretending to do that, but it's just going to get in our way and you're not going to accomplish what you want. So ultimately, I think one needs to have a collaborative relationship between regulators and the regulated community. This is not a blind check. So this goes up until you have malfeasance or negligence or other criminal activity, and then the government can bring a big stick. But I don't think we should assume from the beginning that researchers are a wild breed of animal and need to be tamed by the regulation. We need to have the ability, and that's again, a function of an agency like the Biostar that Dr. Rozo said, although I'm not sure this was articulated in her report, you need to have a mechanism to have this relationship between the researchers and the regulators to find out what works. Here's the problem. Not only are you the ones that are telling me what's going to work, you're the ones who have to put this into effect. And so from both the implementation and design, there's got to be a relationship between the regulators and the regulatory community that's conducive to having these conversations work.

PATNAIK: I think it has to be something like a sustained formation exchange but you have someone independently that is making the decision. It's a lot of like any other sector that is being regulated, right? Like you have that kind of thing. When you have the EPA looking at pollution, right, you have scientists that are getting information from the regulator and then making a decision afterwards. And I think you're right. It has to become like a way where you maximize the benefits. You find the right balance between correcting a market failure and like not killing innovation or killing the work that is important to some degree, right? I want to stay with you, Jerry, because Dr. Rozo talked a lot about her idea of Biostar, like that independent agency. That's an idea that you also had talked about a long time ago, like about bioresponsibility. How do you see her ideas of that agency as compared to what you had envisioned? And like, where do you think that should be situated in the government?

EPSTEIN: I think it's completely consistent. I was so happy to see that. As she said, we had talked to the staff ahead of time, and among the 2,000 people that she reached out to, we and my co-authors in that paper had reached out for them, and it's very gratifying to see that they found some value in it, and what they proposed is very much along the lines of what we said. As to where it goes, that's ultimately a political decision. It's where can you get agreement on Congress to put it. I think the fact that they agency, like the Securities and Exchange Commission or the Nuclear Regulatory Commission, it does not necessarily want to be part of the department because independence is part of what this entity brings. Right now, the Select Agent program is run by CDC and USDA, both of which do research which is subject to the Select Asian program. Now, they have workarounds. USDA inspects CDC. They don't inspect themselves. But still, there's at least a perception that this is not a truly independent mechanism. And so we had argued having an independent agency that doesn't really have a dog in fight about the research itself, we'll give it that perspective. To avoid not only conflicts, but perceived conflicts, because that's really important.

The commission put it in the part of commerce. It's not independent, but it's not known as a huge life science research agency. They have talent and they have capability, but I think it addresses those conflict of interest perspectives. You want an agency like this to be informed by all the perspectives of the government. You want the security agencies. You want FBI and the DHS to be part of it. You want to science agencies, NIH, the National Science Foundation. You want the economic aspects of it, you want the law enforcement, it's certainly a multi-sectoral process. You can, at the oversight level, you

can do that through inter-agency committees, but at the working level, it is really nice to have some one place where that all is resident. And so I think that, just to summarize, I think the proposal was very consistent with what we reported. And if commerce is where you get it, if commerce what works, then I'm for commerce.

PATNAIK: Yeah, you have worked a lot with different parts.

BANNAN: So yeah, and as Gerry said, so USDA does monitor CDC and CDC monitors USDA and of course the third tier of that is the FBI monitoring them both, doing the background investigations and stuff for the select agent. I think Biostar is a, it may be a good idea, it looks good on paper, I've read and everything, but remember after 9/11. Uh... We decided to create another entity we created DHS we created the director of National Intelligence office which would was new so one of the things the government likes to do is in response to a crisis or something that we see as a problem we need to fix is let's create a new entity for it and all that and that may be great and Biostar there's a lot in there that I will say uh... Looks very good but we shouldn't also forget... What do we currently have now in our infrastructure that we should be leveraging more heavily while we're looking at creating Biostar or whatever.

So for instance the U.S. Government spent about 885 billion dollars in research uh... In 2024, last year and about ten percent of that was uh... Life science research and that's meant that's across many government departments and agencies that have a warrant to disperse grant money and contract money for research. So what are those agencies currently doing within their agency? As they're dispersing this research money, what are they doing in order to make sure that research is being done responsibly? That's a question that I have, and I think Biostar will be trying to get a handle on that. But, if you said, if I took a draconian measure... And told every one of those granting agencies you will lose your warrant if something happens that you let slip through the cracks, and I'll give an example, we use the pandemic as an example let's just say you know that was the result of the laboratory research. And NIH or some other entity funded that research.

And there were reports that there were risky research being done at substandard biosafety levels and that wasn't caught by the grant committee. Remember, most grant review committees, study sections

are looking at does the researcher who made this proposal have the bona fides to do the research do they have an institution of the institutional support the laboratory space uh... All the equipment and whatever do they had a collaborator network, domestically or internationally that can well lead to the success of this project or whatever uh... And different factors, there are many different factors but one of the things that lax is the oversight on these for instance If during the course of the grant research a progress report is sent in, and there's gain of function, an alarming gain of function noted in the results of the research, what's the onus on the granting agency to say, all right, before you continue with this research, let's review what you're doing and what's going on? Is this being done at the proper biosafety level? Where is it being done? Is it here in the United States? Is it one of your international collaborators?

We have guidelines within our granting agencies to do that, my question is are they being enforced? And so we can create a new entity to do this why don't we just start right now with making sure that every agency that has a warrant to disperse research money in the form of grants or contracts that they're doing a sufficient job to make sure that that research is being unresponsive.

PATNAIK: That's actually a really good point. We're almost at the end, so two brief questions for Jesse and Gerry. Jesse, related to this, how do you see the role of scientists and culture and transparency from biologists themselves? Do you think there should be more transparency about this kind of research, about if there is a lab accident that happens that could impact a local population, how could that culture be fostered more strongly among the community?

BLOOM: Yeah, I mean, I would say that although I appreciate all the talk about regulation, I certainly think regulation in this area is important. You know, first, just to point out sort of the obvious with the retrospective discussion of COVID origins, which I agree is very important to continue to try to understand. But I mean in the end, the COVID pandemic originated in China. And even though it's to some degree become a U.S. Kind of political issue. In many people's minds, the real reasons that we don't understand better what happened there have to do with the fact that the pandemic originated in China. And there's a lot of reasons to think that the Chinese government has not been fully transparent about everything they know.

