Center for Strategic and International Studies

TRANSCRIPT

Event

"25 Years Since the Anthrax Attacks: Where Are We Now?"

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FEATURING

Wendi Kuhnert

Deputy Director, National Center for Emerging and Zoonotic Infectious Diseases, U.S. Centers for Disease Control and Prevention

Richard Burr

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

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Sophia Hirshfield:

Good afternoon, everyone, and welcome. I'm Sophia Hirshfield, an associate fellow with the Global Health Policy Center here at the Center for Strategic and International Studies.

It has been 25 years since a series of letters containing anthrax powder were distributed through the U.S. Postal System in an act of bioterrorism. In the weeks following the fateful attacks of September 11th, 2001, letters containing a powdery form of anthrax were mailed to several major news media outlets and the offices of two U.S. senators. Amid the uncertainty and fear surrounding these attacks, an estimated 32,000 people across Florida, New Jersey, New York, and Washington, D.C., received preventative antibiotics.

Twenty-two people became infected, five of whom eventually died. Dozens of buildings were contaminated with anthrax spores, with decontamination efforts taking several years and costing hundreds of millions of dollars. The ensuing FBI investigation to find who mailed the anthrax letters became one of the largest and most complex in the history of law enforcement. And much is still unknown about the motivations and origins of these attacks.

During today's conversation we will not only reflect on how the United States responded to the anthrax attacks 25 years ago, but how that experience motivated much of our foundational bio defense infrastructure. We will explore current U.S. efforts and capabilities to deter future bioterrorist attacks, identify and attribute attacks accordingly, and mitigate their impacts on the health and wellbeing of Americans.

Our conversation today will be moderated by CSIS senior advisor Major General Paul Friedrichs, Dr. Friedrichs served as the inaugural director for the White House Office of Pandemic Preparedness and Response, and prior to that held several senior biodefense roles at the White House and the Pentagon. He's also the senior biopreparedness fellow at RAND, and an adjunct professor of surgery and preventive medicine at Uniformed Services University.

Our first panelist is former North Carolina Senator Richard Burr, who is a principal policy advisor and chair of the Health Policy Strategic Consulting Practice at DLA Piper, and a co-chair of our CSIS Bipartisan Alliance for Global Health Security. During his nearly three-decade career across both the House and the Senate, Senator Burr was instrumental in authoring and advocating for landmark biodefense and pandemic preparedness legislation, including the Pandemic and All Hazards Preparedness Act, or PAHPA.

We're also joined today by Stewart Simonson, a senior advisor to the Global Health Policy Center who served in key leadership roles at the Department of Health and Human Services, including during the 2001 federal anthrax

response. He has also served seven years as assistant director general for general management at the World Health Organization and five years as the WHO representative to the United Nations. He's currently a senior advisor with Global Health Strategies.

And finally, we're very pleased to welcome Dr. Wendi Kuhnert, deputy director for laboratory readiness and response at the U.S. Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases. Dr. Kuhnert began at the CDC in 2001, has held roles in the Division of Viral Hepatitis and National Center for Immunization and Respiratory Diseases. And today, her team is responsible for monitoring, identifying, and preparing for high-consequence biological threats.

Before we begin, I'd like to thank Steve Morrison, Michaela Simoneau, Caitlin Noe, Priya Chainani, Emily Wilson, and our exceptional CSIS streaming and broadcasting team for their support in pulling this event together.

And without further ado, please join me in welcoming our panelists, as I turn it over to Dr. Friedrichs to get the conversation started. (Applause.)

Paul Friedrichs: Thank you, Sophia, for that introduction. And I'll echo the thanks to our CSIS team, and to all of you who are joining us. And I also want to give a thanks to the Gates Foundation, because they are helping to make this possible today. They recognize the value of partnering with CSIS. And we're grateful for that, and hope that that will continue.

If you'll indulge me, I'm going to start for a moment making sure that we understand what we're talking about. We're talking about Robert Stevens, an editor at The Sun. We're talking about Thomas Morris, a postal worker who, along with his colleague Joe Curseen, worked at the facility that handled the anthrax letters. We're talking about Kathy Nguyen, who worked in a hospital in New York City whose mail happened to be adjacent to one of the anthrax letters. And Ottilie Lundgren, a 78-year-old resident of Oxford, Connecticut. And for the life of me, I still can't find a compelling explanation for how her mail got mixed up in this.

Letters were sent to Tom Brokaw at NBC, to Senate Majority Leader Tom Daschle. And in case you've forgotten, 24 of his staff actually tested positive for anthrax after the letter was open in his office. Senator Patrick Leahy, multiple other New York post offices, and, as we heard, 32,000 people were eventually treated for possible exposure to anthrax as a result of this attack. It's also worth noting that we still don't have an agreed-upon explanation for who did this. We settled a multimillion-dollar claim from one researcher who we said very publicly was culpable for this, and then retracted that. Another researcher who was identified as a person of interest committed suicide. And there were extensive reviews of that investigation, which

highlighted opportunities to improve our ability to attribute a biological attack.

In this day and age, when the media is filled this week with reports on a death at a lab in Russia, which may or may not have been plague, may or may not have been many things, it's a great reminder that biological threats are a real concern, and will continue to be so. This administration has published their compliance report, which highlights that both Russia and North Korea have bioweapons programs. There are multiple indications of growing natural biological threats as well as accidental leaks, which should lead us to look back at what happened 25 years ago and ask ourselves, what did we learn from this and are we better prepared today than we were before?

And I want to start, Senator Burr, with you. You know, I've been in combat many times, and that was, oddly enough, often less fraught than going in front of Congress. (Laughter.) But you were always very gracious, sometimes very pointed. And you've played such an incredibly important role in this space. Could I ask you to start setting the stage a little bit from your perspective as someone who was on the Hill and very influential afterwards in learning from this?

