# BIOSECURITY FOR THE FUTURE: STRENGTHENING DETERRENCE AND DETECTION

## HEARING

BEFORE THE

SUBCOMMITTEE ON ASIA, THE PACIFIC, CENTRAL ASIA, AND NONPROLIFERATION

OF THE

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# BIOSECURITY FOR THE FUTURE: STRENGTHENING DETERRENCE AND DETECTION

**Wednesday, December 8, 2021**

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ASIA, THE PACIFIC,
CENTRAL ASIA, AND NONPROLIFERATION
COMMITTEE ON FOREIGN AFFAIRS,
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10:06 a.m., via Webex, Hon. Ami Bera (chairman of the subcommittee) presiding.

Mr. BERA. Virtual gavel is banged. The Subcommittee on Asia, the Pacific, Central Asia, and Nonproliferation will come to order.

Without objection, the chair is authorized to declare a recess of the committee at any point, and all members will have 5 days to submit statements, extraneous material, and questions for the record subject to the length limitation in the rules.

To insert something into the record, please have your staff email the previously mentioned address or contact full committee staff.

Please keep your video function on at all times even when you are not recognized by the chair. Members are responsible for muting and unmuting themselves, and please remember to mute yourself after you finish speaking.

Consistent with remote committee proceedings of H. Res. 8, staff will only mute members and witnesses as appropriate when they are not under recognition to eliminate background noise.

I see that we have a quorum and will now recognize myself for opening remarks. I want to thank my good friend, the ranking member, Mr. Chabot, the members of this subcommittee, our witnesses, and the members of the public for joining today's hearing.

For almost 2 years, the COVID–19 pandemic has ravaged communities, devastated economies, and disrupted the fabric of our international global system. It is a reminder of the grave consequences that low-probability, high-impact biological threats can have our daily lives if we are not prepared.

Moving forward, we can do better. As chair of the subcommittee, I have convened multiple hearings related to the 2019 novel coronavirus, including the first congressional hearing on this topic in early February 2020 and on enhancing U.S. and global biosecurity.

In the near 2 years since the first hearing on COVID–19, we have thankfully seen meaningful efforts and expanding investments in technologies and practices such as gene sequencing, biosurveillance, and detection.

Many of these efforts have been crucial in the global fight against this pandemic thus far. For example, advances in rapid sequencing and diagnostic capabilities in South Africa allowed the government to correctly identify and report a new variant of concern to the international community in record time.

New technologies also enabled partnerships between governments and pharmaceutical companies to develop, test, manufacture, and begin distribution of vaccines and therapeutics in timeframes that were previously thought impossible.

Such developments do not occur overnight. They require time, dedicated staff, and resources well before an incident.

As we continue to combat the coronavirus, we were reminded of the importance of making long-term investments in the global health infrastructure and taking other steps to help prevent such catastrophe in the future.

That is the primary focus of today's hearing, to take stock of current resources dedicated to this critical field and to assess what more needs to be done to work with international partners to strengthen biosecurity and about biosurveillance practices globally.

These conversations are particularly relevant when one factors in the possibility of facing pathogens and diseases intentionally created by bad actors.

Biological weapons, and especially dangerous pathogens, existed before COVID–19, but the threat they pose today is now undeniable. Laboratories around the world regularly handle dangerous pathogens, and these threats are only amplified by the widespread availability of new gene-editing technologies such as CRISPR.

It is imperative that we ensure our government has the right strategy and resources to prevent naturally occurring, as well as manmade pathogens from causing the next pandemic. We cannot afford to be stagnant in our preparations and planning for the biological threats of tomorrow.

The pandemic also reaffirms the need for continued U.S. global leadership for a proactive biological security and defense strategy.

Prioritizing investments to counter and prepare for biological threats ranging from research-related or medical center accidents to naturally occurring pathogens to deliberate biological weapons attacks is a national security imperative and requires appropriate resourcing and sustained attention.

Much like the counterterrorism and countering weapons of mass destruction proliferation, the field of biosecurity measures success through the absence of an incident.

But, as the pandemic clearly demonstrates, we must not wait for a devastating crisis to start investing in biosecurity. Particularly in today's interconnected world, a deadly pathogen unleashed in the opposite corner of the world would be upon our doorstep shortly thereafter. Therefore, we must be proactive.

The international community has a collective responsibility to work together to improve biosecurity systems and regimes worldwide. We need to examine how we are making investments in deterrence and detection and ensure that we have well-resourced mechanisms to prevent and defeat both naturally occurring health challenges, as well as acts of bioterrorism.

I want to thank our witnesses today in advance for sharing their expertise with us as we consider this crucial matter.

And, with that, let me go ahead and yield 5 minutes to my good friend from Ohio, our ranking member, Representative Steve Chabot, for any opening comments he may have.

Mr. CHABOT. Thank you, Mr. Chairman, and thank you for calling this important hearing today. I would also like to thank our witnesses for being here and for providing us their uniquely qualified insights.

It is important to be discussing the threats posed by potential new diseases, as well as a new generation of bioweapons, so I commend you for doing this.

This hearing comes at a pivotal time. COVID–19 has taught us, like nothing else, the devastation that can be caused by a previously unknown disease.

The Chinese Communist Party hid the emergence of the disease from the world, allowing it to become a global pandemic. This shows just how crucial it is to detect and address a new disease early on.

But such a contagion could easily begin somewhere that has a less malevolent government but a weak health system. In fact, Ebola did just that.

The bottom line is the world needs to be better prepared to detect and combat new diseases before they get out of control. It is possible, of course, that even deadlier diseases and viruses than COVID–19 could threaten us as well as chemical compounds.

Syria, Russia, and North Korea, for example, have used chlorine gas, Novichok, and VX nerve agent to murder dissidents and perceived enemies both in their own countries and across the globe.

To make matters worse, the Biological Weapons Convention, the international treaty, banning biological weapons lacks enforcement while the U.N.'s Implementation Support Unit has three people on staff and a budget smaller than that of a McDonald's.

Further, according to the State Department, North Korea and Russia have current, offensive bioweapon programs which are illegal under treaty, and China and Iran are engaging in dual-use research in violation of the treaty as well.

All this is compounded by new and emerging science and technologies that have made it easier than ever before for individuals, even with a limited amount of training and knowledge, to genetically engineer new threats.

Such advances, which could potentially do wonders in the fields of health and medicine, are inherently dual-use and, in the hands of our adversaries, pose a threat to our national security.

Unless we take this threat seriously, countries that have already violated their legal obligations not to use chemical weapons could see advances in biotechnology as offering a new range of weapons that are targeted, deniable, and incredibly lethal.

COVID–19 has raised questions about the nature of this technology itself, including around the issue of gain-of-function research. As we now know, scientists have the ability to genetically manipulate and modify viruses without leaving any evidence.

They can even create synthetic viruses from scratch, choosing the level of transmissibility and lethality in humans.

Even before the current pandemic, groups of researchers around the world were using existing techniques to create hybrid viruses known to have pandemic potential and testing new and novel viruses.

Going forward, we must balance our need to predict and detect new diseases that could cause pandemics with the potential for accidents or for the weaponization of new discoveries.

Supporters argue that gain-of-function research is critical to safeguarding public health and that lab accidents are rare and isolated, but they downplay the inherent risks posed by progressive experimentation.

The level of sophistication seen in terrorist groups like the Islamic State makes it more likely, not less, that these new technologies will be exploited by terrorist organizations seeking new asymmetric weapons.

There is no need to hijack an airliner when you can simply release a weaponized virus in an airport terminal. The death toll from the resulting pandemic could be in the millions.

Worse, it might not even take a terrorist acting intentionally. History shows us that lab accidents are frequent. For instance, in 1979, anthrax was accidentally released from a Soviet military research facility.

Despite assurances to the contrary from American and Soviet scientists, we know that this lab leak resulted in infections and the deaths of close to a hundred people.

Moving forward, it is clear that we need to rebalance our priorities to better prepare for such threats.

Chairman Bera, I look forward to working with you as we consider how to respond to these challenges. We are facing a very real threat, one that we are not adequately addressing, I believe, at the present time.

So, again, I want to thank the witnesses for being here today, look forward to their testimony, and I yield back.

Mr. BERA. Thank you, Ranking Member Chabot. Let me go ahead and briefly introduce our witnesses. First we have Dr. Jaime Yassif, senior fellow for global biological policy and programs at the Nuclear Threat Initiative. Dr. Yassif was previously a program officer at Open Philanthropy where she led the biosecurity and pandemic preparedness initiative.

Prior that, she was a science and technology policy adviser at the U.S. Department of Defense where she focused on oversight of the Cooperative Threat Reduction Program and East Asia security issues.

Next, we welcome the honorable Andy Weber, senior fellow at the Council on Strategic Risks, Janne E. Nolan Center on Strategic Weapons. Mr. Weber has had a long career of U.S. Government service, including as Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs from 2009 to 2014.

He also coordinated U.S. leadership of the international Ebola response for the Department of State. He serves on the boards of Healthcare Ready and the Arms Control Association, among others.

Next, we have Dr. Amesh Adalja, who is the senior scholar at the Johns Hopkins Center for Health Security, an adjunct assistant

professor at the Johns Hopkins Bloomberg School of Public Health, and affiliate of the Johns Hopkins Center for Global Health.

Among his many accomplishments and contributions, Dr. Adalja has served on U.S. Government panels tasked with developing guidelines for the treatment of plague, botulism, and anthrax in mass casualty settings for the system of care for infectious disease emergencies.

Last but not least, we have Dr. Kevin Esvelt, an assistant professor at the MIT Media Lab where he leads the Sculpting Evolution group in exploring evolutionary and ecological engineering.

Professor Esvelt helped pioneer the development of CRISPR, the powerful new method of genome engineering, and is the inventor of synthetic viral ecosystems for the directed evolution of biomolecules.

I want to thank all of you for participating in today's hearing, and I will now recognize witnesses for 5 minutes.

Without objection, your prepared written statements will be made part of the record. I will first invite Dr. Yassif to share her testimony.

**STATEMENT OF DR. JAIME YASSIF, SENIOR FELLOW, GLOBAL BIOLOGICAL POLICY AND PROGRAMS, NUCLEAR THREAT INITIATIVE**

Dr. YASSIF. Thank you. Chairman Bera, Ranking Member Chabot, and other members of the subcommittee. Thank you for the opportunity to join today's hearing to share my perspective on biosecurity for the future. I am a senior fellow at NTI, which is a nonpartisan, global security organization focused on reducing nuclear and biological threats imperiling humanity.

Over the past 21 months, COVID has revealed that national governments and the international community are unprepared to respond to pandemics, underscoring our shared vulnerability to future catastrophic biological threats that could match the impact of the current pandemic or cause damage that is much more severe.

To effectively guard against these risks, the world needs a layered defense, comprised of measures for prevention, detection, and response. I will focus my testimony today primarily on actions necessary to prevent catastrophic biological events, and specifically I will discuss three initiatives that NTI has been working to advance.

First, I will start with NTI's work to reduce emerging biological risks associated with rapid technology advances. Bioscience and biotechnology offer tremendous benefits. They are vital for fighting disease, protecting the environment, and promoting economic development.

However, these innovations can also pose unique challenges, increasing the risks of lab accidents or deliberate misuse by malicious actors.

This threat becomes increasingly pressing as the technical barriers to manipulating biological organisms continue to fall. Governments are key to safeguarding the life sciences, but they have struggled to keep pace with rapid technology advances.

And, at the international level, governance is also weak. There is no existing international entity dedicated, as its primary mis-

sion, to strengthening biosecurity and bioscience governance, notwithstanding the importance work of WHO and the Biological Weapons Convention.

To address this gap, NTI is working to develop the International Biosecurity and Biosafety Initiative For Science, or IBBIS. We envision that this new organization will work collaboratively to strengthen global biosecurity norms and develop innovative and practical tools to uphold them.

And the underlying goal would be to safeguard science and to reduce the risk of catastrophic events that could result from deliberate abuse or accidental misuse.