So I think that that's important to keep in mind. And no U.S. Regulation is going to change that fact. And more generally, I certainly think regulation and thinking about regulations in these areas are important. But I also think these sorts of biotechnologies are very rapidly moving, often the line between when exactly some research crosses from not really posing a risk to posing a risk can be subtle. And, you know, the more that there are very broad regulations, the more that they can sometimes just kind of become ineffectively applied to a lot of things. So I certainly think I'm not disputing the need to think about regulation, but to go to your point, I really think that having more discussion and dialog about these issues is important. And I think it's very unfortunate how some of these topics have become very sort of polarized discussion and often have even taken on this political element, which, you I don't really understand why, because they're not inherently political issues. And I think that's really one of the important things.

And so I really appreciated you putting together forums like this, people who are interested in discussing these. And I really think we just need to create a culture where there's more discussion and debate about these issues in a way that's not making people feel threatened, but really sort of getting at the heart of what are really very difficult questions.

PATNAIK: Thank you. I agree. And that was one of the intentions behind this, to have like a productive discussion. Gerry, very quick lightning round. If you could recommend like one policy recommendation that would really change and improve biosafety and biosecurity over the next three years, what do you think it will be?

EPSTEIN: I'll just say the one we said several times, creating this independent or commerce entity that has this as its job.

PATNAIK: And did you want to do a follow up on Jesse? I saw you wanted to say something.

EPSTEIN: I totally agree with everything you said. Transparency is necessary between researchers and regulators. It's necessary between researchers and the community. The one big question which I will explore in the next panel, so this is a teaser to stick around, is we now have a security element. People who are out there, maybe the ones who are misusing this information, can read what we say and can use our analysis. And if we say this is very dangerous process, they can use that. So there's

a little asterisk on transparency that I'm going to explore with panelists you now have a warning. I'm going to explore with the folks in my panel, because I think it is a factor that changes the transparency question, and even though it's very important, there's a but.

PATNAIK: That's a very good point. All right, thank you so much to all three of you. It's wonderful to hear your expertise. Big round of applause, please. And I'll invite our next panelist with Hayley Severance from NTI. Jerry is going to stay on as moderator and we have two online panelists coming in.

EPSTEIN: OK. So now that I'm in a new seat and a new role, we're segueing into our second panel on biosafety policy and future pandemic prevention. The panels here are Hayley Severance in the room with us, the Deputy Vice President at the Nuclear Threat Initiative. And on the screen from left to right, we have Sella Nevo, Director of the Meselson Scientist at the RAND Corporation where he's a Senior Information Scientist. And on right, Rocco Casagrande, a Managing Director at Deloitte Consulting and for over 20 years had founded and run the firm Griffin Scientific, which is done. A lot of the path-breaking work in this area. So I guess we'll just launch off. Let me start going into pandemic prevention, which is clearly the theme of the meeting, and also, we've covered it with both the introductory speakers and the first panel, but I think there's possibly more to say.

One feature of the 2018 National Biodefense Strategy was that it was the first U.S. Strategy to address biological incidents of all causes, whether due to natural outbreaks, laboratory accidents, or deliberate misuse. Some, however, have found this combination to be a forced arrangement with different mechanisms deserving different treatment. And given that each of these mechanisms can create a pandemic, how should policymakers approach preparedness and prevention across these diverse threat types? Are there strategies or systems that can address multiple risks at once, or that can attain synergies? Or on the other hand, are we at risk of confusing things by inappropriately combining things that shouldn't be combined? Let me start with Hayley, and then we'll just continue to the cell and rock them.

SEVERANCE: So first, thanks so much. So, first, thanks so much to Brookings for inviting me to join this panel. Really have appreciated and benefited from the discussions thus far, and I hope we can

find more to add to the conversation, because it's been great so far. So, for those unfamiliar, NTI is a global security organization that focuses on reducing nuclear, biological, and emerging tech risks imperiling humanity. And as Jerry mentioned, I'm speaking today as the Deputy Vice President of the BIO program from the Nuclear Threat Initiative. So you asked Gerry about pandemic preparedness systems. I believe that preventing biological catastrophe really necessitates addressing risk across the spectrum, whether they evolve from a naturally a natural crossover, for example, from animals to humans, or are the result of an accidental or deliberate act.

Pandemic preparedness systems need to be addressing all of these threats, and while there may be certain capabilities, for examples, the ability to collect intelligence and attribute to an accidental or deliberate attack. Those are certain capabilities that are specific to a threat. Systems for the large part are inextricably linked to the various threat spectrums and need to grow and evolve together. So I'll give you a couple of examples. Surveillance systems need to be capable of rapidly detecting emerging zoonotic infections, but they also need to similarly capable of detecting anomalous events that may be due to an accident or deliberate event. Investments in dual use research like what you talked about in the last panel need to grow as your R&D capacity grows. Biosafety and biosecurity systems need to scale as you're developing your laboratory networks in order to better detect outbreaks. So you cannot really have one without the other. It's kind of impossible to separate these systems. And policymakers in particular need to recognize is that you should not have the one without the other. For example, a buildup of laboratory infrastructure or research base without appropriate attention paid to safety and security could pose further pandemic risks that we should seek to avoid.

EPSTEIN: Great, thank you.

NEVO: Yeah, I 100% agree with Hayley and thank you all for having me here. It's an honor to be here. I think, so completely agree, there are many types of responses to bi-risk that just apply across both natural, accidental, and I think mainly in the detection response and resilience, there's more in common and there is a part, Hayley already mentioned bio surveillance, things around transmission suppression, right, whether it's PPE or air quality or built environment, these things will help us across all of these different risks, similarly for medical countermeasures, stockpiling of food and medication, and when something is useful across a wide variety of scenarios, that's a great thing. We should be doubling down and taking advantage of those. But there's also mechanisms that I think are pointed

primarily on a specific type of risk. And I think a lot of things in the prevention space look like that, right, with new zoonotic diseases. Maybe you want to focus more on reducing encroachment on kind of wild habitats. And whereas in accidental, it's more governance of dual use research of concern and biosafety laws and malicious.