Richard Burr: Well, let me also thank the Gates Foundation and Steve for doing this. What I've learned in the United States Senate is – or, Congress – is memories are very short. And to recognize something that happened 25 years ago is challenging for people with our color hair, to remember all the aspects of it. But I think the thing that stood out the most was what we weren't prepared for. And that's not to say that we responded quickly, from an investigative standpoint. It was really a medical response to a crisis. But it took months, if not years, for us to begin to think about, how do we change this so that's not the situation that we're in next time? And I think that's what was initiated out of this.

It initiated partnerships between the federal government and academia, partnerships between the federal government and companies, all targeted at what was stimulated by anthrax. And that's an overall review of what were we capable of doing and, in a perfect world, how would we have done it differently? I think Stu would agree that we're still learning things that we didn't pick up 25 years ago in that review with every incident that we see. And I think the thing that scares me the most is we're headed into a period where attribution is going to be much more difficult, with AI-designed pathogens that really don't – they don't contain the DNA that we are accustomed to looking at, and tracking, and assigning responsibility to.

So, as I've shared with you privately, I'm always scared when there's not an incident in the United States for an extended period of time where most people are happy, because it takes Congress having some type of fear of

something for them to actually appropriate and to enforce the right behaviors. Unfortunately, we're at that point, I think, both in research and in commitment, that not all of the entities that are responsible are getting the funding and the support they need.

Dr. Friedrichs: Well, let me also thank the Gates Foundation and Steve for doing this. What I've learned in the United States Senate is – or, Congress – is memories are very short. And to recognize something that happened 25 years ago is challenging for people with our color hair, to remember all the aspects of it. But I think the thing that stood out the most was what we weren't prepared for. And that's not to say that we responded quickly, from an investigative standpoint. It was really a medical response to a crisis. But it took months, if not years, for us to begin to think about, how do we change this so that's not the situation that we're in next time? And I think that's what was initiated out of this.

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Stewart Simonson: Thank you, Paul. Let me say that from the beginning I had no interest at all in biodefense and public health preparedness. I came to HHS with Secretary Thompson. I came part time, beginning February 2nd of '01. And then on August 20th, I started full time. He said I had no choice. I had to come over to – I had to come over to the department. He said, what kind of job do you want? I said, well, I'd like to be one of the deputy general counsels. I had been his legal counsel in Wisconsin. And he said, all right, you can be the deputy general counsel for public health. It was interesting.

On the day I started, he said, there is one additional responsibility that I would like you to have. You did it in the governor's office, and I'd like you to

do it here. You'll be responsible for emergency management, and working with law enforcement, and so forth. And that's what I did in the governor's office. And I said, well, thank you. I appreciate your confidence. But I don't want to do that. You never get a good night's rest in emergency management. It is always something. And he said, Stu, be reasonable. It's HHS. How much can there be? (Laughter.) So on September 13th, I was – 12th and 13th I was in New York. And we realized then there was no real infrastructure in the Office of the Secretary for emergency preparedness and response. What is called ASPR today did not exist. There was no operation center on the sixth floor. There was really nothing in HHS headquarters to support the secretary in his decision-making responsibilities.

So I started to cobble together something, beginning on September 12th. Recruited D.A. Henderson, who had been the dean of the Hopkins School of Public Health, to come in as an advisor. He had written, with Dr. Parker and others, a consensus paper on how to manage the medical consequences of an anthrax attack. That was in 1989, and he'd updated it a few times. But he was a very accomplished and able man, and an inspirational leader. He came in part time, and eventually, before the anthrax letters, became director of what we call the Office of Public Health Preparedness. But it really wasn't an office. It was bolted onto the Office of General Counsel. And in fact, D.A. and I shared an office. There really wasn't much.

So on October 4th, we heard about Mr. Stevens. Then we said, well, maybe it is naturally occurring. It does happen. And then we heard about another person at American Media, I think it's called, someone who worked in the mailroom. It was very clear at that point that it was deliberate, but whether it was terrorism, as we've come to think of it today, or just something else, a murder, still. So maybe good to step back a bit and say that the attack came in two waves. The first wave was the American Media hit, and –

Dr. Friedrichs: And that's American Media the company, not American media, the enterprise.

Mr. Simonson: That's true. And the CBS and – or NBC.

Dr. Friedrichs: NBC, yeah

Mr. Simonson: The New York hit. I think the New York Post also. That wave was with a type of anthrax that was crude. It clumped and didn't aerosolize particularly well. The second wave was with a highly purified form of anthrax that aerosolized very well. In the meantime, as between these two attacks, we were trying to figure out what it was that we knew about anthrax. And it really wasn't all that much. It's veterinary disease – cows die of it, horses die of it – but not a lot of human cases. Maybe 10 in the last hundred years. And so we're trying to figure out, well, how to predict the response. No one knew, for example,

how clean was clean. If a site was hit with anthrax, how to disinfect it and decontaminate it? It wasn't clear.

So Peggy Hamburg, who had been the assistant secretary in the Clinton administration – and she had been really at the forefront of preparing the country for a biological event. The Clinton administration did an awful lot to prepare the U.S. for anthrax and other biological events. We had all the countermeasures that were available then. We never had a problem with countermeasures that were licensed. We had – there were some gaps, but we had a fair amount of antibiotic and vaccine. So I asked Dr. Hamburg to convene scientists to help us understand anthrax. And so she was at the Nuclear Threat Initiative at the time. And she brought together everyone who knew anything about anthrax, people who had worked in the offensive program, the 1969 – pre-1969 program. There were many, many people there, and it was very interesting.

But what was clear was that there wasn't a lot of rock-solid information that we could rely on. And I remember very specifically as we were talking about the Post Office – this was before the two postal workers were affected – we asked, well, will the Post Office, will the mail system be compromised by this? And the answer was based on what we know, and based on the material that the U.S. made in the pre-'69 program, they didn't think so. And I have a very clear recollection of Dr. Fauci saying, do you mean that the that the postal workers are not at risk? And they said – these were people who had worked with the organism – based on what we know, we don't think so. But that was based on the cruder form of the organism. And it turned out that between the first and second wave, and the second wave was all in Washington – they, he, whoever did it, purified it very significantly, to the point that the folks who were looking at it under the electron microscope were surprised. They had never seen anything like it. And these were people who were experienced with this out of the Army Medical Research Institute.