IBBIS will begin with a narrow focus on improving DNA synthesis screening practices internationally with the understanding that its remit can expand over time.

NTI is working with international partners to continue shaping the vision for IBBIS, and we aspire to launch this new organization in 2022.

We encourage Congress, and specifically members of this subcommittee, to support the goals of this initiative and to help us build broad international support for this effort.

The second portion of my remarks will focus on our initiative for investigating high-consequence biological events of unknown origin. An effective deterrence strategy rests in part on the ability of the international community to demonstrate, to would-be developers or users of bioweapons, that there is a reliable system for attribution and accountability for such actions.

But, to do that, it will be important to bolster the capabilities of the U.N. system to investigate pandemic origins whether naturally emerging, accidental, or deliberate.

And this includes investing more resources in the U.N. Secretary General's Mechanism, which has the authority to investigate alleged deliberate weapons use.

We must also fill gaps, however, specifically in the capabilities to investigate the source of biological events of unknown origin. This important work falls at the seam between existing mechanisms, including the outbreak investigation capabilities of the World Health Organization and the U.N. Secretary General's Mechanism.

To meet this need, NTI is pursuing the establishment of a new joint assessment mechanism for investigating high-consequence bio events of unknown origin. We envision that this mechanism would take an approach that is rapid, transparent, evidence-based, and legitimate in the eyes of the international community.

I hope Congress and this subcommittee will support the establishment of this type of multilateral mechanism, which will be critical for mitigating pandemic effects in real time and for deterring future bioweapons development and use.

The third initiative that I will very briefly address is financing for pandemic preparedness. Building strong systems for early detection and robust response is critical for stopping outbreaks from evolving into global pandemics, and it can also contribute to deterrence.

But none of this can happen without resources. As documented by the 2021 Global Health Security Index, which we are releasing

this morning, most nations have not made dedicated financial investments in pandemic preparedness.

The current shortsighted approach to financing doesn't make a lot of sense because investing in pandemic preparedness is highly cost-effective.

COVID has led to trillions in economic losses and extensive damage to global economies, and yet the international community can effectively guard against these risks with a global investment on the order of 1 to several hundred billion dollars.

To achieve and sustain this level investment, we need to redesign our collective approach to financing. That is why NTI is working with partners to advocate for a new catalytic, multilateral financing mechanism forpandemic preparedness in countries around the world.

We applaud the leadership that the U.S. has already signaled by championing the establishment of a new multilateral financing mechanism at the recent Global COVID–19 Summit.

Now, it must follow through with funding to set the bar for others and challenge them to step up and contribute. The U.S. should contribute at least $2 billion in seed funding and work with partners to mobilize at least $10 billion annually.

Such an investment would constitute a tiny fraction of the potentially catastrophic cost of inaction.

To conclude, COVID has served as a warning shot, highlighting our shared vulnerability to global pandemics, while national and global leaders are understandably focused on the current crisis but cannot afford the essential work to prevent and respond to future, high-consequence bio events.

Chairman Bera, Ranking Member Chabot, and other members of this subcommittee, thank you for inviting me to testify today, and I look forward to answering your questions.

[The prepared statement of Dr. Yassif follows:]

Testimony of Jaime M. Yassif, Ph.D.

Senior Fellow, Global Biological Policy and Programs, Nuclear Threat Initiative

Before the U.S. House Foreign Affairs
Subcommittee on Asia, the Pacific, Central Asia, and Nonproliferation.
Hearing on "Biosecurity for the Future: Strengthening Deterrence and Detection"
Wednesday, December 08, 2021

Chairman Bera, Ranking Member Chabot, and other members of the Subcommittee, thank you for the opportunity to join today's hearing to share my perspective on **Biosecurity for the Future**. My name is Dr. Jaime Yassif. I am a Senior Fellow for Global Biological Policy and Programs at the Nuclear Threat Initiative, which is a nonprofit, nonpartisan global security organization focused on reducing nuclear and biological threats imperiling humanity.

Over the past 21 months, the world has contended with the devastating impacts that a biological event can have on human health, economies, political stability, and security. The SARS-CoV-2 virus has infected more than 265 million people, killed more than five million, and caused trillions of dollars in economic losses. COVID-19 has revealed that national governments and the international community are woefully unprepared to respond to pandemics—underscoring our shared vulnerability to future catastrophic biological threats that could meet or exceed the severe consequences of the current pandemic.

To offer meaningful protection against global biological risks, the world needs a layered defense, comprised of effective measures for prevention, detection, and response. While we address all three of these critically important aspects in our work at NTI, I will focus my testimony today primarily on actions that national leaders and the international community should take with a view to *preventing* catastrophic biological events. Specifically, I will focus on three priority initiatives that NTI has been working to advance, which we view as critically important. NTI is working to:

I. Prevent the deliberate abuse or accidental misuse of bioscience and biotechnology by strengthening international biosecurity norms and developing innovative, practical tools to reduce risks throughout the research and development life cycle.

II. Develop a new Joint Assessment Mechanism to strengthen UN-system capabilities to investigate high-consequence biological events of unknown origin. The ability to rapidly discern the source of emerging pandemics is critical to mitigating their effects in real time and protecting against future risks—and it could help deter development and use of biological weapons.

III. Advocate for establishing a catalytic financing mechanism to fund biosecurity and pandemic preparedness capacity building in countries around the world. Sustainably financed systems for early detection and robust response can stop outbreaks at the

source before they evolve into global pandemics and can help deter would-be perpetrators of bioweapons attacks.

**Reducing Emerging Biological Risks Associated with Rapid Technology Advances**

Bioscience and biotechnology advances are vital for fighting disease, protecting the environment, and promoting economic development—and they hold incredible promise. A prime example is the ability to read, write, and edit DNA and RNA—the underlying blueprint for all life on earth. These developments are part of a broader bioscience revolution, which also is accelerating design-build-test cycles for engineering biology. This includes increasingly sophisticated technologies for automation of high-throughput bioscience experiments, coupled with continued advances in AI-based approaches to this work.[1] Bioscience is truly the revolution of the 21st century, and it holds incredible promise. However, these innovations can pose unique challenges—increasing the risks of accidental misuse or deliberate abuse with potentially catastrophic consequences.

These underlying risks are not new, but they have been exacerbated by the current pandemic, which has led to the proliferation of research into the SARS-CoV-2 virus, as well as its variants and other pathogens with pandemic potential—and new labs are being built around the world to house this work. While this research can have significant value in strengthening public health and pandemic-response capabilities, some of it poses dual-use risks. Moreover, in the wake of COVID-19, malicious actors may now recognize and act on the extraordinary disruptive potential of highly transmissible pathogens and other biological agents and use them to deliberately cause harm. This threat becomes increasingly pressing as the technical barriers to manipulating biological organisms continue to fall.

This has several implications for biosecurity and biological risks. First, these bioscience and biotechnology advances make it easier for a wider group of individuals to engineer novel pathogens or synthesize them from scratch. This could make it easier for a non-state actor to conduct a bioweapons attack with a sophisticated and deadly pathogen. Second, these advances could increase the risks of a laboratory accident with potentially catastrophic global consequences. There is a well-documented baseline rate of laboratory accidents, and these risks are exacerbated by research that involves modifying pathogens in ways that could lead to the creation of a more dangerous agent. Accidents associated with this type of research have the potential for significant and severe impacts—with broad implications for human, animal, and environmental health, as well as global safety, security and economic well-being.

To address these risks, we must safeguard the legitimate global bioscience research and development enterprise against laboratory accidents or exploitation and deliberate misuse by malicious actors.

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[1] Yiren Lu, "The Gene-Synthesis Revolution," *New York Times*, November 24, 2021.
< https://www.nytimes.com/2021/11/24/magazine/gene-synthesis.html >

Governments are key to safeguarding the life sciences, but they have struggled to keep pace with rapid technology advances. The 2021 Global Health Security Index—a project led by NTI in partnership with the Johns Hopkins Center for Health Security—will be released this morning, and it contains important data on the challenges countries have faced with national-level oversight of dual-use bioscience research.

International governance of dual-use bioscience research also is weak. There is no existing international entity—including the World Health Organization and the Biological Weapons Convention—dedicated as its primary mission to strengthening biosecurity and bioscience governance and reducing emerging biological risks associated with technology advances. This global governance gap leaves us all vulnerable.

To address this gap, NTI is working with international partners to develop the International Biosecurity and Biosafety Initiative for Science (IBBIS). We envision that this new organization will work collaboratively to strengthen global biosecurity norms and develop innovative tools to uphold them. The underlying goal will be to safeguard science and reduce the risk of catastrophic events that could result from deliberate abuse or accidental misuse of bioscience and biotechnology.[2] [3]

In advancing this important initiative, we recognize that there is no single silver bullet for fully eliminating risks associated with dual-use bioscience research. To effectively guard against these risks, the world needs a layered defense—encompassing multiple interventions throughout the bioscience and biotechnology research and development life cycle: from funding, through execution, and on to publication or commercialization. In pursuit of this goal, IBBIS will develop practical, innovative tools that can concretely reduce risks at these different intervention points.

IBBIS will have a broadly defined mission so that it can take a comprehensive approach to this challenge. It will begin with a narrow focus on improving DNA synthesis screening practices internationally, with the flexibility to expand its remit over time. Such screening is critically important for preventing the building blocks of dangerous pathogens from falling into the hands of malicious actors. And yet, it is not legally required in any country—and only an estimated 80% of the global market share of DNA synthesis orders is screened on a voluntary basis. To drive this number closer to 100% and to improve screening practices around the world, NTI has been working with the World Economic Forum and an international consortium of experts to develop

[2] "NTI | bio Convenes Stakeholders to Strengthen Global Biosecurity Architecture and Prevent Biological Risks," *NTI News,* September 18, 2020. < https://www.nti.org/news/nti-bio-convenes-stakeholders-strengthen-global-biosecurity-architecture-and-prevent-biological-risks/>

[3] "NTI | bio Convenes Experts to Establish Global Entity Dedicated to Reducing Biotechnology Risks," *NTI News*, May 25, 2021. < https://www.nti.org/news/nti-bio-convenes-experts-establish-global-entity-dedicated-reducing-biotechnology-risks/ >

an international Common Mechanism for DNA synthesis screening.[4] We envision that IBBIS will take responsibility for overseeing and managing this work. This is a useful starting point for IBBIS because it is clearly defined, impactful from a risk reduction perspective, and achievable.

NTI is working with the World Economic Forum and other key international partners to continue shaping the vision for IBBIS and to build international support for this initiative. We aspire to launch this new independent organization in 2022, and we are working energetically toward this goal.

IBBIS has the potential to significantly reduce catastrophic biological risks to the U.S. and to populations around the world. However, the success of this initiative will depend on diverse international support across regions and across multiple sectors. We encourage Congress, and specifically members of this Subcommittee, to support the goals of this initiative and help us build a broad coalition of global support for this entity and its critical mission.

**Investigating High-Consequence Biological Events of Unknown Origin**

Effective prevention of catastrophic biological risks also should encompass work to shape the intentions of powerful actors, who might otherwise seek to develop or use biological weapons to meet strategic or tactical objectives. An effective deterrence strategy rests in part on the capability of the international community to demonstrate to would-be developers or users of biological weapons that there is a reliable system for attribution of and accountability for such actions.

To do so, it will be important to bolster the capabilities of the United Nations' system to investigate pandemic origins—whether naturally emerging, accidental or deliberate. This includes strengthening and investing significantly more resources in existing capabilities, such as the United Nations Secretary-General's Mechanism, which has the authority to investigate alleged deliberate bioweapons use.

The international community must also fill gaps. There is a gap in international capabilities to investigate the source of biological events of unknown origin, which falls at the "seam" between existing mechanisms—including the outbreak investigation capabilities of the World Health Organization and the United Nations Secretary-General's Mechanism. The ability to rapidly discern the source of emerging pandemics is critical to mitigating their effects in real time and protecting against future risks, and UN investigative capabilities must be strengthened for this purpose.