Maybe we hear more about access controls and deterrence and attribution. Um, and I think. It's important to do these things well enough. I think in general, biological risks are important enough not to choose one or the other. You know, it's been only five years since the pandemic killed about 20 million people. I hope that our collective attention span is long enough for us to still recognize that it's worth both a significant and diverse investment in different causes of biological risk.

CASAGRANDE: Yeah, I mean, I've disagreed with the other two speakers. And yes, thanks for inviting me. I wish I could have been there in person today. Yeah, just to emphasize what Sella was just talking about, the mechanisms for response and preparedness and to mitigate pandemics are similar across all of them, yet the very specific mechanisms to prevent the various causes of an outbreak Are worthy of investment individually because prevention is so, so much more cost effective than response or mitigation. And so, you know, right of boom, once the event has happened, early detection, medical response, public health response, resilience mechanisms all look similar and can address the whole variety of pandemics that could be caused by the three different causes that were listed, prevention is really, really cost-effective. And there you have... Elements that are often specific, like understanding the risks of human fallibility in a laboratory is going to be specific to only the one mode of laboratory accidents, whereas understanding how an untrained scientist could manipulate the tools of biology to intentionally cause harm, that's also going to be specific to just one mode, the intentional threats to biosecurity space.

Whereas looking at the propensity of certain viruses to naturally evolve in a particular direction towards human infection would be, once again, only amenable to understanding risks and natural emergence. But even with that said, there are some elements that are cross-pollinating, let's say, when it comes to prevention. So for instance, personnel reliability. In a laboratory can let you understand information about competence to adhere to normal safety measures, but also to see if they would adhere to normal security measures that could prevent outside access or indeed help you

understand a little bit more about insider threat in a lab. Could someone that you've hired unbeknownst to you be a malicious actor that wishes to cause harm or exfiltrate dangerous equipment or materials. You know, those types of investments in prevention can overlap. And so I think you can get a little bit of a twofer there.

EPSTEIN: Thank you. I'm going to stay on the prevention point a bit. The title of this panel, as I said at the outset, is Biosafety Policy, and I'll generalize that to biosafety and biosecurity because we're certainly going to talk about both, and future pandemic prevention. We've just run a worldwide experiment on how to not prevent a pandemic. We had one. And presumably there are lessons in what the country or the world got wrong last time that might help us prevent the repeat. At the same time, I'm very cognizant of this eternal warning about don't prepare to fight the last war since the next one might be different. So given that, I would like all of my panels to pick either or both if you'd like. I'd like to either identify an important lesson observed from COVID-19 that we should turn into a lesson learned or identify a lesson that wasn't necessarily taught by COVID-19, but might be critical to preventing the next pandemic, whether it be natural, accidental or deliberate. Let me just throw it at the panel and let's start reverse order. Rocco, why don't I start with you.

CASAGRANDE: You know, I think saying what went wrong on prevention is a little bit difficult because, as was mentioned, the origins of the pandemic are still murky and certainly controversial. But I think one thing that we can learn is, given I think that everyone agrees, it is feasible that a laboratory accident that involves highly transmissible and novel pathogens could lead to a pandemic, not that it did, but that it could be. I think the biggest lesson learned is that we're drastically under-investing in biosafety, specifically that we don't really invest in biosafety as a science, meaning that we are not really spending even 1 percent of the total treasure that we are investing in researching pathogens on understanding, doing experiments to determine how to do work more safely. So every other high industry that has some risk associated with it, whether it be nuclear power or chemical manufacturing or transportation, invests significantly in research into the causes of accidents and to ways that mitigate them.

That investment has been direly absent. In biosafety since basically the 1980s. The amount of resources that the U.S. Spends on empirical biosafety research over the last 20 years is much less

than a million dollars. And so, yeah, I think that is perhaps the biggest lessons learned is obviously there's a positive return on investment in understanding how accidents happen and what mechanisms can best prevent those accidents.

EPSTEIN: Thank you. Sella, before I turn to you, I did want to jump in and say, I did not mean to be prejudging and saying we failed to prevent it, that it was a lab origin. If it was spillover, we did not prevent it by permitting wet markets or whatever the route was. So it wasn't meant to bias the question. Sella?

NEVO: Yeah, I'll go ahead on the first thing that came to mind, hit a swell on this question, which is just, it's just so evidently clear, whatever people think about the evidence on what happened in this scenario, it is so evident clear that both, a zoonotic spillover through that market and a lab leak is very plausible. No one says a priori, it could not have happened, right? There are many arguments on, you know, the evidence, the epidemiological evidence and the genetic evidence and so on, but it's very clear that it could have happened. And I wish people would... Conclude from that that they should be treating both of these options as meaningful options that need to be protected against, but instead, yeah, both the uncertainty and the kind of polarization around this has made it so that it's very difficult to make progress on either.

But since Rocco has touched on that, I'll say one other thing, which is, I feel like this is a bit meta, but I feel like we've forgotten almost every lesson that we learned during the pandemic. I think that during the pandemic, you know, every newspaper and pretty much every person I talked to was talking about how negligent governments were in not preparing for this and how the experts have been, you, know, warning about this for many years and so on. But the work that has been done during the pandemic is already being dismantled you know, biosecurity companies were experiencing a boom and now most of them are downsizing or closing governmental investments, depending on from bitterness, are dropping. And I just think it's really good to you know, how cost-effective these investments are. COVID is assessed to cause more than $60 trillion in harms. Even with very conservative estimates, it would probably still be cost- effective to spend $90 billion a year every year to prevent events like these. You are assuming they only come every one or two centuries, and that's a conservative estimate, and if you're ignoring the fact that there's plausible worse scenarios.

Now, during the COVID pandemic, that pandemic-related governmental investments were tripled, which is good. But even during the height of the pandemic, we were willing to spend only a small fraction of what would obviously be cost-effective to prevent these acute harms. And now we're kind of slowly taking that as well. So I'll say slightly general, which is like, if we only could remember some of the things that we actually cared about these during the pandemics, I think that of it really. Really useful.