So trying to determine how to respond to this was a real challenge at HHS, because there was no culture of working with law enforcement. And even within HHS, there wasn't a lot of information sharing between the CDC and the Office of the Secretary. This is what ultimately led to the Office of Public Health Emergency Preparedness, which later became ASPR, with the objective of serving as the secretary's planning and analytic arm for a biological, nuclear, chemical event. It was never, back then, contemplated as an operating division. It was purely a planning and analytics. And as a result, we didn't know what they were finding at these various laboratories. And eventually we got a lot more clarity on it. And Tom Ridge had been appointed the director of the Office of Homeland Security, and he brought a lot of, I think, coordination and clarity to it.

But what I learned in all of this, and it informed the next five years for me, was, first of all, when it comes to the life sciences, and infectious disease maybe in particular, there's a lot we don't know. Even diseases that have been around for time immemorial, a lot we don't know. And you have to be very humble in approaching it. And I never heard Dr. Henderson or others in our office talk about anything with certainty. It was always, well, this is what we know. The other thing I learned is how important it is to have a culture that can work vertically within the department, but also with the interagency community. And that is an enormous challenge. And particularly with law enforcement and intel. That was not within the culture of HHS, CDC, NIH. There was no history of that. We had one secure phone, that we could never quite get to work, in the secretary's office. So that was something that was addressed in what became ASPR. I had maybe five or six former FBI agents, police, just to have that sort of connection. The CDC did the same thing. And so I don't think today you would find any of that disconnect with the law enforcement and intel community.

And I think the final thing is that countermeasures matter. Development of new countermeasures is essential to stay ahead of this. We had, I said, thanks to Dr. Hamburg and President Clinton, we had plenty of doxy and cipro, and we had plenty of a 1970s-approved vaccine. We had no therapeutics, right? Once the spores began to germinate, there was no way to deal with that toxin. You either lived or you died. Thanks in large part to Tony Fauci, we began developing what we call extra-regulatory approaches, what we would do in a general emergency. And for example, at the NIH we set up a plan to run plasmapheresis clinics to four soldiers who had been – an airman and Coast Guardsmen – who had been immunized against anthrax, to get those antibodies and try to use that as passive therapy. Today we have three therapies, I believe, in the stockpile. At least we had. Two monoclonal antibodies and old-fashioned and highly dependable anthrax immunoglobulin. But we still have the 1970s vaccine. And that's something that has to be addressed.

I have to say, though, we tried. There were a lot of mistakes made by me, in particular. And we failed. That vaccine – was called the recombinant protective antigen vaccine – never made it even into trials. There was a lot of politics in that too, because the minute that vaccine went into trials and looked to be developing toward licensure, the current maker of the approved product got engaged. And so what was – what they were not satisfied with at HHS they litigated on Capitol Hill. And that's something you can't win in a government agency, at least not an agency that I worked in. So those are my lessons.

Dr. Friedrichs: And, Stu, you've covered a lot of ground there. And one of the things –

Mr. Simonson: In 10 minutes? (Laughter.)

Dr. Friedrichs: Give or take a little bit. And I think, you know, one of the things that you touched on was ASPR. And I just want to publicly recognize the members of Congress, in particular Senator Burr, because you played such a crucial role in the legislation that authorized the creation of ASPR. Can you – before we go to Dr. Kuhnert, can you say just a couple of words about that?

Senator Burr: Yeah, because it actually started as something very different. There was a recognition that in a full-fledged emergency response, and we'd seen this with some other things that had happened in the meantime, that to initiate that response had to involve the White House, and it had to involve the Oval. So the original legislation had the vice president of the United States serving in the role that ASPR ended up as a job description. And it was Vice President Cheney who, when he read the legislation, he said, hell no. (Laughter.) And we went back to the drawing board, and that's where we created the ASPR inside of HHS.

Mr. Simonson: He wasn't so bashful behind the scenes, I'll tell you. (Laughter.)

Senator Burr: Well, I will say this, that when President Trump won, the administration assigned the vice president – if you remember, he was on Air Force Two when he got the call as it related to COVID. I actually called the vice president and said, this is how it was supposed to work.

Mr. Simonson: Exactly. Exactly.

Senator Burr: And I think it took about six days before the microphone was taken out of his hand, which was an important aspect of the executive branch bringing the American people up to date for a very brief period every day in the afternoons. And he was doing a great job of it, until it became a two-hour event. And that's where they sort of lost the trust – the interest of the American people.

Dr. Friedrichs: And I will say, and you had one final legislative action related to this that helped shape where we are today in the movie, and that was the creation of OPPR. So could you say a few words about that?

Senator Burr: Well, I was glad you were over there.

Dr. Friedrichs: I haven't forgiven you, by the way. (Laughter.)

Senator Burr: Listen, it was a natural thing, given how the architecture looked at the time, that these were decisions that needed to be assessed and a plan put together inside of the White House. And any other construction of this would not work. And I think, regardless of what this administration does in its last two

years, the next administration will reinstate the power of that component too. Because it's a critical component to our ability to determine the risk and respond to it.

Dr. Friedrichs: And I think both of you are touching on a truth that hopefully is evident to everybody in the room and online, and that's that while this may start as a public health discussion, when people are sick, it quickly becomes a discussion that moves into the economic space, and the national security space, and the political space. And you can't – you can't ignore that reality. And –

Senator Burr: Well, Stu danced around this, but he said it. He did it diplomatically.

Dr. Friedrichs: As he always does.

Mr. Simonson: (Laughs.)