[4] "NTI and WEF Convene Second Annual Meeting of DNA Synthesis Screening Technical Consortium," *NTI News,* May 7, 2021. < https://www.nti.org/news/nti-and-wef-convene-second-annual-meeting-dna-synthesis-screening-technical-consortium/ >

To meet this need, NTI is pursuing the establishment of a new Joint Assessment Mechanism for investigating high-consequence biological events of unknown origin. We originally recommended creating such a mechanism in the 2020 report, "Preventing Global Catastrophic Biological Risks," which is based on lessons learned from a senior-level tabletop exercise hosted in partnership with the Munich Security Conference (MSC).[5] To advance this goal, NTI convened a diverse group of international experts in July of this year to continue to explore this concept and solicit feedback from a wide range of international stakeholders.[6] NTI is continuing to refine the Joint Assessment Mechanism concept by working with global experts to address key policy, institutional, technical, and operational considerations.

We envision that the Joint Assessment Mechanism would take an approach that is rapid, transparent, evidence based, and legitimate in the eyes of the international community. We also believe that this should be a 21st century mechanism, taking advantage of new tools, methods and technologies—such as bioinformatics, data science, and AI—to build a capability suited to today's threat environment.

Establishing this mechanism and ensuring its effectiveness will require a broad coalition of international support. I hope Congress and this Subcommittee will support the establishment of this type of multilateral joint assessment mechanism—which will be important for mitigating pandemic effects in real time and for deterring future bioweapons development and use.

**Health System Financing**

Building strong systems for early detection and robust response is critical for stopping outbreaks from evolving into global pandemics. Importantly, having such capabilities in place can also help deter malicious actors from developing or using biological weapons. However, none of this can happen without resources. Failure to invest now risks a return to the same cycles of panic and neglect that led the world to be woefully unprepared for COVID-19.

As a national and global security priority, the U.S. Government needs to lead the way by dedicating substantially more resources to building the global systems required to effectively detect and respond to infectious disease outbreaks before they become global threats. That being said, we cannot do this alone. Countries around the world must also invest in their own pandemic preparedness capabilities.

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[5] Beth Cameron, Jaime Yassif, Jacob Jordan and Jacob Eckles, "Preventing Global Catastrophic Biological Risks: Lessons and Recommendations from a Tabletop Exercise held at the 2020 Munich Security Conference," September 29, 2020. < https://www.nti.org/analysis/articles/preventing-global-catastrophic-biological-risks/ >

[6] "NTI | bio Workshop Advances Efforts to Strengthen International Capabilities to Investigate High-Consequence Biological Events of Unknown Origin," *NTI News*, August 6, 2021. < https://www.nti.org/news/nti-bio-workshop-advances-efforts-to-strengthen-international-capabilities-to-investigate-high-consequence-biological-events-of-unknown-origin/ >

As documented by the 2021 edition of the Global Health Security Index, most countries have not made dedicated financial investments in epidemic and pandemic preparedness. As a leading expert in the field framed this challenge at the joint NTI-MSC tabletop exercise conducted earlier this year, when it comes to financing pandemic preparedness, "we have been trying to fight a tsunami with a teaspoon."[7]

The current short-sighted approach to pandemic preparedness financing is counterintuitive because it is, in fact, highly cost effective to invest in pandemic preparedness capabilities. I do not need to remind you that COVID-19 has led to trillions in economic losses and extensive damage to national and global economies. And yet, the international community can effectively guard against these risks with a global investment on the order of one to several hundred billion dollars. To achieve and sustain this level of investment, we need to redesign our collective approach to financing.

That's why NTI is working with partners to advocate for a new, catalytic multilateral financing mechanism for pandemic preparedness in countries around the world[8]. Our vision is that this funding mechanism should incentivize national governments to invest in their own preparedness over the long term. The mechanism should be managed within a country's national budget to increase accountability, incentivize domestic resource mobilization, and promote a sustainable way to shift accounting lines away from donor balance sheets to national budgets. This mechanism should also be driven by countries and address their respective pandemic preparedness needs and gaps. Funds disbursed should prioritize preparedness activities, strengthening long-term national-level capacity and ensuring that preparedness remains a political and budget priority.

The U.S. has already signaled leadership in this area by championing the establishment of a new multilateral financing mechanism for pandemic preparedness at the Global COVID-19 Summit. Now, it must follow-through with significant funding to set the bar for other countries and partners and challenge them to step up and contribute as well. The United States should contribute at least $2 billion in seed funding to stand up this fund and work with partners—across governments, international institutions, the private sector, and civil society—to garner contributions and mobilize at least $10 billion annually. This $10 billion is the bare minimum required; other estimates point to much higher funding-level requirements. Even at higher levels, such funding would constitute a tiny fraction of the potentially catastrophic costs of inaction.

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[7] Jaime M. Yassif, Kevin P. O'Prey, Christopher R. Isaac, "Strengthening Global Systems to Prevent and Respond to High-Consequence Biological Threats: Results from the 2021 Tabletop Exercise Conducted in Partnership with the Munich Security Conference," November 23, 2021. < https://www.nti.org/analysis/articles/strengthening-global-systems-to-prevent-and-respond-to-high-consequence-biological-threats/ >

[8] Amanda Glassman, Carolyn Reynolds, Courtney Carson, Margaret Hamburg, Hayley Severance, Jessica Bell, Jacob Eckles, "A New Multilateral Financing Mechanism for Global Health Security and Pandemic Preparedness," August 2021 < https://pandemicactionnetwork.org/wp-content/uploads/2021/08/A-New-Multilateral-Financing-Mechanism-for-Global-Health-Security-and-Pandemic-Preparedness.pdf>

**Conclusion**

COVID-19 has served as a warning shot, highlighting and making real to citizens around the world our shared vulnerability to global pandemics. While national and global leaders are understandably focused on the current crisis, they cannot afford to neglect essential work to prevent and respond to future high-consequence biological events—which could match the impact of the current pandemic or cause damage that is much more severe.

We encourage Congress and this committee to take action on three key issues:

I. Support, domestically and internationally, the launch and sustainment of the International Biosecurity and Biosafety Initiative for Science, toward its critical mission of safeguarding science and reducing the risk of catastrophic events that could result from deliberate abuse or accidental misuse of bioscience and biotechnology.

II. Urge colleagues in the international community to support the establishment of a new Joint Assessment Mechanism for investigating high-consequence biological events of unknown origin.

III. Champion the establishment of a new multilateral financing mechanism for pandemic preparedness, along with the provision of significant seed funding for this mechanism—which will be critical for strengthening rapid detection and response systems globally, and for deterring bioweapons development and use.

Chairman Bera, Ranking Member Chabot, and other members of the subcommittee, thank you for inviting me to testify today. I look forward to answering your questions.

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Mr. BERA. Thank you. I now invite Mr. Weber for his testimony.

**STATEMENT OF THE HONORABLE ANDY WEBER, SENIOR FELLOW, COUNCIL ON STRATEGIC RISKS**

Mr. WEBER. Thank you. Chairman Bera, Ranking Member Chabot, and members of the committee. I am honored to appear before you today. I would like to applaud the committee for hosting this hearing on what I believe is one of the most consequential issues for the United States and the international community: deterring biological weapons threats and preventing pandemics.

I have focused on countering biological threats for the bulk of my career. In the 1990's, I worked with the Department of Defense Nunn-Lugar Cooperative Threat Reduction Program and saw firsthand the massive scale of the Soviet Union's offensive biological weapons complex.

One facility we completely dismantled, at the request of First President of Kazakhstan Nursultan Nazarbayev, was capable of producing 300 tons of anthrax agent during a mobilization period of about 8 months.

Another laboratory in Koltsovo, Russia, perfected viral weapons to cause horrific diseases like smallpox, Marburg, and Ebola.

Biological weapons threats are increasing due to several factors, including advanced North Korean and Russian offensive programs, China's huge investments in dual-use biotechnologies, and a revolution in biotechnology that is making it easier and cheaper for even small groups or individuals to misuse biology.

The United States should now pursue a strategy based on two reinforcing goals. The first is preventing future outbreaks from ever again reaching pandemic scale. This goal is more achievable than ever. Though it will take leadership and sustained investments in biodefense, the U.S. bio economy, and international partnerships.

The second focus ox on deliberate biological threats, which are increasing.

The United States should lead the world in making biological weapons the first category of weapons of mass destruction to be effectively eliminated or rendered obsolete.

Deterrence is at the heart of this proposal. Specifically, we are calling for a U.S. strategy of deterrence by denial. This type of deterrence strategy would focus on ultimately denying the attackers' success in their aims regarding biological weapons.

Today, U.S. innovation has created a new paradigm. We now have the technologies and tools needed to make deterrence by denial, regarding deliberate biological threats and pandemic prevention, a reality.

Our task today is to deploy such advanced technologies effectively and integrate them via a systems approach to addressing the full range of biological threats. We need fast and precise pathogen early warning.

We need these systems to produce and share robust data that can be used for rapidly characterizing pathogens and tailoring diagnostics and countermeasures, vaccines, and medical treatments to help stop them.

One of the top opportunities to enhance early warning stems from the Biological Threat Reduction Program at the Department of Defense. This program, which I helped create, has long been used for advancing biosurveillance and biosecurity with many partners around the world.

This paid off heavily. Several U.S. allies and partners have been leaders in detecting and monitoring COVID–19. I deeply appreciate that this year, you, in the House of Representatives, on a bipartisan basis, restored the severe and inexplicable Pentagon cuts to the Biological Threat Reduction Program.

It will also be critical to revitalize and expand another Department of Defense program that has suffered budget cuts and underutilization in recent years, the Pentagon's Chemical and Biological Defense Program, or CBDP.

Despite a strong track record of performance and extensive national capacities, in recent years Department leaders have slashed CBDP's budget, even during a pandemic, and restricted its ability to respond to COVID–19 early in the pandemic.

I am heartened, however, that, in launching the first ever Pentagon Biodefense Posture Review last month, Secretary of Defense Lloyd Austin commanded the Department of Defense to prioritize biodefense across the full spectrum of biological threats, from naturally occurring to accidental and deliberate biological incidents.

To enact a national strategy to take biological weapons off the table as a weapon of mass destruction threat and to prevent future infectious disease threats from growing to pandemic scale, I and my colleagues recommend an investment plan that we call "10 plus 10 over 10."

This entails investing $10 billion per year for 10 years for deterring and addressing biological weapons threats, plus $10 billion per year for 10 years for global health security and direct pandemic prevention initiatives.

The details of this $200 billion, 10-year plan will be published in our forthcoming handbook for deterring biological weapons and preventing future pandemics. The Council on Strategic Risks will release it this month.

In conclusion, the United States has made significant progress in addressing biological threats over the past several decades. The COVID–19 pandemic was a wake-up call.

The good news is that it is within our reach to take biological threats off the table. To do so, we must summon the political will to set a bold strategy for the United States and our partners around the world. Thank you very much, and I look forward to answering your questions.

[The prepared statement of Mr. Weber follows:]

**Written testimony as submitted by The Honorable Andy Weber**
Senior Fellow, The Council on Strategic Risks

**To the U.S. House Foreign Affairs Committee**
**Subcommittee on Asia, the Pacific, Central Asia, and Nonproliferation**

**Biosecurity for the Future: Strengthening Deterrence and Detection**
Wednesday, December 8, 2021, at 10 am EDT

Chairman Bera, Ranking Member Chabot, and Members of the Committee, I am honored to appear before you today.

First, I would like to thank the Committee for hosting this hearing on what I believe is one of the most consequential issues for the United States and the international community in the coming years: biological threats, and how the nation can aggressively pursue solutions in this area.

Second, I would like to begin my testimony by also thanking you for including *deterrence* in the subject of today's hearing.