SEVERANCE: Yeah, and I think, Gerry, in the question that you asked, you were talking about, you know, not preparing to fight the last war, you know, learning from COVID, but not over indexing on COVID when we're preparing for the next pandemic or, you know, biological crisis. And I think that's really important. You know, I think we fell into that trap in the past. After 2009 swine flu, all our plans were targeted specifically at influenza. And post-Emerithrax, bioterrorism was seen only as bacillus anthracis or botulinum toxin. And so I think we kind of fall into – well, we knew it happened, so we need to prepare for that again. And I – well, I think it's important to understand that. It can happen again, let's not constrain ourselves in our imagination and not, again, prepare to fight the war we already fought.

And I think that comports with what Sella and Rocco said, and I totally agree with Rocco's point about the underinvestment in biosafety compared to the increasing investments we're making. Which have now been, you know, probably disrupted to a certain point in R&D infrastructure to, you know in an effort to be better prepared next time. So just to preface that, I think in addition to those areas already mentioned by my fellow panelists, I think one of the biggest areas for improving, for improvement post-COVID is, and this is, again, agnostic to the next threat is preparing to empower more localized responses. I think one of the ways that we lost trust from the public is that some of the non-pharmaceutical interventions lasted too long. The school shutdowns lasted too long and weren't necessarily based on the actual risk posed to that community.

And so if we can figure out a better way to empower local leaders to make better decisions, be more confident in, for example, reopening schools and have the data and kind of the trigger points that which, okay, we can safely reopen with maybe these modifications. I think that would have been really

helpful in gaining trust in the public. And this, my second point goes to Sella's, we need to increase, not cut our domestic and global investments in pandemic preparedness. World remains dangerously unprepared. We have the Global Health Security Index, which looks at 195 countries' health security capacities at NTI. And it showed, for example, in 2021 that 155 out of 195 countries have not allocated national funds within the last three years to improve health security capacity outside of emergencies. So this is not like a problem of only a couple of countries not doing this. This is a global issue. And so what do we do? I think domestic leaders should prioritize filling gaps in the U.S. But also look for opportunities to catalyze global investments. You know, the investments we make globally in shoring up pandemic preparedness capacity. One good example is by contributing to the Pandemic Fund in its first two funding rounds.

The pandemic fund, which is aimed at providing investments in other countries to shore up their pandemic preparedness capacities. Their first two grant rounds totaled $885 million to 75 countries, but they were able to mobilize an additional $6 billion. So they We invested $885 million, but we're able to mobilize $6 billion in international co-financing. And country co-investments. So it's really kind of stimulating and acting as a force multiplier for pandemic preparedness across the world. And then two final points, decision makers need to be exposed with how to deal with emerging biological events, especially given incomplete information so that they feel more confident in making decisions during a crisis. So I admire programs that are kind of preparing future leaders for this, like Brown University's Game Changers. And then finally, sustained investment in basic and applied research, we've heard it many times, is critical. Removing financial risk barriers and adapting regulatory processes are really necessary for us to enable the rapid development of medical countermeasures, which during COVID saved millions of lives.

EPSTEIN: Thank you. And particularly following on your discussion of the international aspects, I'm going to go jump to something I was going to cover later but prompted by an audience question which was submitted in advance. I'll just go ahead and come there. On similar topics, I'll combine the two. We all recognize that biothreats are global, whether they're natural, accidental, or deliberate, and that addressing them in the United States alone is not sufficient to protect us. How can the United State best promote global safety, biosecurity, and bio responsibility. In a way that protects our safety, our security, and our values? Does setting an example domestically inspire others to match it? Or could it

lead to a brain drain if we put in place processes that researchers don't find acceptable that would undercut our security as well as our prosperity? Other than leading by leverage, other than leading example, what leverage do we and then I'll tack on the audience question. Given current geopolitical dynamics, which state or international organization is best postured to advance political will in meaningful ways to increase global transparency into how individual governments are going to address by safety, gaps, and concerns. Let me try the permutation. I don't think I've done yet. Let's go Rocco, Hayley, Sella on this one.

CASAGRANDE: Great. Well, thanks for the question. I really appreciate it. I'm going to sound a little bit like a broken record by advocating for more research here, but I think more biosafety research is truly the tide that will lift all boats internationally. Ironically, it would even help reduce accidents that arise from potentially covert and malicious programs like, you know, states offensive weapons programs because no one wants to have an accident. So research conducted anywhere in how to conduct laboratory work more safely is likely to reduce risks everywhere.

Also, the good news story here is a lot of that research is amenable to be conducted in low resource settings. Some of the work that we conducted under a grant that was provided to us by Open Philanthropy. Was done for, you know, with thousands of dollars or tens of thousands of total dollars in laboratories in relatively low- and middle-income countries, because the main resource you need is laboratorians' time just to do hundreds of replicates of relatively tedious experiments to see how often rare mistakes occur. And so… Honestly, anyone funding life science research that relates to understanding the causes and effective mitigations in biosafety could reduce accident risk worldwide by researchers that live in almost any country and even in low resource settings. So I think it's a really good news story there.

SEVERANCE: Yeah. And I just want to foot stomp the need for biosafety globally. Again, our Global Health Security Index demonstrates that we have a lot of work to do. Only 17 countries out of the 195 score above a 60 out of 100 for biosafety. Biosecurity is kind of a worse news story. Only 178 countries scored below 50 out of a hundred points for biosecurity. 94 percent of countries have no national oversight measures for dual-use research as of 2021. So it's a relatively neglected component, again, of that overall pandemic preparedness system that we talked about at the

beginning. This is not the entire solution, but programs – this is an example of how the U.S. Leads by example, but also directly partners in addition to kind of the work Rocco mentioned, um, the cooperative threat reduction program, which, you know, a little bias, our, our co-founder, um, Sam non was, uh, Senator Sam down was a co-sponsor of the cooperative threat reduction legislation, uh following the fall of the, uh, so the union and the cooperative effort it took to, um reduce the risks of loose WMD materials.

So It is one of the leading global efforts to advance biosafety and biosecurity through cooperative programming with countries in recognition that a biological catastrophe would not only be devastating in the country in which it originated, but also to the U.S. And to our allies. And so by continuing to support those types of programming, where we're working with countries to really shore up their capacities, I think is really critical and an example of how U.S. Leadership can really shape biosafety and biosecurity globally. Also, I think it's really important for policymakers to recognize that we cannot allow a race with China on AI and biotechnology to be a race to the bottom on safety and security. So, to ensure that we're promoting responsible innovation, we should provide... Resources and political support, and I'm sure we'll talk a little bit of what that responsible innovation looks like, but we should provide resources and support to elevate, for example, the U.S. AI Safety Institute to evaluate and advance solutions that reduce risks, including biological risks associated with AI advances as a vital U. S. National security interest.