Senator Burr: Is what we learned was agencies don't work well with other agencies. You know, government is stovepiped, like a lot of other things. And it's simply because the power in Washington is determined by the size of a budget. And you're not going to share. Even though you might – I might be aided by what you can provide to this issue at any given point in time, you're going to want some budget to do it. And I'm not going to want to give it up. So I'm going to try to concentrate that in my bucket, so Congress doesn't take money away.

Dr. Friedrichs: And I think, you know, that waxing and waning nature of our political system changes all the time, as you said. It'll change from one administration to the next. But biology doesn't change that much. And that's where CDC comes into this discussion. And very glad that you're here, Wendi, because CDC played an important role. And in fact, you know, I went back and I reread – and for those of you who haven't looked at it in a while, there's a really good report from the GAO from 2004 that critiqued the CDC. And it was quite complimentary. They highlighted excellent communication, a real effort to put facts out, what we knew and what we didn't know. So, Wendi, maybe you could share a little bit from inside the CDC of what you all reflect on what happened 25 years ago, and where you are today.

Wendi Kuhnert: OK, I'll try to do that. It's a challenging subject. I think for us, we actually look at it starting in 1999, because I think, to the point of diagnostics, we didn't have one in 1999. You know, we were doing culture. We were doing very basic technologies. And I guess there was some forethought. And we did work on a molecular test. It was PCR at the time. That was the state of the art. Not anymore. You know, so I think we were lucky to have that test when we did. I think there's probably a lot of other things we could say we didn't have, but I was glad we actually had a test. And I think that was really important, and was really critical to the diagnosis for some of those cases. I

think – to the struggles that you've pointed out, I think the environmental testing, the ability to screen environmental surfaces, I think that – you know, that existed then, and, unfortunately, I think it still exists now. That is one of the gaps that we still recognize.

But one of the things I tried to think about as I looked back over the last 25 years is what have we done? And I tried to think about it in four different buckets of work. And the first bucket was thinking about our laboratory capacity. You know, we still do have world-renowned anthrax experts. You know, I think the funding maybe isn't what it should be, but we still do have the staff. And I think that's been a real highlight of the agency and our ability to maintain that expertise over time. We have also really focused on the laboratory response network. And it doesn't test for everything. It does still test for anthrax, and it tests for a number of other biothreat agents. And it is really a very unique laboratory network that includes environmental testing, military labs, veterinary labs, and, obviously, the public health labs. So I think that's pretty critical.

Within CDC, we have looked at our ability to move our diagnostics forward. And I think with the initiative, the Advanced Molecular Detection, we've worked really hard to help push forward molecular technologies for both CDC as well as the public health sector, in a way that I – we were losing ground about 10 to 12 years ago, and I think we've improved. And then, finally, I think the legislation for the Select Agent Program. And I think we haven't mentioned that, but I think that's really important for how we look at the biosecurity and biosafety of managing these pathogens, knowing where they're at. Again, not perfect, but I think it's really been a move forward over the last 25 years. I think we've done a lot with diagnostics. Am I worried that we still have a long ways to go? Yes. I think there are concerns with, you know, the biosecurity and the way these pathogens can be engineered. I think that is scary. But I think for now, for some of the most basic tests, I think our advanced molecular detection has come a long way.

We have tried at CDC to work on data modernization. And I think the newest initiative, the Biothreat Radar, I am hopeful that that will really bring a lot of these things together and will help us move forward with – you know, from a data consolidation and a surveillance perspective, to bring all these things together. Medical countermeasures was already brought up. I think we have a number of things for anthrax. We still have a ways to go with that. I think it's also important that what we learned then was something we had never done before, and I think we've gotten better at it over the last 25 years. But it's mass dispensing and producing the clinical guidance. Those were things we had never really done before, you know, especially at that scale. So I think that's important. I also think we've worked on coordination. Something that I hadn't thought about until thinking about today is we didn't have an

emergency operation Center in 2001. The first EOC at CDC was in 2003. And now it's everywhere. It's a term that's, you know, all over the world.

So I think that's – for me, it's pretty interesting to think back, like, what did we do? You know, as I sit and look at where we are now with our Ebola response, and looking at, you know, how we bring people together for that, it had to have been a real struggle to manage that response even internal to just CDC without that that coordination. So I think that's really important. I do think CDC has worked hard at our communications. And we've developed a number of mechanisms to be able to speak more clearly, but also faster, and to be able to convey some of this in a little bit more timely fashion than I think we were doing at the time. So I think that's maybe where I'll pause for now. I know there's probably additional questions, but that's kind of my thoughts on the last 25 years.

Dr. Friedrichs: Well, thanks. And, before we open it up to the audience for questions, I just want to pull out a couple more threads that several of you have touched on here. So, you know, we've talked about what happened 25 years ago, and what we've learned from it, and we can't ignore the elephant in the room. There was a COVID pandemic. It affirmed we still had work to do in the testing space. And I think you've spoken to some of the things that CDC continue to learn after that, and to improve on with that. All three of you have touched on the need to continue to fund biosurveillance, to continue to fund research, to continue to fund communication platforms, and how to communicate. And also, and Wendi, you touched on this, we need to continue to fund and improve our ability to distribute countermeasures during an event.

And that's really critical. When we talk about lessons learned from what happened 25 years ago, lessons learned from what happened six years ago, and, as we're seeing now with Russia, you know, there's an approach to every outbreak that starts with very common themes. So let's start with biosurveillance. You had mentioned environmental surveillance as an area for improvement. So we have had BioWatch. And we've had a variety of projects. I'm excited that ARPA-H is working on the BREATHE program now, and is coming up with a successor to that. I think that's really good news there. You had mentioned AMD. That's another real step forward in bringing new technologies into the biosurveillance space.

Sir, you had mentioned attribution. And given that we're talking about deliberate attacks, can you say a couple more words about that? Because it would be a mistake, I think, for anyone to assume that because we're not perfect, somehow that means that we're an attractive target.