I have focused on countering biological threats for the bulk of my career. In the 1990s I worked with the Department of Defense Nunn-Lugar Cooperative Threat Reduction Program, and saw first hand the massive scale of the Soviet Union's offensive biological weapons complex. One facility we completely dismantled, at the request of First President of Kazakhstan Nursultan Nazarbayev, was capable of producing 300 tons of anthrax agent during a mobilization period of about eight months. Another laboratory in Koltsovo, Russia, perfected viral weapons to cause horrific diseases like smallpox, Marburg, and Ebola.

My experiences also include decades of working hand in hand with nations around the world who share U.S. ambitions for countering such threats. As we will hear in depth from my colleagues testifying alongside me today, biological weapons threats are increasing due to several factors, including advanced North Korean and Russian offensive programs, China's huge investments in dual-use biotechnologies, and a revolution in biotechnology that is making it easier and cheaper for even small groups or individuals to misuse biology.

Today, the United States is on the cusp of game-changing shifts in addressing biological threats. This has to begin with giving deterrence a central role.

Current U.S. strategy focuses on "risk management" for addressing biological threats. Our nation's strategy to date has been strong, but as we've witnessed all too terribly, it has been insufficiently bold.

In terms of defense strategy, the current U.S. approach relies heavily on the threat of our nation using nuclear weapons to retaliate if another nation conducts a strategic biological weapons attack. A

second emphasis of current U.S. strategy is to focus on developing capabilities that would allow U.S. military personnel to continue operating if they are attacked with biological weapons.

We owe those who risk their lives for the nation better than this. Furthermore, deterrence by threat of nuclear retaliation may not be seen as credible by those who we wish to deter, and this is one reason I believe candidate Biden rightly proposed making the sole purpose of nuclear weapons to deter nuclear attacks. Most importantly, a far superior strategy for deterring biological attacks is now more achievable than ever before, thanks to decades of biodefense investments and innovation.

As my Council on Strategic Risks colleagues and I have written in recent months, the United States should now pursue a concerted strategy based on two interrelated goals. The first is *preventing future outbreaks from ever again reaching pandemic scale*. This goal is more achievable than ever, though it will take leadership and sustained investments in biodefense, the U.S. bioeconomy, and international partnerships. Luckily, the nation appears to be moving in this direction now, with support from policymakers across party lines.

The second focuses on deliberate biological threats, which I strongly believe are growing. I and my colleagues at the Council on Strategic Risks believe that the United States *should lead the world in* ***making biological weapons the first category of weapons of mass destruction to bæffectively eliminated or rendered obsolete.***

Deterrence is at the heart of this approach. Specifically, we have proposed a U.S. strategy of ***deterrence by denial*** regarding deliberate biological threats.[1] This type of deterrence strategy would focus on ultimately denying an attacker success in their aims regarding biological weapons, such as causing mass casualties, mass confusion, and erosion of operational capabilities.

Deterrence by denial is a common goal and practice for defense forces. While it is not yet a written strategy for the United States regarding biological weapons threats, the U.S. Department of Defense, and many of our partners around the world, have actually embraced this approach for years. Yet there is a crucial difference today: When I was a key leader at DoD, this was our aim, but it was seen as a decadal transition. We knew the nation had to work hard to push technologies and methods in the right direction---and in many cases, we did.

Today, U.S. innovation and that conducted by others around the world have created a new paradigm. We now have the technologies and tools needed to make deterrence by denial regarding deliberate biological threats---and pandemic prevention---a reality.

Our task today is to deploy such advanced technologies effectively, and integrate them via a systems approach to addressing the full range of biological threats.

What this looks like is not altogether new. However, the preparation must be much more robust than it has been, accelerated faster than ever, and deployed at a broader scale than in the past. We need fast and precise pathogen early warning. We need these systems to produce robust data that

[1] Christine Parthemore and Andy Weber, "A Deterrence by Denial Strategy for Addressing Biological Weapons," *War on the Rocks*, September 23, 2021.


can be used for rapidly characterizing pathogens and tailoring diagnostics and countermeasures---vaccines and medical treatments---to help stop them. And we need increasingly fine-tuned plans for putting these capacities to use, quickly and effectively, against every emerging pathogen that raises concerns that it could devastate the nation and the world.

**Next Steps for the Nation**

Some of the suggested topics for this hearing included technology and tools, bio threats from a defense perspective, and leveraging and bolstering treaties and multinational collaboration.

My testimony today, which I am honored to share, will weave among these themes and show just how interconnected such efforts need to be for effective pandemic prevention and strong deterrence.

Modern technology and tools are central to the strategy I described. The good news is that the international community is in the early stages of advancing and deploying better technologies than ever before for halting biological threats before they cause mass casualties.

At the Department of Defense in the decades in which I helped oversee and drive development of such technologies, we had several aims. One was for new biodefense technologies to be as pathogen-agnostic as possible. As we were concerned about engineered biological weapons from other nations---given that the Soviet Union had been working in this direction---we needed technologies that went beyond testing for and detecting one specific pathogen at a time, or working against a static list of threat agents.

Other goals were to have diverse tools for diverse settings. For biodefense, we need diagnostics, testing equipment, the ability to deliver countermeasures to affected people, and data systems and connectivity that can withstand a wide range of field settings---not just be useful in a modern, climate-controlled laboratory.

Perhaps most importantly, we needed speed. For some biological weapons threats, if you are not prepared or do not respond quickly, fatalities can increase to catastrophic levels. Even for some infectious disease threats that are slower to cause mass casualties, they can still sow chaos and confusion, and lack of trust in governments, in ways that could provide advantages to attackers.

Real-time and effective early warning for biological threats has therefore long been a cornerstone of U.S. strategy. With tools based on genomic sequencing, CRISPR-based technologies, and advances in machine learning and AI contributions to threat analysis, we can now truly move to pathogen early warning that is timely enough to halt emerging biological threats before they cause mass death.[2]

I expect that my colleagues at this table with deep experiences in science and technology will likely cover this in greater depth, so I will focus on opportunities related to how the United States can best

[2] Natasha E. Bajema, William Beaver, and Christine Parthemore, *Toward a Global Pathogen Early Warning System: Building on the Landscape of Biosurveillance Today*, Council on Strategic Risks, 2021.

advance such early warning work, alongside ever-more rapid medical countermeasure development and other necessary aspects of both biological threat deterrence and pandemic prevention.

To begin, there is increasing consensus that the United States should work with partners across the world in creating a global pathogen early warning system. This could be one of the most important tools at our disposal. Achieving it will be complex, though doable.

First, we need a surge for advancing and deploying tools with the highest utility for addressing *novel and wide-ranging* disease threats, including those that may be deliberately introduced. The United States is at the forefront of next generation sequencing, metagenomics, cutting-edge environmental sensing, wearable and point of need technologies, and other relevant tools that will help to achieve early warning for infectious disease threats.

They also hold the potential for revolutionizing our ability to determine whether specific disease threats occurred naturally or were introduced deliberately.

As such, U.S. plans for the coming years should prioritize targeted deployment of tools that can help to detect and characterize the preponderance of pathogen threats, including those like the novel SARS-CoV-2 virus that the world had not encountered before 2019, as well as engineered pathogens. These include widely-deployed next generation sequencing and metagenomic tools. In the coming years, this will likely extend to diagnostic tools as well, including CRISPR-based diagnostics and at-home, point of person tests that can be affordably and consistently deployed to help catch new disease threats in targeted populations.

Earlier in my career, we made great strides in this direction by fostering the development of tools to detect and diagnose several disease threats together---not just one at a time. Today, the technologies exist to do so for several hundred pathogens at a time, and even *all* biological organisms present in a targeted sample.

Starting immediately, we need to surge existing and historically-strong U.S. programs to help advance such early warning tools. One of the top opportunities stems from the Biological Threat Reduction Program (BTRP) at the Department of Defense. This program, which I helped create, has long been used for advancing biosurveillance and biosecurity with about forty key partners around the world. This paid off heavily. Several U.S. allies and partners have been leaders in detecting and monitoring COVID-19, and in many cases specific U.S. defense partnerships were the genesis of the capabilities that led to this outcome. I deeply appreciate that this year the House of Representatives, on a bipartisan basis, restored the severe and inexplicable Pentagon cuts to the vital BTRP program. Unfortunately, the Senate has thus far failed to act.

Now, the United States must surge resources for moving ever more-advanced early warning technologies to key U.S. labs and bases, and for sharing them with allied and partner nations around the world.

Similar and complementary efforts can extend to bolstering treaties, international collaboration, and data-sharing. Advanced machine learning and AI systems, cutting-edge environmental monitoring


tools, and next-generation genomic sequencing can all help advance the international community's toolkit for understanding the sources of new biological events as they occur. They can also be used for countries seeking to collaborate in demonstrating compliance with treaty commitments regarding the peaceful uses of biological technologies.

We should also explore new international efforts to enhance biosecurity and biosafety to increase transparency and monitoring of high biocontainment laboratories and to curtail risky pandemic prevention research. Last year Kazakhstan President Tokayev made one such bold proposal to the United Nations General Assembly in calling for the creation of an International Biosafety Agency.

This kind of technology-forward diplomatic and defense cooperation surge would mirror decades of cooperation with allies and partners, and serve to advance mutual security measures.

The people of every nation benefit from halting outbreaks before they become pandemics, and every nation benefits from high confidence that their adversaries will not attack them with biological weapons. Nearly 100 years after these tenets were first enshrined in international law, it is time for the United States to retake a leadership position in advancing them again.

The national strategic approach I am proposing---deterrence by denial of effects of biological weapons and international cooperation to prevent pandemics---needs to be an all hands on deck strategy for the United States.

In the immediate term, it will be critical to bring back to health and then expand U.S. Department of Defense programs that have been inflicted by budget cuts and under-utilization in recent years. Topping this list is the Pentagon's Chemical and Biological Defense Program, or CBDP. Despite a strong track record of performance and extensive national capacities, in recent years department leaders have slashed CBDP's biological defense budget---even during a pandemic---and restricted its ability to respond to COVID-19 early in the pandemic in ways that may have cost the lives of Americans.

This stems in part from the department taking an overly-restrictive definition of its mission regarding biological defense. CBDP's current focus centers on U.S. forces continuing to operate in an environment in which biological or chemical weapons are used. This is important---but it is not a strategy.

The CBDP's mission should be expanded to include deterrence specifically. This step alone would allow the nation to bring the program's full, vast capabilities to bear for all emerging and potentially catastrophic biological risks.

Indeed, I am heartened that in launching the first ever Pentagon biodefense posture review last month, Secretary of Defense Lloyd Austin commanded that "the Department of Defense will prioritize biodefense across the full spectrum of biological threats, from naturally occurring to accidental and deliberate biological incidents." He further called on the Department to "act boldly to continue the fight against COVID-19 while we also prepare for future biological threats."


Another important step will be to fully bring the Department of Energy's National Laboratories to the table. The National Labs have significant, and in many cases world-unique, capacities for addressing biological threats. My colleagues and I have proposed several steps to fully leverage the invaluable national assets resident in the Labs. They center on making the National Labs a key actor in engineering biology, with adjustments in program authorities and funding to allow this shift. We also propose a Biosecurity Reserve Corps by which talented scientists and technologists in the country can serve limited stints in public service over a committed term, and by which they would be pre-cleared and credentialed to work alongside public sector counterparts to help surge in quashing emerging biological threats.

Of course, the Department of Health and Human Services will continue to be central. Its leadership in Operation Warp Speed and its ongoing successor, in full partnership with the Department of Defense, showcases what should be the new minimum baseline for rapid development of medical countermeasures and diagnostic tools. New and proposed programs, like RADx and ARPA-H, should help to continue maximizing the innovation in both the public and private sectors to advance national interests and promote a strong bio-industrial base. Likewise, past U.S. legislation tilting toward an all-hazards approach to biological preparedness and responses has proven prescient, including the creation of the Biomedical Advanced Research and Development Authority, or BARDA, to speed the development of new biodefense tools in our national and global arsenals.