Now this may take different shape as Biostar kind of gains traction that's up to you know up for debate, but now we have these AI safety institutes, so helping them better evaluate and advance solutions that reduce risks, supporting research for guardrails for biological AI tools and agents to meaningfully reduce biological risk while enabling innovation, advancing safeguards that have been co-developed and vetted by communities that include reps from industry, academia, and security community. We heard a lot about the importance of co-developing solutions so that they'll be likely adopted. And actually in alignment with one of the principles for action in the national – I call it the NSEB report, the National Security Commission on Emerging Biotech, that Dr. Rozo co-chaired, work with the international community, including China, to develop best practices and standards for biosafety and biosecurity to prevent misuse. Especially as these emerging technologies are evolving.

So I think it's really important that the U.S. Collaborate even with countries that may seem as, or that are definitely global competitors in this space.

EPSTEIN: I'll be previewing my next set of questions. I was about to remark that it was amazing. We'd gone an hour and a half into two panels and hadn't heard AI in a Washington meeting, so that's where I'm gonna go. And I'm particularly happy to have the three of you on this panel because I know you've all done deep work in this area. What specific biosecurity risks arise from AI's use in lab settings and what policy interventions are needed to mitigate these risks and prevent accidental or deliberate misuse? How might AI be misused outside of established labs? Could AI be leveraged to, also in the other hand, could AI be leverage to enhance biosafety and biosecurity? And let me just put an asterisk, given the expertise on the panel. If I asked you the wrong AI question, please answer the right one. Sella, let me start with you, and then we'll go to you, Rocco. Hayley, you just covered that. If you have anything to add, Sella, please.

NEVO: Yeah, there's a bunch of questions there, so I'll try to tackle some of them and leave some others to the other panelists. So, I mean, as I think many people here know, AI interacts with biology in a variety of ways. There are different ways in which different AI models, some of the foundation models, some of biological design tools, interact with different steps both on, you know, an attacker's path to developing a bioweapon as well as defenders can use them. So let's start with the adaptive side and concerns. My biggest concern around AI in biology and biological labs is the threat of it increasing the circle of capability for truly terrible outcomes. So already today, expert biologists can do some really scary stuff. Brilliant biologists might be able to do genuinely terrible things even on their own. But we've never seen a large scale successful biological attack.

And I think one of the reasons we haven't seen that is because, you know, the people who can implement these kinds of attacks are rare, and usually terrorist organizations or other organizations that might have an interest in doing so struggle to recruit them. So my biggest worry is that things that are already possible today, things like, you know reconstruction, rescue, and amplification of existing pathogens, modifying existing pathogens to become more virulent or infectious, that these would become available to a much wider set of people. And therefore, when people do have the interest in creating truly large-scale harm, that'll be easier for them to do. And my theory is that this seems to be

a pretty likely outcome of the trajectory that we're currently on. We're building experts in every part of the process that everyone will have on their cell phones. Widely available biological design tools can already correlate sequence to function better than experts. Cloud labs, which require no human intervention, still have a way to go. I don't mean to imply they kind of can do the whole stack but are still able to do more and more every year. And large language models can already interface with all of these tools and give people suggestions for how to overcome existing methods to try to stop them from doing that, including in ways that we know of work because they've been shown to work in red teams.

Maybe just to kind of give a concrete example, just a week ago, SecureBio put out a new benchmark that looks into questions about practical implementation of virology work that has dual use potential. And these were constructed by professors based on questions that they frequently get from students that don't know as much about biology, but they need the professor's expertise to be able to do that kind of pathogen related work. And the results show that the latest generation models, including DeepSeq R1, are far better than experts, even when experts are only asked about their own subfield, even within virology. So, already, we all have something that is better than leading experts on our phones that can guide us through dual-use experiments. And in order to overstate this, of course these benchmarks are not identical to reality. There may still be many barriers in reality that are not represented in these benchmarks. But we're kind of getting uncomfortably close. The set of excuses for why we should be confident that we're not there or we won't be there too soon seems to be kind of shrinking over time.

And so that's what I'm worried about where we'll get to. In terms of what we can do to prevent that, I think preventing that is very doable. But I think that will require... Some level of pre-appointment evaluation and the application of access controls or mitigations for these models so that we don't just say okay everyone can do whatever they want with them which right now is not really happening as most Bio AI models are open sourced. In terms of how AI can be leveraged to enhance biosafety there's many ways to do that. I would think we should be using AI enabled biological design tools to screen synthesis requests if you know Hundreds of thousands of people can now use these tools to better create things that have new capabilities. We should be using those safe tools to check out, okay, if I'm going to create physically this strand of DNA, what, what traits will it have? What will it

allow people to do? We should be using AI to detect novel pathogens in wastewater, which is a really promising approach to detecting novel pathogens and novel pandemics very early. But there's still a lot of work to be done. Yeah, there's a lot of things we could be doing with AI.

EPSTEIN: Thank you. Rocco.

CASAGRANDE: Yeah, just picking up where Sella left off, because I agree with basically everything he said. Some of the ways that AI can enhance biosafety and biosecurity is a lot of these AI tools can greatly boost efficiency in the laboratory. So as an example, the tools that can predict whether a protein, a novel protein structure will fold properly and therefore work in a biological context. Can basically, they won't help you design a new structure. You still have to do that. But of your 100 different guesses at what the best design might be, it'll tell you like which five of those 100 are likely to fold properly. So back before these tools existed, you would have had to build and create all 100 of these, which means there are 100 times more lab hours where people in the lab potentially making mistakes and, you know, and, and the costs associated with it would be much greater, whereas these tools could narrow it down to like the five that might fold properly.