Senator Burr: Well, this is – I don't get too deep into it, because I'm going to have to put my intelligence committee hat back on, and I tend not to go there. The reality is

that the first is the medical response, but the second has to be, who did this. And who could be a naturally occurring, or it could be intentional. But that's absolutely crucial, from the standpoint of what the next steps after that are. And I think as we talk about AI engineered, AI directed, we begin to lose the fingerprints that have, at least historically, been there to suggest, well, we need to look at this region of the world, or we need to look at this particular group. And we really are going to be in a situation where we'll have an architecture that addresses the most important thing, which is response. But everything that we tried to build up to this point happens in that total architecture. And I think we saw it in real time in COVID.

We haven't reauthorized PAHPA, which was the – which was the architecture. And I think one of the reasons, Stu, that we got better over time, was we had certain things that happened during that five-year period that we were smart enough to reflect in the reauthorization of the bill. Which said, hey, maybe we don't need the president to be the one to trigger emergency use. Maybe we should let the secretary do it, because we can't get the president's attention. And that was a real life experience that we went through.

Dr. Friedrichs: That's right.

Senator Burr: So we changed it over three different iterations, or four different iterations. And that's why it's a workable architecture today. But we haven't affected the changes in the last five years, which incorporates all of COVID. And it certainly doesn't take into account the advances that have been made from a technology standpoint that should be incorporated in that architecture, because it may expand collaboration between agencies. It may suggest the areas that Congress needs to fund. And so I really see PAHPA reauthorization is a crucial component to our ability to not just respond, but to understand how to address everything thereafter.

Dr. Friedrichs: Well, and, you know, having just been in China with Dr. Morrison and others, I think it's interesting that others view our approach to this, this very holistic approach, as a different way that they seek to understand. And I think this has been one of our real strengths. And, you know, others may challenge me on this, but while AI and biotech and that convergence creates risk, it's also fascinating to see the partnership between the Department of Defense, now Department of War, and the Department of Energy. How we are choosing to continue, as you said, to learn. I hope that our congressional colleagues are taking note of this, that they still need to reauthorize PAHPA, and it needs to be updated with those lessons learned.

But while we're waiting for that to happen, I want to give credit to the people who are doing that work to keep moving forward in this space, because there is some really important work being done. If we move on from biosurveillance and all the work with wastewater and other streams of data,

we talked about medical countermeasures. And one of the other things that you and others helped to bring to life was the BioShield program. And, Stu, I wonder if you could say a couple of words about that from your perspective.

Mr. Simonson: So BioShield was our first attempt at trying to create an industrial base to support biodefense countermeasure development. The idea was to create a market. There is no commercial market for these – many of these countermeasures. And BioShield was introduced in the president's State of the Union in 2004, I think, and passed in 2005 sometime. It was 5 billion (dollars) over five years. And did a fair amount of – I think, other than the anthrax vaccine – a fair amount of really good development. But it cannot be overstated, it was a deeply flawed bill.

And the bill that came after it, the two that came after it, the biodefense – the biodefense authority research and development authority, and the Pandemic and All Hazard Preparedness Act, these were strong, good statutes that learned from some of our failures, and I think have made the country – I know, have made the country safer. So I join you in that, Senator Burr. I hope they will reauthorize it. Senator Burr is uncommonly modest for a politician – (laughter) – because he really – he really did move the needle in a way that I think few others have done, certainly on this issue.

Dr. Friedrichs: Well, and I would echo that. You know, none of us get anything for saying this, but it is the truth. And for those who are not familiar with it, you have been one of the leading voices in this space, literally for decades. And, you know, as I said at the Pentagon and then at the White House, there were a handful of people that you could count on to always say, as uncomfortable as it might have been, this is still true north. And you were one of those for whom I'm personally very, very grateful.

And I think saying where true north is gets to the last point that I wanted to bring up. And, Wendi, I'm going to go back to you. And that's our ability to tell the American public what we know, what we don't know, and what is going to happen next. And, you know, again, the GAO really gave CDC a lot of credit for their response 25 years ago. Can you say a little bit about what we've learned since then and what CDC is doing in that space?

Dr. Kuhnert: I mean, I touched a little bit upon it. I think we have really tried to improve our coordination, improve our communication. It is hard. I think as scientists, it's hard to say what you don't know. That is not comfortable for, I think, scientists in general. And I do think that's what a large part of CDC is. So, you know, I guess, you know, is that what you're looking for? I mean, I guess that's my initial reaction, that I think we struggle with that, but we're trying.

Mr. Simonson: What I would say is that – I agree with that. The problems that we had in 2001 responding to anthrax were cured. They were addressed in subsequent administrative action and legislation. I feel very confident about that. Remember, this was a time, as you said, there was no operations center in Atlanta. There was no emergency or national security history, really, for the CDC, with the exception of the Epidemic Intelligence Service. So there was a lot of change in the works beginning on 9/11. And I found, even though there were times when it was very frustrating, the people at CDC were strong, and scientifically reliable. And the rest was about coordination. And I think so much, as I said, has changed since then, and for the best.

Dr. Friedrichs: Yeah, And, Stu, I absolutely agree with you. I think if you look over 25 years where we've come as a country in this space, you're right. We now have these emergency operation centers. We also have a much clearer understanding that the Constitution, that pesky document that started about 200-some-odd years ago, lays out very clear responsibilities at the state and local level. And one of the things that I will applaud CDC for is to continue to work from the mindset of supporting the state and local officials, who are ultimately the people on the ground dealing with this every day. And, you know, that's a journey, as we figure out how to do that in an era in which the speed of communication is increasing rapidly, and the volume of information of questionable validity is also increasing rapidly. But I think that CDC has done a lot of work in that space.