**Investing Now for the Future**

As I've emphasized, we have many of the technologies and tools needed to achieve this vision. The U.S. government also has in place most of the programs and mechanisms that will be required. Yet they must be resourced well and coordinated, and they must permeate U.S. national strategy and investments.

To enact a national strategy to take biological weapons off the table as a mass destruction threat, and to prevent future infectious disease threats from growing to pandemic scale, I and my colleagues recommend an investment plan that we call *10 plus 10 over 10*.

This entails investments of $10 billion per year for ten years for deterring and addressing biological weapons threats, plus $10 billion per year for ten years for global health security and direct pandemic prevention initiatives.

While this may sound like a huge sum, it is far more affordable than insufficient action. The COVID-19 pandemic alone cost an estimated $16 trillion to the United States in under two years, in addition to the human toll and detriments to national security which are not well quantified. U.S. department leaders have had a difficult time even calculating the costs to U.S. national security. The 10 plus 10 over 10 plan also represents a small fraction of U.S. government and Defense Department spending overall. I encourage everyone to explore the details of this plan that we provide in our forthcoming "Handbook" for deterring biological weapons and preventing future pandemics that the Council on Strategic Risks will release later this month.[3]

[3] "A Handbook for Ending Catastrophic Biological Risks: How the United States Can Deter Biological Weapons and Prevent Future Pandemics." A product of the Janne E. Nolan Center on Strategic Weapons, an institute of the Council

**Conclusion**

The United States has made significant progress in addressing biological threats over the past several decades. The COVID-19 pandemic was a wake-up call that though we have come far, we have much more to do, and fast. The good news is that this work is within our reach if we gather the political will to set a bold strategy for the United States, and pursue it in force alongside our partners around the world.

on Strategic Risks. Authors: William Beaver, Dr. Yong-Bee Lim, Lillian Parr, Christine Parthemore, and Andrew Weber. Contributing authors: Dr. Natasha Bajema, Dr. Rohit Chitale, Jackson duPont, Dr. Chris Fall, Dr. Nikki Teran, and Dr. Alexander Titus. Edited by Francesco Femia and Christine Parthemore. December 2021 (forthcoming). Will be accessible at: https://councilonstrategicrisks.org/a-handbook-for-ending-catastrophic-biological-risks/

Mr. BERA. Thank you. I now invite Dr. Adalja for his testimony.

**STATEMENT OF DR. AMESH ADALJA, SENIOR SCHOLAR, CENTER FOR HEALTH SECURITY, JOHNS HOPKINS UNIVERSITY BLOOMBERG SCHOOL OF PUBLIC HEALTH**

Dr. ADALJA. Chairman and Dr. Bera, Ranking Member Chabot, distinguished members of the subcommittee, thank you for the opportunity to offer testimony today on the biosecurity for the future, strengthening deterrence and detection.

I am a senior scholar at the Johns Hopkins Center for Health Security at the Johns Hopkins Bloomberg School of Public Health. The opinions expressed herein are my own anddo not reflect the views of Johns Hopkins University.

As our country and the rest of the world continue to grapple with the devastating impacts of the COVID–19 pandemic, it is appropriate and important to put surveillance systems and strategies in place to detect in the future the emergence or reemergence of dangerous viruses with pandemic potential.

Because many infectious diseases are contagious and transit between humans easily, infectious disease threats anywhere can universalize very quickly.

We are now seeing firsthand that pathogens no longer travel at the speed of a steam ship. They travel at the speed of a jet. Borders are porous, and diseases seep through them quickly.

The U.S. needs to have as comprehensive global situational awareness of infectious disease threats as possible.

As the U.S. Government decides how to best invest limited resources in early warning systems for detection of future viral threats, it is critical to prioritize surveillance activities that, one, are the most likely to uncover actual rather than hypothetical threats; and, two, are practical and add value every day to preparedness even between outbreaks.

Too often our limited surveillance dollars are funding overly broad surveillance and basic analysis that includes a vast collection of animal samples with the goal of identifying potential infectious diseases emanating from animals in spillover or zoonotic events.

Given the history of viruses such as SARS-CoV–2, Nipah, Ebola, and HIV, zoonotic spillover events are an appropriate priority. However, focusing our surveillance efforts on the constant sampling of animals can be like looking for a needle is a never-ending haystack.

While this type of surveillance can play a part in early warning systems and it helps us to improve our understanding of disease in animal species, we should be careful not to place an overemphasis on viral cataloguing efforts.

These are indeed essential virologic and scientific tasks but should not be construed to be synonymouswith early warning or a substitute for pandemic preparedness activities.

We should complement the broad sampling of animal species with a more targeted type of surveillance, focused on sampling of viruses present in patients in clinical environments.

A microbe most likely to cause a pandemic or a disruptive outbreak is likely one that possesses the ability to infect humans to some extent now. These are infections that are occurring in hu-

mans by pathogens—these are infections that are occurring in humans by pathogens that have the capacity to do so now.

Such a microbe may go unnoticed, mistaken for other causes, or occur in populations where diagnostic technology is not available and may be spread by the respiratory route and cause a respiratory infection such as pneumonia. It may also have characteristics that can cause a brain or central nervous system infection like meningitis.

And critically it is likely to result in sepsis or septic shock as the final common pathway to severe disease and death.

The majority of these cases go without identification of the virus and without a specific diagnosis. The empiric treatment either works or it doesn't. This is something I witness in the United States, and it is very common internationally.

I liken the undiagnosed syndromes to biological dark matter which likely contain key information about what is making people sick, some deathly, today, right now, everywhere.

The first COVID–19 cases in Wuhan were mixed in with influenza, and they were missed. A few weeks would have saved lives if there was early detection. The first U.S. case of the novel 2009 H1N1 pandemic virus was only identified because people went to a naval surveillance study site and got this virus identified much earlier.

Whether what is lurking in the biological dark matter is the first human foray for an emerging pathogen, a change in behavior of a known pathogen, or an ordinary infection that went undiagnosed, it is valuable information.

We need to commit and spend more time diving deep to understand this dark matter. This is a no-regret investment because it is likely to uncover actual, rather than hypothetical, threats.

The value is fivefold. First, if it is a new emerging pathogen that is obscured because it is causing a familiar clinical syndrome, its discovery could be an early warning for the entire world.

Second, if a new property has evolved in a known pathogen, it can be valuable clinical information.

Third, inappropriate use of antibiotics for these undiagnosed syndromes contributes to antimicrobial resistance worldwide.

Fourth, we will learn a lot about the epidemiology of what is circulating.

And, fifth, we will engage in global health diplomacy.

I believe Congress should prioritize augmentation of diagnostic technologies as part of the international biosurveillance enterprise. These technologies exist today. It doesn't necessarily involve building a very big lab. I think it is about improving bread-and-butter diagnostic capacities, and I think it will help us all.

Thank you for the opportunity to testify.

[The prepared statement of Dr. Adalja follows:]

Statement of Dr. Amesh A. Adalja, MD
Senior Scholar, Johns Hopkins Center for Health Security

U.S. House Foreign Affairs Subcommittee on Asia, the Pacific, Central Asia, and Nonproliferation
December 8, 2021
"Biosecurity for the Future: Strengthening Deterrence and Detection."

Chairman and Dr. Bera, Ranking Member Chabot, distinguished Members of the Subcommittee, thank you for the opportunity to offer testimony today on the "Biosecurity for the Future: Strengthening Deterrence and Detection."

I am a Senior Scholar at the Johns Hopkins Center for Health Security at the Johns Hopkins Bloomberg School of Public Health. The opinions expressed herein are my own and do not necessarily reflect the views of the Johns Hopkins University.

As our country and the rest of the world continue to grapple with the devastating impacts of the COVID-19 pandemic, it is appropriate and important to put surveillance systems and strategies in place to detect in the future the emergence or re-emergence of dangerous viruses with pandemic potential. Because many infectious diseases are contagious and transmit between humans easily, infectious disease threats anywhere can universalize very quickly. We are now seeing firsthand that pathogens no longer travel at the speed of a steam ship; they travel at the speed of a jet. Borders are porous, and diseases seep through them quickly. The U.S. needs to have as comprehensive global situational awareness of infectious disease threats as possible.

As the US government decides how best to invest limited resources in early warning systems for detection of future viral threats, it is critical to prioritize surveillance activities that: (1) are most likely to uncover actual, rather than hypothetical, threats and (2) are practical and add value every day to preparedness, even between outbreaks. Too often, our limited surveillance dollars are funding overly broad surveillance and basic analysis that includes a vast collection of animal samples with the goal of identifying potential infectious diseases emanating from animals in spillover, or zoonotic events. Given the history of viruses such as SARS-CoV2, Nipah, Ebola, and HIV, zoonotic spill over events is an appropriate priority. However, focusing our surveillance efforts on the constant sampling of animals can be like looking for a needle in a never-ending haystack. While this type of surveillance can play a part in early warning systems and it helps us to improve our understanding of disease in animal species, we should be careful not to place an overemphasis on viral cataloging efforts. These are, indeed, essential virological and scientific tasks but should not be construed to be synonymous with early warning or a substitute for pandemic preparedness activities.

We should complement the broad sampling of animal species with a more targeted type of surveillance focused on sampling of viruses present in patients in clinical environments. A microbe most likely to cause a pandemic or a disruptive outbreak is likely one that possesses the ability to infect humans, to some extent, now. These are infections that are occurring in humans by pathogens that have the capacity to do so now. Such a microbe may go

unnoticed, mistaken for other causes, or occur in populations where diagnostic technology is not available. It may be spread via the respiratory route and cause a respiratory infection such as pneumonia. It may also have characteristics that can cause a brain or central nervous system infection like meningitis. And, and critically, it is likely to result in sepsis or septic shock as the final common pathway to severe disease and death.

These types of syndromes occur all over the world every day, even in the US. In some cases, we discover that the cause was a known pathogen such as pneumococcus, influenza, or the like. But the majority of these cases go without identification of the virus and without a specific diagnosis. The empiric treatment either works or it doesn't. This is something I commonly witness in the hospitals in which I round in the Pittsburgh area--it is much more common internationally.

This passive status quo makes us much more vulnerable to infectious disease threats. This vulnerability derives from the fact that we lack full situational awareness of the microbial threats that we are facing now and will face in the future. Testing people already sick to aggressively pursue a specific microbiologic diagnosis is not only practical, but high yield as it is aimed at uncovering, not theoretical threats that have not yet materialized, but ones already present.

I liken the undiagnosed syndromes to biological dark matter which likely contains key information about what is making people sick – some deathly – today, right now, everywhere. The first COVID-19 cases in Wuhan were mixed in with influenza and, because they are clinically indistinguishable, they were missed. This caused weeks delay in digging into more about this emerging novel virus. Imagine having even a few weeks head start on this pandemic. It would have translated to even faster scientific understanding, faster medical countermeasures, less economic disruption. A few weeks would have saved lives. The first U.S. cases of the novel influenza H1N1 virus that sparked the last flu pandemic in 2009 were only identified because the young children who were infected happened to go to a medical facility that was part of a U.S. Navy study that strived to figure out what viruses were making people sick, even mildly sick.

In many international locations, in which the US government and the Department of Defense have assets, infectious disease diagnosis is largely based on a generic syndrome such as pneumonia and first line medications are prescribed without a specific microbial diagnosis -- which organism is responsible -- but arrived at by local epidemiology (what is common) and clinical presentation. While this is valuable and astute clinicians are extremely valuable it is not enough. For example, during the 2013-2014 West African Ebola outbreak it was often emphasized that West Africa had not seen Ebola before (save one isolated case in the Ivory Coast) but by analyzing blood samples of those thought to have another viral hemorrhagic fever, Lassa Fever, revealed Ebola had been present for over a decade mixed in with Lassa. Imagine how useful that information would have been when health authorities in Guinea took 3 months to realize it was Ebola they were dealing with and not some virulent form of cholera. Lives could have been saved, epidemic curves bent, and spill into other countries prevented by an early warning followed by prompt containment strategies that had been deployed successfully in every prior Ebola outbreak.