So it basically saves you 20-fold opportunity for accidents and also costs. In a more like traditional biosecurity realm, so prior to my work as a consultant, I worked in the UN as a weapons inspector in Iraq. I would have given my eye teeth for some of the tools that exist today related to overhead imagery. There's a company, Planet.com, that has microsatellites that look over every stretch of landmass several times a day and have AI to analyze that all for you. So Iraq's the size of California. I would have given anything to know where are they digging, where are any new excavations in the last couple of weeks or months. Like having that level of granularity and that level scrutiny for the AI systems to look at the entire country with that much precision would have been incredibly beneficial. I mean, additionally, a lot of what we knew about Iraq's weapons program, some it came from mismatches in important export data and in use data. Having AI systems that could comb through reams and reams of those data for a lot more facilities than we had it for would also be great to point humans at the right facilities to inspect.

Um, as far as like what to do about it, I think. Many of the main players in industry are already investing a ton in improving safety and reducing risk of misuse. I think they need to be encouraged to do that. And we need to develop standards that prevent a free rider problem. So right now, the industry leaders that are investing significantly have models that are less prone to abuse than others. But there's nothing preventing competitors coming in, not investing that money, and having unsafe models that are potentially close to as capable. And so if we can set standards for what responsible conduct looks like in this industry globally and also within this country, and also set a bar with which basically the only—the U.S. Government will only do business with AI industries that prove that their models are relatively safe. I think that would prevent the free rider problem and also help the responsible companies, which largely happen to be based in the U.S. So it would help with an on-shoring, off-shrink and competitiveness problem as well.

EPSTEIN: Thank you. Hayley, anything to add or should we go ahead?

SEVERANCE: No, I really think they covered the landscape on that. The only thing I'll add to Rocco's last point is about the importance of those, of kind of like globalizing the standards of norms and best practices, I think is both difficult but necessary, you know, we're trying to do a small part of it through our AI bio global forum, but I think that will help, yeah, Ensure the continued competitiveness of U.S. Products through a level playing field, but also just generally begin to shape the norms of what's ethical use, et cetera. So I think it will have multiple benefits to begin having these conversations with global partners.

EPSTEIN: I realize I've just sabotaged my future career as a daytime talk show host, because I can't get you guys to disagree with anything. We're going to turn to bioeconomy supply chains, where I'm afraid we'll have the same consequence. We've talked about it a bit, but I think we can drill down some more. Biosecurity and biosafety concerns have traditionally been focused on research laboratories, and in particular, academic ones. However, we're now in the midst of an expanding bioeconomic, as Dr. Rozo's study made very clear, including bioindustrial manufacturing, in which the sites, the locations. The purposes and the intents of people working with biotechnology have vastly diversified. We're seeing the development of industrial ecosystems in which things that skilled

researchers used to have to do themselves, with considerable time and effort invested, can now be purchased from specialized vendors.

All of you worked on the challenges of this expansion, specialization, and what I might call commodification of the biotech ecosystem has created. Can each of you talk about some of the new challenges that this economic and geographic expansion has brought about and what new regulatory mechanisms are needed to deal with and again, I think we've got into this some, but let's deal with this a little deeper. Let's try Hayley, Sella, and then Rocco.

SEVERANCE: Yeah, sure. And as I mentioned, I think we've all mentioned previously, our proposed approach to biotech governance, industry needs to be part of the solution set, academia needs to be a part of this solution set. You know, unlike previous technological disruptions of global security, you know, we think about nuclear at the Nuclear Threat Initiative, which were mainly driven by governments. In this case, market forces and commercial enterprises really dominate this innovation space. And so solutions will require those visionary partnerships between policymakers and, again, those innovators in the private sector.

I think US policies are evolving to address this fact. And these emerging threats is not the first case where they have to work with private partners. But I think there are important vulnerabilities that remain, and we heard this come up quite a few times in that, there's a lot you can do with federal funding as an incentive. So you can put controls on the type of research that's on how it's done, how safely and securely it's gone if you have federal funding as a carrot. But for those research efforts, which I would argue in the Bio, that leverage point. However, there still remains a leverage point in those private funders. And so that's something that we would really like we're trying to address at NTI is to address that gap of how to incentivize safety and security through privately funding research. Last year, we partnered with CEPI, the Coalition for Epidemic Preparedness Innovations, to establish a public commitment. By bioscience and biotech funders to incorporate biosecurity and biosafety into their decision-making processes before funding is rewarded, you know, understanding the risks, the potential risks posed by research efforts and seeking to either mitigate those or, you know, refuse to fund the work in the hopes that we can reduce the likelihood that, you know non-governmentally funded funders will support unduly risky bioscience research. And also incentivize scientists and

technologists to adhere to biosafety and biosecurity best practices. We really need to kind of expand the community that's taking this area seriously. And we also provide a forum in which funders can come together to discuss some of the challenges and opportunities.

I won't pretend this is the entire solution, but we're trying to be a part of the solution. It's not a regulation step per se, but it's a way to address risks where, as we heard from the Senator, regulation would be particularly difficult. The other thing I wanted to touch upon in terms of regulation is that Dr. Rozo mentioned DNA synthesis screening. I think, as she mentioned, and I think Gerry, you mentioned, it's unclear who kind of. Is responsible for enforcing the requirements for nucleic assets screening framework. And I think it was made even more unclear with the repeal of the Biden-era executive order on the safe, secure, and trustworthy development and use of AI. The framework is still in place, but again, that responsibility piece and accountability is a bit unclear.

I'm glad to see progress in the House through the Nucleic Acid Standards for Biosecurity Act to address the lack of consistent screening standards so we can continue to protect U.S. innovations while also shaping global standards, and I encourage the House and Senate to positively consider this bill. But we still need further congressional action, especially since we don't have a Biostar currently. To make DNA synthesis a more clear requirement, DNA synthesis screening, a more clearer requirement. And I hope that this is only, as Dr. Rozo also mentioned, this is one technological challenge that we're facing. We're gonna have many, including as AI evolves. And so I hope Congress continues to work with industry and academic partners, as well as security professionals by introducing smart legislation that promotes responsible innovation. And, you know, I really look forward to continuing conversations on how Biostar will help address that, you now, that problem of keeping up – of governance keeping up with the pace of technological development on deck with us.

EPSTEIN: Thank you. Sella?