So as we pull all this together, I think that, you know, the one final point that you touched on, Wendi, that I want to just highlight, that's a real improvement, is the Federal Select Agent Program. As I worked around the world with our NATO allies and with other countries, there's no country that I'm aware of that has not emulated that in some way. It is a starting point for understanding risk and trying to mitigate it. It is also, I think, a cautionary tale for us, because it is very much predicated on the assumption that biology doesn't change. And you, perhaps more than any of us because of your background, know that biology is always changing. And so, you know, one of the real takeaways from the last 25 years, as you touched on, sir, is at least every five years we've got to refresh this. We've got to assume that change is inevitable.

Dr. Kuhnert: I think that's a really good point, and probably one that we need to take back and think about, because the Select Agent Program hasn't changed much in its principle. I think it still does what it needs to do for those agents as they stand, but with synthetic biology and with superintelligence, we will lose pace with that. And I think probably there are some things that we should be thinking about for the Select Agent Program, in addition to other aspects of what we're doing, to really understand the way these organisms could change.

Mr. Simonson: Maybe we should say what the Select Agent Program is. It is the way the United States regulates, through the CDC, the high consequence pathogens – smallpox, anthrax, botulinum, tularemia. And it's a –

Dr. Kuhnert: Both animal and human.

Mr. Simonson: Animal and human. The USDA does the animal side. But it is an important program, and one that I believe also came out of the Clinton years. I think that was all part of the biodefense initiative that he started. So I agree with you, though. It has not been updated to reflect technology.

Dr. Kuhnert: No. No.

Dr. Friedrichs: And I and I'll echo your points, and I'll say also for the audience and those online, one of the remarkable things about the Federal Select Agent Program, having recently gone back and read a review about the language, is how well Congress wrote that language, and has done a few updates over the years. Because it actually does give really good authorities to address and regulate the users of things that can cause biological harm, related to those agents. And, you know, that's an area where I want to give credit where credit is due. That was actually well written legislation. I agree with you that needs to be updated.

You talked a little bit about AI and biotechnology. I also want to give a shoutout to, you know, those who are continuing to work on updating legislation. Because not only do we need to update the legislation that talks about the users of these sorts of tools that are being developed today, but also the companies that develop them. You know, just as the FDA regulates other pieces of equipment out there. These are all things that will come as a result of our continued effort to improve.

Senator Burr: And, Paul, let me say, Stu alluded to this, that it's pretty tough to develop a countermeasure for something that doesn't have a market. And there are things we learned in COVID that are not reflective in statute yet.

Mr. Simonson: That's right.

Senator Burr: The architecture has not encompassed that, because we haven't reauthorized it. And I think the most alarming thing right now is that COVID created a skepticism about vaccines. And we're fighting a measles outbreak that's very regional, but could be national at any point. And Congress should go back in and should authorize with – explicitly with that in mind. If they don't, then we're going to continue to see these pockets of problems. And those pockets of problems, with the combination of an unclearly defined marketplace, means that the attraction of capital can only happen from government. It can never happen from the private sector.

And we've got so much invested in technology today. Specifically, if you look at the capital dollars invested in AI, if Congress tomorrow did the wrong type of regulatory structure where companies didn't have the ability to IPO, put it off for a year, the stranded capital that's there that can't come out is the capital that in the past has fueled a lot of these successes that we've had, because companies have used overage of dollars to do some R&D work that was more for the good of the society, versus the profit of the company.

Dr. Friedrichs: Well, the reality is there is no universe in which there won't be another naturally occurring biological event. I can say with absolute confidence, they've happened since the dawn of time and they will continue to happen. The reality is that there is a profusion, an explosion of labs doing research in this area. The lab in Russia has been around for 90 years, but there's a large number of new labs being built. Unfortunately, there's no profusion of people with 20 years' experience to work in them, nor is there a profusion of regulators and people to provide oversight to mitigate risk. And there's a profusion of countries and nonstate actors thinking about bioweapons. And for all of those reasons, we should be going back and looking carefully at what happened 25 years ago, what we've learned, and how we've moved forward.

And I want to just finish my comments before we open up for questions pulling a thread that all three of you touched on briefly, but it's worth stating. The partner that's not up here with us today is industry. Whatever you may think about a particular company, there are exactly zero drugs in the United States that are not made by a pharmaceutical company. There are zero masks that are not made by a PPE company. And where we've had great success is when we have figured out how to partner. And I think, you know, to your point about reauthorizing PAHPA, one of the great successes of the COVID outbreak was that we were able to leverage a partnership between academia, and regulators, and industry, and produce very safe and effective – not perfect – but very safe and effective vaccines in a short period of time.

And we should continue to look at the legislation, the executive actions, and the education that needs to happen so people feel comfortable that the right thing to do on the next-worst day in American history is that we partner. We partner within HHS, as Stu talked about. We partner with the interagency. We partner with industry. And we partner with the American people to explain what's happening, as CDC did so well 25 years ago.

So, with that, I'd like to open it up to those in the audience and see what questions or comments you all may have for us. And there's a microphone right over there. So I'm looking out and I see a lot of familiar faces. I would be shocked if someone didn't have something to say after all of this.

Audience Question: This is not really at my height, but I think the room can hear me. I'd like to first thank all of you for your comments. You've talked a bit about biosurveillance. And so I would just ask, you know, for the audience both here and online, for Congress, if there is one – we know how slowly the wheels turn sometimes, and we know what season it is. But if there's one thing that Congress, you know, could potentially affect action on related to biosurveillance, what might that – what might that be? And how would they – you know, how could they start?

Dr. Friedrichs: So I'm very mindful of the fact that Dr. Kuhnert is a serving member of the government and has very strict constraints on what she can say. So I'm not going to put you in an awkward spot. But I think you did touch on something that Congress has already authorized, and that's Biothreat Radar. Do you maybe want to say something about that, and where that could go?