Whether what is lurking in the biological dark matter is the first human foray for an emerging pathogen, a change in behavior of a known pathogen, or an ordinary infection that went undiagnosed it is valuable information. We need to commit and spend more time diving deep to understand this dark matter. It is a no regret investment because it is most likely to uncover actual, rather than hypothetical, threats and it is practical and will add value every day to preparedness, even between outbreaks.

The value is five-fold:

1. First, if it is a new emerging pathogen that is obscured because it is causing a familiar clinical syndrome, it's discovery could be an early warning for the entire world to look and prepare for it.

2. Second, if a new property has evolved in a known pathogen, it can be valuable clinical information that can inform care and possibly elevate the threat level of a previously known pathogen.

3. Third, many of these syndromes are treated with antibiotics injudiciously contributing to the world-wide antimicrobial resistance global crisis. Specific diagnoses allow antibiotics to be stewarded – and persevered – more easily.

4. Fourth, even if nothing strikingly new is gained by being aggressive with diagnosis it will add to the epidemiological knowledge of circulating pathogens which could help with public health priorities such as vaccines and also set a more accurate baseline so that aberrations from it could be detected more easily when pathogens change or emerge. The aggregate de-identifed data generated alone, would be invaluable to epidemiology and preparedness.

5. Lastly, helping countries improve their infectious disease outcomes and gain epidemiological insight is a method of global health diplomacy.

I believe Congress should prioritize augmentation of diagnostic technologies as part of the international biosurvelliance enterprise by specifying that a substantial proportion of funds devoted to these activities be directed towards enhancing every day health care facility diagnostic capacity. Additionally, Congress should direct agencies to view such activities as an integral part of U.S. preparedness for biological threats and not exclusively as humanitarian aid to improve international healthcare infrastructure.

I also want to emphasize that to make these diagnostic capabilities routine does not require sophisticated futuristic machines. The technology and tools exist today and are being used in healthcare facilities every day. In the past several years, technology has improved to such a degree that sophisticated molecular detection techniques such as PCR or the equivalent, can be done at home by an untrained person. Diagnostic panels that check for a multitude of organisms all at once can not only be done in an ordinary hospital lab, but even at the point-of-care. These machines exist now and are used routinely in many hospitals and medical facilities around the globe. Some of them can be used point-of-care with little training. As such, they will not require constructions of fancy labs but could be as simple as just

augmenting diagnostics laboratories that already exist. The Defense Threat Reduction Agency (DTRA) Cooperative Biological Engagement Program (CBEP)had placed a major priority on augmenting host country diagnostic capacity and these programs have had positive impacts, but they should not be narrowly construed as only early warning systems for exotic or biothreat organisms. The ability to improve routine infectious disease care will, as I have argued, naturally, also have major implications for early detection of all infectious disease hazards. The interconnection and dependency of U.S. domestic infectious disease response on international detection and characterization of COVID-19 variants such as Omicron, achieved through ordinary sampling of people ill with COVID-19, concretizes this fact.

When considering how to optimize biosurveillance capabilities internationally and deploy technology and data tools, there is a lot of value in augmenting ordinary clinical diagnostic capabilities. While it may need seem as cutting edge as trapping animals, exploring caves, and searching for gorilla droppings, the cascading benefits that will be realized will not only make clinical care better internationally, but make the US more situationally aware and, therefore, more prepared and ultimately safer.

Mr. BERA. Oops. Professor Esvelt? Did we lose Professor Esvelt? Looks as though we may have lost Professor Esvelt.

STAFF. Sir, we are just getting back on here.

Mr. BERA. OK. Professor Esvelt?

Dr. ESVELT [continuing]. Individuals.

Mr. BERA. Teresa, can you work with Professor Esvelt?

STAFF. Chair Bera? Oh, there—so we are seeing Dr. Esvelt on the line again. Dr. Esvelt, if you wouldn't mind——

Dr. ESVELT. Apologies. Could you not hear me?

STAFF. No, sir.

Mr. BERA. We couldn't hear you. We lost you for a moment there. If you want to start your 5 minutes of testimony.

Dr. ESVELT. [Inaudible.]

Mr. BERA. Teresa, we have lost him again. Is that correct?

STAFF. Yes, sir. Sir, if you wouldn't mind, we will work with Dr. Esvelt on his bandwidth issues, and we can come back to him if that is OK with you.

Mr. BERA. OK. That sounds fine. Why do not we, in the interest of time, we will now move on to questions, and then, when Professor Esvelt gets back on, we can allow him to do his opening testimony.

I will now recognize members for 5 minutes each, and pursuant to House rules, all time yielded is for the purpose of questioning our witnesses.

Because of the virtual format of this hearing, I will recognize members by committee seniority, alternating between Democrats and Republicans. If you miss your turn, please let our staff know, and we will circle back to you.

If you seek recognition, you must unmute your microphone and address the chair verbally.

With that, we will see if Professor Esvelt is on, and not seeing him at this moment, I will recognize myself for 5 minutes of questioning.

You know, Mr. Weber, I applaud your optimism that we could actually reduce the threat significantly down to zero, but I do worry about the readily available technology and the fact that high school students are learning how to use CRISPR technology, which isn't a bad thing.

You know, as a doctor, you know, we have made remarkable achievements in the therapeutics that we have to treat oncology, you know, cancers, and remarkable advances. But I do worry about the down side.

I am going to ask, you know, I guess each of the witnesses one thing that we touched on was biosurveillance and how we ought to use biosurveillance.

We have invested, you know, billions of dollars into gene sequencing, which was woefully inadequate here in the United States but also worldwide, and we are doing a much better job around COVID–19 in terms of addressing those threats.

You know, maybe starting with Dr. Yassif, as we, in Congress, think about these investments, beyond COVID–19, what are the regimes and biosurveillance that we should be thinking about both here domestically but then also internationally to identify as quick-

ly as possible, naturally occurring pathogens but also manmade pathogens?

Dr. YASSIF. Thank you, Chairman Bera.

I appreciate that really timely and important question. Certainly biosurveillance is critically important for part of the layered defense that we need to protect against high-consequence biological risks. I will share three quick points.

One is that we really need to integrate gene sequencing technology, as you have mentioned, into biosurveillance systems, both domestically and internationally. I would argue that, before COVID, that wasn't really in place, and I think that is still a work in progress.

Second, we need to ensure that our biosurveillance systems and data-sharing capabilities are integrated across countries and across regions. This has been a significant challenge that experts in the community have been discussing for years, and we have a long way to go to create an integrated global system.

I think, third, I would offer that we need to have a combination of a baseline set of data so we know what normal background, biological noise looks like, and so we can detect unusual events and new pathogens that we might not have been looking for, so we can detect unknown unknowns, especially as we are looking to the future where we might have to contend with engineered pathogens. So those are some recommendations that I would offer. Thank you.

Mr. BERA. Mr. Weber, do you want to add?

Mr. WEBER. Yes. I completely agree with you that these new technologies, like metagenomic sequencing, give us incredible capabilities to improve our biosurveillance and early warning systems, which are the key to both preventing pandemics, isolating outbreaks before they become epidemics and pandemics.

But also an important part, just as we have a nuclear detection system to prevent biological terrorism, having early warning against deliberate biological threats needs to be a big part of our deterrence strategy. Our adversaries need to know that they will be detected and caught if they launch biological weapons attacks.

So I think it is an exciting time. And one of the tools that the U.S. Government has is the Biological Threat Reduction Program that is implemented by the Defense Threat Reduction Agency.

I was involved in that for decades, and one of the goals was to enhance global biosurveillance, working with partners all around the world, and I think, in the next phase, with sufficient funding from Congress—it is a shame that the Department cut over a hundred million dollars from this program in the current year, Fiscal Year 2022 budget request, but if we can restore that funding, we can use those dollars to surge technologies that will enable genomic sequencing to be used broadly as part of our early warning system against pandemics and bio attacks. So the opportunity is really incredible.

Also, metagenomic sequencing gives us new opportunities to identify unknown pathogens. We do not have to just test for a list of 10 or 12 specific pathogens, but we can take a sample and test it for everything, virtually hundreds of potential pathogens. And it is getting much cheaper and faster to do this.

So I agree, we need to, both domestically and abroad, deploy these new capabilities on a massive scale.

Mr. BERA. Right. Wonderful. I see I am out of time. I do see Professor Esvelt on.

Professor, do you want to give your testimony? And then we will come back to the ranking member, Mr. Chabot.

**STATEMENT OF KEVIN ESVELT, DIRECTOR, SCULPTING EVOLUTION GROUP, MASSACHUSETTS INSTITUTE OF TECHNOLOGY**

Mr. ESVELT. Thank you, Chairman Bera, Ranking Member Chabot, members of the subcommittee. First, I am going to check, can you hear me now?

Mr. BERA. Yes, we can.

Mr. ESVELT. Wonderful. Thank you for inviting me here today and additional thanks to my fellow witnesses for outlining the situation. As a practicing biotechnologist, I am deeply concerned that pandemic viruses pose a proliferation threat greater than that of nuclear weapons. The U.S. Government can take specific steps that would greatly reduce this risk.

The threat is severe because new technologies have given thousands of skilled individuals the ability to assemble infectious viruses using materials and equipment that can be ordered online.

If scientists learn and share which viruses could cause new pandemics, no matter how pure our motives, everyone with these skills will be getting access to credible weapons of mass destruction.

For example, even though there are no virologists in my own lab at MIT, perhaps a third of us could order synthetic DNA in the mail and successfully follow published, step-by-step, virus-assembly protocols.

Thankfully scientists do not yet know of any animal or lab-created viruses that would cause another pandemic, but some well-meaning programs that aim to prevent or mitigate natural pandemics are trying to identify all of the viruses that could cause them and publish a list of the most threatening ones. This inadvertently threatens U.S. national security and the world's future.

I do not believe that there are remotely commensurate benefits. The vast majority of the pandemic viruses would never naturally jump into humans, and finding the remainder would not speed vaccine development.

The main proliferation risk comes from laboratory experiments performed by EcoHealth Alliance and similar programs to determine which viruses would likely cause pandemics.

These experiments are the equivalent of nuclear tests. They first received Federal support back when it was much harder to make viruses, and funding has continued under administrations of both parties.

Nations from the Netherlands to China to Germany have also funded these kinds of experiments. In my opinion, they should be stopped, not just in China and in the U.S., but everywhere.

If successful, pandemic virus prediction will give thousands of actors the ability to ignite more pandemics at the same time than would normally occur in a century. If there is published, peer-re-

viewed research describing the potential of these viral weapons, threats to use them will be all too credible.

Imagine a rogue State warning that infectious samples of all the top-ranked pandemic viruses will be released in airports if their regime is overthrown. Extremist groups, apocalyptic cults, or even a lone wolf bioterrorist could kill more people than any nuclear weapon.

So what can be done to minimize our vulnerability to pandemic proliferation? First, Congress should issue a finding that pandemic virus prediction threatens the security of the United States. That alone would change the tenor of the discussion and leave Federal agencies with little security expertise to rethink their support and oversight of such experiments, which are only performed by a tiny fraction of virology labs.

Second, the U.S. and other governments should limit access to synthetic viral DNA. The California State legislature recently passed well-targeted legislation with this intent, but it was vetoed on the grounds that security bills should be enacted federally.

Third, the U.S. could work with China on these issues, because this is one case where our interests are aligned. Both Nations have little to gain and much to lose if pandemic viruses become widely accessible. Any diplomatic benefits or leverage that we gain here could be applied to more sensitive challenges.

Fourth, as the other witnesses have emphasized, we should invest in detecting biological threats early. A sequencing-based nucleic acid observatory focused on travel hubs, such as airports, could reliably detect any emerging biological threat, and it could be done using current technology, we believe, for less than a billion dollars a year. This would improve our response time to all pandemics and deter attacks.

Last, Congress could amend the Bioterrorism Act of 2002 to regulate all viruses with evidence suggestive of pandemic potential through the Federal Select Agent Program, which applies to all research as well as export control.