NEVO: The first thing I'm going to say, whenever someone asks me a question that includes what specific regulatory mechanisms should we rely on or develop, I always want to check what you think, Gerry. So just a flag that I'm always interested in your thoughts as well. But in the meantime, I want to take a step back and explore how this diffusion or expansion influences our regulatory option space at

a high level. Herman Kahn kind of famous Arandite, once wrote, you know, assume that it was possible to manufacture a doomsday machine from approximately $10 worth of available materials. While it might be unthinkable that the world would be destroyed by such a doosey machine, it would also be almost inevitable. The only question would be, is it a matter of minutes, hours, days, months or years? And then it goes on to say, okay, if it costs thousands or tens of thousands, the analysis does really change.

But if it cost millions or tens of millions, then only a smaller number of organizations could use them, and they could be much more easily regulated. So the bottom line for this, or things true to this day, is, you know, when the technology, materials and skills proliferate to be genuinely ubiquitous, if, you know, people can do this in their own home and so on, they become almost impossible to regulate. Um, now, Hayley already made a great point about the funders being an interesting leverage point. I want to highlight another one, which is there's a big difference in whether they proliferate in the sense that really anyone can do them or if they prolificate in the sense as I think is happening in at least a lot of components in the bioeconomy, they proliferate through services, people specialize and then provide those services to third parties.

So, for example, right, it's not that everyone today can synthesize nucleic acids on their own, but rather everyone buys it from synthesis providers. Or we can also include here maybe buying synthesis machines from a small number of companies that produce those. In fact, the number of people, the number labs and researchers that actually do nucleic acid synthesis themselves directly has gone down in recent years because it is so cheap and easy and efficient to buy that from providers. And that can end up being a net benefit of it from a security and government's perspective because then you could implement controls there in those companies that could be incredibly effective. So this is a continuation to the things that Hayley has already said. I think that whether it's synthesis screening, whether it is producing other controls, access controls. In other parts of the supply chain, both in fetal serum, things like that. I think there are a lot of opportunities there, but we gotta make sure that we direct them in the places where people genuinely rely on areas that are all-regulable as opposed to others.

CASAGRANDE: Yeah, so just to kind of add on slightly to what Hayley and Sella already said, you know, I think when you look at the services industry and biotechnology, there's a gap in terms of even in this industry, even understanding principles of biosafety and biosecurity and understanding what their responsibilities are, related to existing laws and regulations like export control and the select agent rules. And that's because much of this industry came out of biotech that has nothing to do with toxins or pathogens, unlike those that work in laboratories where you're directly working on viruses and bacteria and toxins. And so in this industry, I would say there's often a gap that could be filled with outreach and education, saying, okay, here are risks. Here are the laws that already pertained to your industry, and here's how you comply with them, but also here's some data on how things went wrong in the past, how accidents happened or people tried to exploit the life sciences to cause harm. I think just that would have a tremendous benefit due to the difference in background of. People who normally work on things that are dangerous versus people who are more technologists who have these highly capable companies that people can go to.

EPSTEIN: Okay, thank you. Again, I appreciate the questions that have been turned in from the audience. We're not going to be able to get to very many of them, but let me throw one in at this point, and it's quite a step away from things we've been talking about. I think it's a really important topic. How can you control and contain the spread of misinformation during crises when that misinformation could put people's lives in danger? You're close so I'm starting with you.

SEVERANCE: Great. Yeah, this is not my area of expertise, but I agree that it is an important factor to consider. You know, for example, when you're looking at kind of the full spectrum of how AI is impacting bio-weapon development and use. I heard an interesting kind of framing of this, you know, we usually, and I think here on this panel, we think about, you know AI impacting the capabilities to design, synthesize, you really kind of the production phase of bioweapon development, but there's a whole lot of stuff that happens before that. There is ideation, there's justification, why is this, the weapon we want to use? And then kind of on the other end when they're think, you know, they've designed it and they're thinking about deploying, there's looking at the field conditions, how this will impact people. And I think part of that is also misinformation and disinformation, especially if you want to avoid getting caught. And so you deploy like a misinformation or disinformation campaign as part of your, you know destructive aims in using a bio weapon.

And so I think there are. And using AI to kind of facilitate better reach with your misinformation, disinformation, I think is a concern, as well as using AI kind of in all those different stages. I think we need to think clearly about how it's impacting the different components, just how we think about how AI is impacting the life cycle of research and biotechnology development. We also think how it is impacting the cycle of bioweapon development and where opportunities where we can disrupt and prevent the kind of the advantage AI gives a malicious actor. I don't know the answer to helping address kind of the using AI to facilitate better like a misinformation campaign. But I think it's an important part of addressing that whole life cycle of BW development. I would look forward to what my colleagues think about this.

EPSTEIN: I now realize I shouldn't have called you out, I should have offered any of the panels who wanted to answer that, recognizing that if this is too hard to answer, then you could take a pass. But anybody would like to contribute to this?

CASAGRANDE: Yeah, so, I mean, on the good news story, a lot of these AI tools that we've been talking about are very good at understanding humans and comparing it to a body of what you might call truth and basically being able to automatically identify misinformation or disinformation at the same speed at which it's being developed and then also create counter narratives that are closer to that body of truth. That's the good news. So here, AI is not only a tool for the offense in that they can generate misinformation and disinformation in various voices targeted to a bunch of different audiences at the speed of copy and paste, but also other AI tools can identify and counter that with equal alacrity. The problem is, and I think we're living this now, is that misinformation is difficult to identify objectively from viewpoints that represent all of society.

So, for instance, related to vaccines, someone might say, oh, my aunt just got vaccinated against X and then she had a heart attack. That may be true. So, countering that with just information on, well, the rates of heart attack are no different in vaccinated and unvaccinated populations and blah, blah, blah, is not particularly convincing. Also, the viewpoint on what you think are acceptable risks and acceptable actions to take and the acceptable costs of those actions all differ markedly, depending on your viewpoint. And so we really will struggle as a society to say, this is the true body of information

against which everything else should be judged, especially if we're trying to do this internationally. However, when applied in the right way and directed, the AI tools do have that capacity. We just have to kind of come together as a society as to what our goals are, which is going to be very difficult.

EPSTEIN: Great, thanks. Or you're gone?

NEVO: I'm happy to say, maybe I'll add one last thing, which is I think one really important in the engagement with misinformation is focusing on the majority and not the fringe. There are some people who believe in conspiracy theories because they love the conspiracy, they have a distrust of authority, and health is one instance where that can be applied. And those are hard to, you know, very hard to convince otherwise. It's a game of whack-a-mole. You explain one thing, they come up with another. But the majority of people are not that the majority people are genuinely trying to understand what to believe what is true with limited time, you know, limited domain, specific expertise and a lot of noise coming at them from different directions.