Dr. Kuhnert: Sure. You know, I mean, I think it's built upon, you know, some of the things that we started during COVID, and I think in a very unique way it offers us the opportunity to bring things together in a way that I don't even think CDC had thought about when we started wastewater and traveler genomic surveillance, and things like that. And then what is the system that puts it all together? But I think that's really what's important for all of this, and pulls it all together, is that having a system that can pick up the unusual and tell us that something is there is really what's going to be critical. And so I'm, you know, looking forward for Biothreat Radar, and very positive about it. But, you know, we'll have to see. I think it is – it's still yet to be fully funded.

Dr. Friedrichs: Well, and so I will say what you cannot say, which is it needs to be authorized, and it needs to be – there needs to be an appropriation that expands it. And now I'm going to riff off of something you said, sir. We're in an era in which we have enormous amounts of data. We know that 70 percent of human outbreaks start in other species. We have these robust data streams from the ag community, the plant community, which need to be more visible. We also know there's work on deliberate threats. We need to merge animal, plant, and human data with the intelligence community. We know that there's great data in social media that allows us to see that a community is having an outbreak of some sort, even before the first patient walks into an acute care clinic. That's all data that exists today. And I really am excited to see a handful of people working on aggregating that data, and shifting our visibility of what's happening far to the left of where it has been before, as a result of some of the data modernization and other efforts that you talked about.

Audience Question: Gerry.

Good afternoon. Gerry Epstein.

I don't really have a question, because your panelists were very comprehensive. I really appreciate the retrospections you give. You did invite comments, though. So, Mr. Simonson, I'm just going to add on your – the story of the HHS that you stepped into, with this mission, the emergency preparedness, not really being a major mission. I worked in the White House Office of Science and Technology Policy during the Clinton administration. And one of my HHS colleagues, Bob Knouss, who ran the HHS Office of Emergency Management, with a very few million-dollar budget. He always said he rested supremely confident that the second biological attack on the United States would be somebody else's problem. (Laughter.)

Dr. Friedrichs: Well, and I would say that, you know, my hope when I was in the White House was the next biological attack happened the day after I left, not while I was there. (Laughter.) If it ever happened. Because it is inevitable. And, all joking aside, and if you'll forgive me I'm going to riff off of what you said. So I spent 37 years in uniform, nearly two years working at the NSC and the White House. To your point about the waxing and waning nature of interest in this on the Hill, we should be crystal clear that there is no universe in which this threat is going away, or it's diminishing. We should be crystal clear in speaking with one voice about the character of the threat, the prevalence of the threat, and how it's changing over time.

Senator Burr: I want to just make this point. Because we know the pattern that Congress will follow, the challenge is for those agencies in the federal government that this is their work, that they present to Congress new ways to accomplish their mission so that there's some need for direction from Congress, but it's being asked for. You know, you hit on the key thing. All of this data, well, let's ask Congress to construct something that provides the avenue for that data to be sorted and understood, because that's typically the last thing that agencies – they're dealing with a checklist of things that are most important, and infrastructure is way down here at the bottom. Yet, AI provides us the ability in minutes to sort millions of bits of data and come to a solution. But Congress is the only one that can initiate that. I mean, agencies can do it, but internally you can never prioritize it as today's thing.

Dr. Friedrichs: And the one slight caveat to what you said is, and industry can do it. Because I think if you look across what's happening in American industry right now, you've got companies who learned from COVID that they needed early warning about outbreaks. And they are paying vendors to give them early warning that they feel comfortable with. And those vendors are starting to look at some pretty creative things that even go beyond Biothreat Radar. There's a real opportunity. And, you know, Gerry, I'm riffing off of what you said there, but, you know, for those of you who are in the space to influence these discussions, it's a yes, and. It is Congress that ultimately needs to appropriate – authorize and appropriate what the federal government's role will be. It's also Congress that creates a space in which industry can bring

new solutions forward that the federal government can embrace, because there's some pretty cool stuff happening out there. I mean, ingesting data is not something the federal government has a unique mandate for. There's lots of companies that do that well. And we need them at the table as well with us.

Next question. Yes, ma'am.

Audience Question: Thank you. Michelle McConnell. Thank you really for an excellent panel.

And I have a quick question, but maybe a quick comment first. Reflecting on some of the things you said, Stewart. So I was a newly minted CDC EIS officer in 2001. I was deployed to New Jersey, given the keys to a rental car, and told to drive around the state and find postal workers that were sick and hospitalized. And I'll comment on two things. One, I was either before or after the FBI agent that came in the hospital room. And we were definitely not coordinated. So that's a huge win, I think, that's happened with the crim-epi courses and the coordination with law enforcement.

The second is, is that you know, I think as often happens, the first case of inhalational anthrax in New Jersey was identified by an astute physician who looked at a sick patient and said, I think this is anthrax. I'm going to call the CDC. And I think, you know, Wendi, to your comments about the advances in biosurveillance, it's really extraordinary what we can detect today that we wouldn't have been able to detect then. My quick question is – I won't direct it to anyone in particular – but you've mentioned industry, you've mentioned medical countermeasures. I'm interested in diagnostics and what we've learned on that, and our ability to scale. If anyone can speak to that, thanks.

Dr. Friedrichs: Well, I will say that, as complimentary as the GAO report was in 2004, they identified that specific point, of testing and diagnostics, as an area for improvement. And I will also say that, you know, in the Pentagon in 2020 that was an area where we recognized we were still stumbling as a country. And I want to give credit to CDC because Dr. Mandy Cohen and her team in the previous administration invested heavily in building partnerships with a variety of companies, and actually building surge capacity. I'm not sure what the status is of that. And that's not in your lane, so I don't know if you're –

Dr. Kuhnert: No, but I'm aware of the contacts. And actually for zika we used them. It was very early on. They had just been awarded. And we had some spare money at the end of the fiscal year. And actually, Dr. Cohen said, put it out. And so we did. I think there was some ups and downs. We learned a lot. I think we learned about how to write requirements that maybe we didn't do so good job. But, you know, we did do it. And I know that they did some with flu. So I think we are using them. We're probably still learning how to use them, but

I think we've made some steps forward in that direction that we didn't do during COVID.