If we act now, we can greatly reduce the chance that viruses will be used as weapons. Pandemic virus prediction is a needless game of Russian roulette, and we keep adding more ammunition. Thank you.

[The prepared statement of Mr. Esvelt follows:]

House Foreign Affairs Committee
*Subcommittee on Asia, the Pacific, Central Asia, and Nonproliferation*

# Pandemic virus prediction and the proliferation of accessible weapons of mass destruction

**Congressional Testimony of Professor Kevin M. Esvelt, Massachusetts Institute of Technology**

**Introduction**

Chairman Bera, Ranking Member Chabot, and members of the subcommittee, thank you for inviting me to testify today on the subject of pandemic weapons of mass destruction.

More U.S. citizens have lost their lives to COVID-19 than have perished in combat in all of our nation's wars. While pandemic prevention is commonly viewed to be a problem of public health, recent technological advances have made pandemics a still greater, largely unappreciated challenge for national security and nonproliferation.

Bluntly, any virus capable of causing another pandemic is a weapon of mass destruction (WMD).

If successful, efforts to identify particular viruses that could cause pandemics, whatever their motive, would deliver blueprints for how to make biological WMDs. At that point, anyone who could obtain samples of the virus would have their hands on an arsenal.

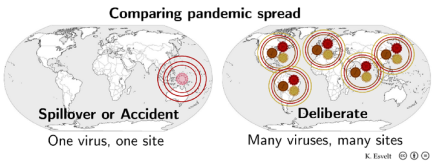
Thanks to advances in virology and biotechnology, many actors are capable of producing most viruses by following detailed step-by-step protocols – hundreds of times more actors than there are nuclear-armed states. Worse, a subset of our well-meaning efforts to prevent or mitigate natural pandemics explicitly seek to identify particular viruses that could cause them, inadvertently threatening our security without accelerating vaccine development.

As a practicing biotechnologist who specializes in controlling evolution, using viruses as engineering tools, and inventing ways to edit organisms in the lab that will controllably spread to affect wild species,[1] I am reasonably confident that pandemic virus prediction poses a greater immediate and potentially catastrophic national security risk than anything else in the life sciences.

To help understand the framework for this conclusion, my assessment considers questions of threat magnitude, proliferation, credibility, utility, and potential defenses. Fortunately, there is much we can do to delay the identification of pandemic-class weapons for long enough to build sufficient defenses.

**Pandemic weapons can inflict harm greater than nuclear weapons or equivalent natural pandemics**

SARS-CoV-2 has demonstrated that a single pandemic virus spreading from a single point of origin can cause more deaths than any nuclear weapon, inflicting trillions in economic damages and disrupting lives worldwide. This can occur regardless of whether the origin is a natural spillover or a lab accident, which are known to occur at high rates no matter what did or did not occur in Wuhan in 2019.[2]




[1] Esvelt, Carlson, and Liu, "A System for the Continuous Directed Evolution of Biomolecules"; Esvelt et al., "Concerning RNA-Guided Gene Drives for the Alteration of Wild Populations"; Noble et al., "Daisy-Chain Gene Drives for the Alteration of Local Populations."

[2] Sewell, "Laboratory-Associated Infections and Biosafety"; Merler et al., "Containing the Accidental Laboratory Escape of Potential Pandemic Influenza Viruses"; Klotz and Sylvester, "The Consequences of a Lab Escape of a Potential Pandemic Pathogen"; Lipsitch and Inglesby, "Moratorium on Research Intended to Create Novel Potential Pandemic Pathogens"; Gryphon Scientific, "Risk and Benefit Analysis of Gain of Function Research"; Manheim and Lewis, "High-Risk Human-Caused Pathogen Exposure Events from 1975-2016"; Bloom et al., "Investigate the Origins of COVID-19."

Engineered viruses could be much worse than any natural pandemic, at least for a time. However, enhancement requires a full-scale and uncertain research project. A malevolent actor could much more easily cause severe damage by releasing many natural pandemic viruses – perhaps more than would normally spill over from animals in a century – across several travel hubs. This possibility suggests we should not only strive to reduce the number of individuals capable of acquiring pandemic weapons of mass destruction, but also to minimize the number of known pandemic viruses.

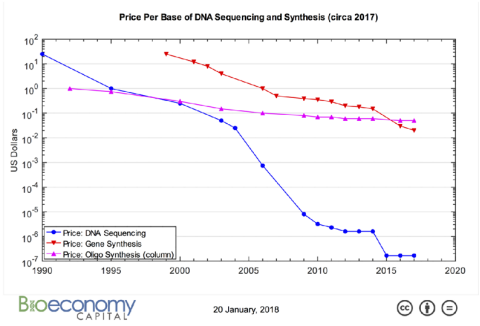
**<u>Successful pandemic virus prediction will increase WMD proliferation at least a hundred-fold</u>**

How many actors currently have access to credible pandemic-class weapons? As far as we know, zero.
How many are likely to acquire them in the near future? Thousands.
Can such proliferation be delayed or prevented? Yes.

This is why pandemic nonproliferation appears to be a national security issue of the utmost importance.

Acquiring a pandemic-class weapon requires 1) knowing of a virus that would cause a new pandemic, and 2) obtaining an infectious sample. Twenty years ago, the only way to obtain physical virus samples was from clinical specimens or laboratory stocks. Today, most viruses can be assembled using synthetic DNA and a virus assembly protocol.

*Synthetic DNA*




In 2002, poliovirus was successfully assembled from chemically synthesized DNA.[3] Since then, the cost of synthetic genes has fallen by a factor of a thousand. The members of the International Gene Synthesis Consortium, an industry group, have taken the lead in voluntarily screening customer orders for dangerous agents at their own expense, going well beyond the weak regulatory requirements imposed by the Department of Health and Human Services.[4] However, members comprise only an estimated 80% of the market and the membership list is publicly available[5], making it straightforward to obtain DNA that is not screened.

*Virus assembly protocols and skilled individuals*

Meanwhile, virus assembly instructions have been developed for nearly all families of viruses to aid research on treatments. For well-studied viral subfamilies, these step-by-step protocols are so detailed that they are readily accessible to non-specialists. A recently published step-by-step protocol to engineer

[3] Cello, Paul, and Wimmer, "Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template."
[4] Diggans and Leproust, "Next Steps for Access to Safe, Secure DNA Synthesis."
[5] International Gene Synthesis Consortium, "Harmonized Screening Protocol V2."

SARS-CoV-2 explicitly stated that it aimed to "enable researchers from different research backgrounds to master the use of the reverse genetic system" and was made freely and indefinitely available.[6]

As a result, many scientists, engineers, and lab technicians have the skills required to obtain infectious viruses from publicly available genome sequences. In the U.S. alone, twenty-five new individuals receive their doctorate in the life sciences or bioengineering each day.[7] Over the last 30 years, over two million people have received an equivalent degree per OECD records.[8] Even assuming that only one in twenty received any training in mammalian cell culture – which is especially common among biomedical researchers – and that just one in twenty of the remainder are skilled and well-practiced enough to successfully follow a virus assembly protocol, over 5,000 doctorates worldwide can generate most known viruses for which a relevant assembly protocol is available. The number of research technicians and students may be comparable. Many presumably already have access to relevant laboratory facilities, which can in any case be obtained with an upper-middle-class salary in most developed nations.

The skills of these individuals are vital to developing the bioeconomy, which will be essential to human health, industrial production, environmental protection, and the continued development of a flourishing and sustainable society. Therefore, it is safe to assume that the number of individuals capable of single-handedly assembling viruses from synthetic DNA will continue to grow.

With publicly accessible viral assembly protocols, many individuals with the skill and facilities to use them, and a lack of comprehensive DNA synthesis screening for illicit activity, it's safe to assume that thousands of individuals could assemble an infectious pandemic-capable virus once we identify one.

**Credibility is required before a pandemic virus can be used as a weapon**

Malevolent actors won't bother trying to assemble a virus as a weapon unless they're at least marginally confident that it would cause a pandemic. There are millions of viruses in nature and probably only a few hundred could cause pandemics, so the odds are poor. Even if a foreign weapons program were to identify or create one, they can't use it to threaten or coerce the United States or the international community without evidence: we don't believe nations are nuclear powers until they've conducted a nuclear test. The global scientific community, arguably the arbiter, will only believe a virus is pandemic-capable if the right experiments are performed, ideally by multiple independent laboratories. If governments block the key experiments required to raise the scientific credibility that a given virus could cause a pandemic, it won't be assembled, used to threaten others, or released as a weapon.

Software tools can help predict whether a given virus might infect humans using its sequenced genome, and knowing that a virus is present in many different species is a useful indicator, but infection alone doesn't make a pandemic. Anyone who wants to learn whether a given virus could cause another human pandemic must perform laboratory experiments: the virological equivalent of nuclear testing.

Here's the general logic: viruses currently circulating among humans are very good at infecting us and making our bodies churn out more viruses. But because most of us have already been infected and acquired some immunity, they mostly spread to kids who haven't previously been exposed or people

[6] Xie et al., "Engineering SARS-CoV-2 Using a Reverse Genetic System."
[7] National Center for Science and Engineering Statistics, "Doctorate Recipients from U.S. Universities, 2019."
[8] OECD, "OECD: Graduates by Field."

with weaker immune systems. Pandemics happen when a new virus jumps from animals to people, and is able to spread well between people: no one has much immunity, so it spreads like wildfire. Once most people have encountered the new virus and developed resistance, it becomes much like its relatives.

That means any virus that can infect human cells, replicate in human cells, and/or be transmitted between animals chosen for their similarity to humans nearly as well as a human-infecting virus from the same family is much more likely to cause a pandemic in humans. Even if it's subpar at one or two of these, it just needs to be good enough for a variant to arise with a mutation that makes it better, just as the original SARS-CoV-2 has been outcompeted by the more infectious variants.

This explains why scientists attempting pandemic virus prediction perform experiments measuring infection and replication in human cells and transmission in model animals such as engineered mice, ferrets, or primates. Virus hunters perform them on newly collected agents, such as the bat coronaviruses gathered by the Wuhan Institute of Virology, to learn whether they might cause new pandemics.[9] Scientists working to enhance the transmissibility of especially lethal animal viruses, like the bird flu strains engineered to be transmitted more efficiently between ferrets, also run these experiments to see whether mutated versions of these viruses have acquired the ability to cause a pandemic.[10]

**The utility of pandemic virus prediction: who can do it and who would benefit**

Pandemics killed over a million people in 1889-90, 1918-19, 1957-58, 1968-69, and 2019-20. Would pandemic virus prediction actually prevent or mitigate future pandemics? If governments limit virus prediction research over proliferation, would bad actors conduct it, and would that increase risks?

Whether prediction would enable prevention is hotly disputed; it wouldn't plausibly accelerate vaccines; and other actors appear to lack the capability or the strategic interest to pursue prediction if we don't.

Groups promoting prediction research – like EcoHealth Alliance and the Global Virome Project – appear to believe that identifying a pandemic virus before the first cases appear will both catalyze vaccine development and help prevent spillover by limiting human-animal contact and blocking transmission. But other researchers have argued that pandemic virus prediction will not actually help with either.

Vaccine acceleration seems highly unlikely now that we have mRNA vaccines. As Moderna's SARS-CoV-2 vaccine was designed in less than two days, if they're possible at all, they can be done quickly. Knowing the identity of the virus in advance can't possibly save any development time during any severe pandemic in which we sensibly combine Phase I and II trials unless we're willing to run Phase II challenge trials (i.e., deliberately infect people) with a large number of viruses that have never infected a human and may never do so. Moreover, there are so many viruses that we're unlikely to identify the next one to actually cause a pandemic, and pandemic virus prediction siphons resources away from early warning efforts often funded by the same program.[11]

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[9] Hu et al., "Discovery of a Rich Gene Pool of Bat SARS-Related Coronaviruses Provides New Insights into the Origin of SARS Coronavirus."
[10] Herfst et al., "Airborne Transmission of Influenza A/H5N1 Virus between Ferrets"; Imai et al., "Experimental Adaptation of an Influenza H5 HA Confers Respiratory Droplet Transmission to a Reassortant H5 HA/H1N1 Virus in Ferrets."
[11] Holmes, Rambaut, and Andersen, "Pandemics: Spend on Surveillance, Not Prediction"; Wille, Geoghegan, and Holmes, "How Accurately Can We Assess Zoonotic Risk?"