And for these, you, know, I think that sharing information, providing that reliable information and being very transparent about it both about uncertainties and how it was produced and so on. I think it's really useful. And I think that often in media, there's a tendency to go to the extreme, you know, as we're talking about vaccine hesitancy which Roger mentioned, talk about the people who believe that Bill Gates is using microchips to put it in people's, you know putting microchip in people. Whereas I think a lot more common is, you know things like, wait a second, we did this vaccine faster than ever. Does this mean we have less tests? Does it mean I can trust it less? This is a very legitimate question that people might have concerns about and it's worth explaining exactly what has changed in the process and so on. So, not that that fixes the problem, but I think that's an important thing to not be distracted by the extremes and aim at the majority.

EPSTEIN: Great. We're kicking down to the end of the session. I had another topic I'd actually left to tease before last time, which I might want to get to, but I also wanted to preview that we're going to have around a final jeopardy at the end, where I'm going to say, is there anything I should have asked you and didn't, and invite you to add something that we haven't covered yet. So I'll need a combination. I'll ask a question about the transparency versus restricting information, which, I'd like to

hear you, but if you're more concerned about the thing that you really wanted to say I haven't given you then that can be option B. We've heard in a previous panel about the importance of transparency and openness to fostering public trust, and that of course is necessary in democratic societies to welcome the kind of research and technology that we've been talking about today.

At the same time, everybody on this panel has wrestled with concerns about what we've come to call information hazards, the fact that the dissemination not of misinformation but the disseminate of true information that may be needed to reduce biological risk can nevertheless be exploited by people to do harm. It's not so much a safety issue. We know pathogens evolve, they mutate, they defeat antibiotics. They don't read the paper. So if we're talking about the safety things we're doing, we're not so worried about what the pathogen is gonna learn now. It's a big problem for security because our adversaries are trying to figure out where we're able to defend and they're trying to defeat that. So there's all sorts of ways in which information hazards can pop up. It might be a novel scientific finding that reveals vulnerability nobody had realized and we're gonna have a hard time rebooting the human body to fix. It could be an analysis of somebody's in fact, even some of the questions we were considering on the panel, what do you think is the most concerning approach?

I'm not sure I really want to answer that because people might be interested. So let me offer the general question of the tensions between not being able to say everything we know when we do know that we need to get people's engagement and trust on board, and that typically requires transparency. So that's one set of questions. And then the other possibility is, Gerry, that's not the right question. I really wanna talk about something else. So let's go over in reverse order. Let's go Rocco, Hayley, and Sella on column A or column B.

CASAGRANDE: Yeah, the good news is a lot of the information that's needed to understand pathogenesis or to take defensive actions or to make the right investments is not the same that could be misused. So careful consideration about what truly can be redacted or shared only within trusted networks is, I think, a very potent tool there. I think the bad news is we often think about control of information at the publication level, where there is at least some level of review with peer review and the publisher, et cetera. But honestly, that's kind of late in the process in that the experiment was already done, one. But two, oftentimes you've talked about it at several scientific conferences, et

cetera. And so... Really, we have to be thinking about dual use and potential misuse of information very early on in the process and understanding exactly what we want to communicate early on.

And unfortunately, that's going to require extensive, once again, outreach and education because sometimes these issues are caught very, very late in the process, if at all. Also, I want to say that We've kind of known what to do. For decades now when it comes to this, but we're really bad at doing it, like, still, you see journal publications on a, I would say, monthly basis that have details that at least I wouldn't like to see in print. And so getting this out in a way that is more robustly acted upon is a very valuable thing. And I think, and maybe Hayley wants to talk about this more, the funders compact might be one way of doing that. Thank you.

NEVO: Yeah, first of all, I completely agree with everything Rocco said. I think the, maybe I'll say my original background is in information security and cyber security. And in that field, it is pretty standard practice that when you discuss vulnerabilities, you first share them with defenders and the relevant authorities, then defenders fix those vulnerabilities, then you talk about them with others. Now, the fields are very different, okay? One big difference is that in cybersecurity, most vulnerabilities, not all, but most are much easier and faster to fix than most biological vulnerabilities. So the implementation phase will look different, but I think the principles still apply.
I think that when we're talking about important large-scale vulnerabilities that have, you know, a lot of importance to them, these should be discussed, but they should be discuss with the stakeholders that can do something positive about them rather than kind of shouted from the town square. Um, but then you know, to Rocco's point, we do need to do something about them. I think, you know I've read multiple red teams of various things, some by people with us here today, that, you know, many, many years ago said, okay, well, clearly a malicious actor could do one, two, three, but that doesn't get fixed. So I think the pressure really should be on first reporting it to the relevant authorities, then actually fixing them. And then great, let's talk about them more publicly, but not while they could directly endanger the safety of the public.

EPSTEIN: 76 seconds and bring us home.

SEVERANCE: I won't take that much. So, yeah, what Rocco alluded to, I think there is a lot of leverage at the funding stage to kind of drive best practices for, you know, what information should can be published and for them to drive those standards. Because I agree, by the time you're getting to publication, it's very late in the stage, given preprints and, you know, all the things that are currently kind of the practices that are used in scientific publication. So targeting the scientific journals is probably not the most effective thing you can do. So starting kind of like earlier in that intervention cycle with the funders, I think could be a really promising potential solution, and Rocco will take that into consideration in our next forum meeting, so thanks.

EPSTEIN: I just want to take this opportunity to thank the panelists. I may be selfishly thinking this has been a fascinating discussion. I want to thank Brookings for putting this on. Not only the two panels, but the speakers before I thought were fascinating. At one point in Washington, I made a rule I was never going to go to a talk by a politician because they're just going to say something political, but I thought Senators Peters were right. So, Sanjay, I guess I'll invite you to close us off.

PATNAIK: Thank you very much. This was really fascinating and enlightening, and I want to thank all of you for sticking with us. It's a long event, but I think these are really important conversations that we have to have in a, as Jesse said, in a productive, in respectful way, and we look forward to doing more in that space. Thank you, have a good evening, everyone.