Dr. Friedrichs: And I'll go back – I'll go back to your point, sir, that this is the sort of thing where, as we have Department of Homeland Security and Department of War, and Department of Veterans Affairs, and HHS all thinking about this, this is – what a great opportunity to have appropriate committees authorizing those departments to work together. Here's a newsflash. A hundred percent of the people sitting in the VA come from one place, the Department of Defense – or, Department of War. We're still trying to get those two departments to be able to see each other's data and fully coordinate that ability to learn from that data.

Those are the sorts of things I think you were referring to, where a clear demand signal would say that we can move forward faster if those various committees have some common language that they're putting out, that there's an expectation that departments and agencies will collaborate because it's the right thing to do to preserve the health of the American public, the health of our economy, and our national security. That was a great point, Michelle. Thank you.

Dr. Parker, I can't wait to hear what you have to add, sir.

Audience Question: Howdy. Thanks for the invitation and wonderful discussion. And just maybe a few comments, a little question.

First, just to kind of foot-stomp the biosurveillance, Biothreat Radar. To me, that's our highest priority, is a Biothreat Radar real-time biosurveillance situation. That's important. It's essential for attribution, deterrence. And then that that early detection, characterization drives the whole response enterprise. So it is our top priority, in my opinion.

This conversation also brought back some bad memories. (Laughs.) You know, it was a pretty intense time. But a lot of leaders stood up and tackled it. And I was proud to play my part up at Fort Detrick, but that was also a pretty intense time, especially when the Ames strain was identified. And getting to the Select Agent Program, to me, the most important part of the Select Agent Program is personal reliability. And as we think about, you know, the future of AI and maybe something that doesn't quite fall into the Select Agent Program, you know, the risk-based, not list-based. We have to think about how we also include personal reliability in those kind of things. That's really the most important thing, much more important than kind of counting vials and pathogens and so forth. It's personal reliability. That's a lesson learned.

And then finally, you know, I want to thank Senator Burr, everybody that's been in this space but especially Senator Burr, for his leadership. And we need to also point out that Senator Burr had a very strong partner in this, and that was the late Senator Kennedy. And this was extremely nonpartisan topic. And it should be today. You know, I treat it as nonpartisan. But maybe a question for Senator Burr is, we seem to be a little divisive now, much more so than back then. How do we get back to this being a nonpartisan issue? And I think most of us practitioners, it is nonpartisan. But we have to maintain that. And we have to communicate that. And that's going to be part of also building back public trust, where we do have a public trust deficit. So that's a little bit of question, if you have any thoughts on that.

Senator Burr: Yeah. Thanks. Thanks for the comment, Gerry. Listen, people's nature doesn't change quickly, but it does change. And I think we're faced, at least for the next couple of years, with two specific dynamics – a White House that is at the end of their at least official life expectancy, and the fringes on two parties that have moved so far right and so far left that, you know, you're no longer reliant on a bridge from one side to the middle. You've got two middles that have to come together, because there's no communication far-right, far-left. And it's going to take about 20-some days before we know what that middle looks like. But for people who are focused on, who do I target next year, who should we develop as champions, it's going to be on both sides in the middle. And we're going to start with people that have – we have some history with. But this at some point has to be an initiative that leadership on both sides, whether it's verbally or a wink and a nod, says do this, we need it. And that's sort of bypassing the politics of downtown.

It's a Hill that wants to find a way to accomplish something really, really tough. And I think if agencies are able to highlight how they could utilize technology to make massive advances, whether that's in diagnostics or – I'm less concerned, Stu, with the MCM development. I'm more concerned with where technology gives us an incredible ability to look inside to understand better what we're faced with. And it's not a particular threat. It's every threat. And I just don't think we're there yet as to how we're looking at it. And if we're able to convey that to Congress then they're not waiting for something to happen to take action. They're addressing something that is like an umbrella on a rainy day, anybody under it is protected. And I think up till this point it's been incident by incident which gets people engaged. Unfortunately, when it doesn't happen for a while, led by appropriators in all honesty, the money begins to go. Therefore, the passion begins to go. And you get a deterioration of our capabilities. So.

Dr. Friedrichs: And I'll add to that, that I think we need to take a hard look in the mirror, every one of us who's here in the room, and ask how well we have communicated through these waxing and waning periods of political interest. Because the feedback that I get all the time from the Hill is every

single person who comes through the door seems to maybe be talking about the same thing, but they use different words. They have different priorities. We, I think, can help substantially influence what Congress does if we speak with greater consistency and greater clarity. Because it's not hard. You know, if you take out a dollar bill it says, e pluribus unum, out of many, one. There's not one of these pathogens that discriminates between Democrats and Republicans. There's not a single pathogen that we're worried about, naturally occurring, accidental, or deliberate, that discriminates between those who live above the Mason-Dixon line or below it, or any other geographic distinction, or ethnic distinction.

We should treat this as something in which we speak with some degree of consistency. Biosurveillance, Gerry, you're exactly right, the technology exists to do that better than anybody else in the world. And we should be all over this, leading the world in that space. We can do it. We just need Congress to give us the right appropriation and authorization to do it. And then our ability to develop countermeasures quickly, that's within the realm of possible. The CEPI 100 Day mission lays out very clearly how we get to that point. We should all advocate for the investments needed to make that. Our ability to distribute, that you talked about, and to explain to people the pros and cons of what we're offering there, those are all things that don't require new technology, but they do require new approaches and new collaboration as we move forward across communities.

But I take some comfort in the fact that our country, for 250 years, has found a way, when we really have to, to work together for our collective good. And we have found that middle. Those courageous political leaders who say, this is the right thing to do for our country. And they've stood up. We need to help them be able to say that. So with that, I want to thank our panelists. And please join me in a round of applause. (Applause.)

(END.)