Judging by the history of nuclear weapons, many will argue that malevolent actors will eventually perform the research anyway, so it's better for the good guys to find all the dangerous advances first. This may have been true of the atom bomb, but the strategic calculus is different for pandemic weapons.

First, rogue nations and extremist groups would gain tremendous coercive power by gaining access to acknowledged weapons of mass destruction, which could serve as "dead-hand" switches for rogue regimes or as convenient ways to inflict mass death for extremists, mentally disturbed individuals, or terrorists such as the apocalyptic cult Aum Shinrikyo, the scientifically-inclined Aurora shooter James Holmes, or Ted Kaczynski.[12] But these actors generally lack the technical capability to perform basic science research, especially at the scale needed to find the pandemic needle in the animal virus haystack. Although recent technological advancements have made this process much more efficient, leading scientists have already spent well over $100m searching for pandemic viruses without finding any truly credible threats. Therefore, while rogue states or bioterrorists could assemble any pandemic-capable viruses that major nations helpfully identify for them, smaller malevolent actors probably can't find suitable viruses on their own even if they decide to try.

Second, even if some rogue actor defies the odds and eventually comes up with data pointing towards a pandemic weapon, and professional scientists are reckless enough to make it credible by confirming the results, "eventually" will give us time to develop defenses. As COVID-19 showed, we need it.

Third, larger nations can be persuaded that pandemic virus prediction is not in their strategic interest. Pandemic-class weapons are not useful to existing powers because they kill indiscriminately and cannot currently be engineered to spare one's own population. Large nations that attempt to vaccinate their own populations in advance would likely be discovered by foreign intelligence agencies, and even were population-specific targeting possible, its use by a nation-state would be so obvious as to invite mass retaliation. Therefore, pandemic-class weapons appear to offer little if any strategic utility to powerful nation-states. Indeed, to prevent rogue states, bioterrorists, or mentally disturbed individuals from acquiring the ability to blackmail the global community and cause large-scale harm, it is in the interest of global security to join forces on preventing the identification of credible pandemic capable viruses.

As the largest spender on pandemic virus prediction, if we and our allies don't identify believable pandemic WMDs, others probably won't either, at least for some years.

That means we just need to determine whether we ourselves believe the potential benefits of performing the small subset of virology experiments relevant to pandemic virus prediction are worth the cost, or not. With rare and little-publicized exceptions,[13] security concerns over pandemic weapons of mass destruction have seldom been raised at all.

One possible way to decide is to assume everything will work as perfectly as possible for pandemic virus prediction – there will be zero accidents and prediction will let us completely prevent every natural pandemic – then ask if that ideal outcome is worth proliferation:

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[12] Levy and Smithson, "Ataxia: The Chemical and Biological Terrorism Threat and the US Response"; Wikipedia contributors, "James Holmes (mass Murderer)"; Kaczynski, "The Unabomber Manifesto: Industrial Society and Its Future."

[13] Inglesby and Relman, "How Likely Is It That Biological Agents Will Be Used Deliberately to Cause Widespread Harm? Policymakers and Scientists Need to Take Seriously the Possibility That Potential Pandemic Pathogens Will Be Misused"; Katz et al., "Mapping Stakeholders and Policies in Response to Deliberate Biological Events"; "A Spreading Plague: Lessons and Recommendations for Responding to a Deliberate Biological Event"; Sandberg and Nelson, "Who Should We Fear More: Biohackers, Disgruntled Postdocs, or Bad Governments? A Simple Risk Chain Model of Biorisk."

**Should we give thousands of actors the power to release dozens of million-plus-death pandemic viruses at multiple travel hubs throughout the world in exchange for preventing the natural pandemics that spread from a single animal once every 20 years or so?**

If the answer is clearly yes, pandemic virus prediction might still be a very bad idea because real-world accident risks are far from zero and preventing every natural pandemic seems implausible. But if the answer is even equivocal, then the decision has been made without needing to argue over potential benefits vs accident risks.

**Key defenses against pandemics**

COVID-19 demonstrated that we remain profoundly vulnerable to pandemic viruses spreading outwards from a single point of introduction. There is no question that we would fail miserably if faced with multiple pandemic agents simultaneously released in travel hubs, let alone anything designed to inflict harm. But we need not remain helpless.

***Recommendation I – aid nonproliferation by announcing findings, redirecting funds, and fixing oversight***

Our best defense against pandemic weapons of mass destruction is to keep them from being developed in the first place. This may not last forever, but at worst it can buy us time to build other defenses.

- First, nonproliferation efforts would be easier if Congress made a clear finding about the threat. Specifically, Congress could release findings that research designed to make it more certain that a particular virus can cause a pandemic threatens the security of the United States.

- Second, the federal government should stop funding pandemic virus prediction efforts. Existing programs focused on naturally collected viruses or those generated by gain-of-function research are primarily funded by governments, especially ours. I deeply respect the researchers who run these programs, who have dedicated their lives to preventing natural pandemics. Most scientists seldom if ever are encouraged to consider the possibility of misuse,[14] and those who do are unlikely to be sufficiently aware of critical tech-specific national security considerations for bioweapons nonproliferation (e.g., falling DNA synthesis costs, easier virus assembly protocols, the history of nuclear weaponry, and strategic game theory) to grasp the implications on their own.

  The largest pandemic virus prediction efforts are offshoots of larger One Health programs focused on useful monitoring work at the animal-human interface,[15] so there would be no need to revoke any funding or break contracts: the programs could simply direct funds towards early warning systems rather than lab-based virus experimentation. Similarly, behavioral studies and public health interventions which are important for reducing the spillover of animal pathogens into human populations should continue.[16] The virus characterization experiments arguably equivalent to nuclear tests represent considerably less than 1% of virology, so impeding such experiments would be much less of an imposition on the field than the security measures governing nuclear physics.

[14] "Opportunities Exist for the National Institutes of Health To Strengthen Controls in Place To Permit and Monitor Access to Its Sensitive Data."
[15] "WSU to Lead USAID's Global Sampling Project for Discovery of Emerging Viral Zoonoses - Global Biodefense"; "STOP Spillover."
[16] Saylors et al., "Socializing One Health: An Innovative Strategy to Investigate Social and Behavioral Risks of Emerging Viral Threats.".

- Third, Congress can fix an oversight problem with current regulations, namely that funding agencies and recipients are meant to review security issues themselves:

  > "The Department of Health and Human Services (HHS) Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens is intended to guide HHS funding decisions…"
  >
  > "Funders of life sciences research and the institutions and scientists who receive those funds have a shared responsibility for oversight of DURC (dual use research of concern) and for promoting the responsible conduct and communication of such research."

  No funding agency or recipient can be expected to perform oversight for itself; that's the definition of a conflict of interest. Requiring greater transparency and review by individuals with security expertise may help prevent future well-meaning research from going awry.

***Recommendation II – leverage shared strategic interests to achieve global pandemic nonproliferation***

The nature of many emerging technologies places the U.S. and China at loggerheads, but our strategic interests are nearly perfectly aligned when it comes to pandemic weapons of mass destruction: both nations have little to gain and much to lose. This is an opportunity for the United States to gain leverage by offering information exchange and inviting co-leadership in global health security, and may help build diplomatic channels to address more challenging issues around other key technologies.

One way to marshal global action against pandemic virus prediction would utilize the Biological Weapons Convention (BWC), which prohibits the "development, stockpiling, acquisition, retention and production of biological agents" while "permitting the fullest possible exchange of equipment, materials, and information for peaceful purposes." Today, it's impossible to identify a credible pandemic-capable virus without allowing thousands to assemble a weapon of mass destruction by following a step-by-step protocol. There is a strong argument that Article III compels BWC signatories to block pandemic virus discovery. This may also be an opportune time to revive talks to add verification procedures.[17]

***Recommendation III – require DNA synthesis screening matching or exceeding the industry standard***

Most researchers who can follow a virus assembly protocol can't make their own DNA, so the fact that we can order synthetic viral DNA and have it come in the mail substantially increases the number of actors capable of assembling a pandemic weapon. California's legislature passed a bill that would require all providers of synthetic DNA and manufacturers of synthesis machines to screen orders at least as well as the International Gene Synthesis Consortium, but it was vetoed on the grounds that it should be federal legislation to avoid a regulatory patchwork.[18] Passing a federal version would exert market pressures on domestic and international providers to screen, nudging firms to engage with the NTI/WEF stakeholder discussions on a framework for universal screening as well as the SecureDNA project on implementing new advances, including in "desktop" synthesizers, that will allow automated screening for the latest threats without having to disclose customer orders or jeopardize trade secrets.[19] Similar regulations could be encouraged internationally using the BWC or other diplomatic means.

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[17] Butler, "Bioweapons Treaty in Disarray as US Blocks Plans for Verification."
[18] "California Legislature - AB-70 Gene Synthesis Providers."
[19] "Biosecurity Innovation and Risk Reduction: A Global Framework for Accessible, Safe and Secure DNA Synthesis"; The SecureDNA team, "Secure DNA Project - DNA Synthesis Screening."

***Recommendation IV – Build a reliable early warning system and adequate physical defenses***

All rapidly growing biological threats can be reliably detected with "metagenomic" DNA sequencing of sufficient samples, suggesting a way to build a robust early warning system that could deter malevolent actors from threatening the United States with pandemic-class weapons.[20] The cost of sequencing has dropped a million-fold over the past 20 years, allowing public-private partnerships to perform sufficient wastewater sequencing of all 328 U.S. ports of entry for a few hundred billion dollars per year.

Once the threat is known, targeted detection could provide greater sensitivity at all sampling sites, allowing rapid diagnostics to pinpoint exactly where the virus(es) can be found. Biomedical countermeasures may not be achievable for every threat (see HIV vaccines), let alone in a reasonable timeframe, but an American who is physically protected from infection is a safe American. If we develop comfortable and highly reliable personal protective equipment, at least as protective as current unattractive and uncomfortable $1000-market-price powered air purifying respirators, and provide it to our most essential workers, the United States will be able to keep food distribution systems moving, the water flowing, the lights on, and the hospitals open in the teeth of a 30% lethality pandemic until it burns out within our borders. While recent divisions over pandemic policy have sowed doubt about our ability to pull together, I am confident that Americans will rally to defend our nation and protect one another if confronted with a high-lethality threat or a clear attack by a malevolent actor. But we will suffer terribly and needlessly if we do not invest in defenses. For useful investments, see the Apollo Program on Biodefense and the White House's American Pandemic Preparedness Plan.[21]

***Recommendation V – Amend the 2002 Bioterrorism Response Act to update the Select Agent program***

The Federal Select Agent & Toxin Program (FSAP) is unique in regulating all research in the United States, not just federally-funded entities, and additionally impacts the export control list. However, it is updated slowly, doesn't include most viruses that might be pandemic-capable, and the Act was last amended before we developed techniques such as virus chimerism, directed evolution, ancestral protein reconstruction, and machine learning approaches that can generate new threats from existing ones.

Congress could update FSAP to 1) cover anything that uses pieces of Select Agents to builds hazards that wouldn't currently be covered but are just as dangerous, 2) automatically add any virus with a single experimental result indicating that it may be pandemic-capable[22], and 3) immediately lift all restrictions on any Select Agent confirmed to be actively spreading in order to enable research on countermeasures. In addition to reducing accident risks and requiring background checks of anyone working with a virus that may be capable of causing a pandemic, these rules would disincentivize researchers from performing experiments to determine whether their favorite virus is a weapon of mass destruction, as doing so would render it a Select Agent.

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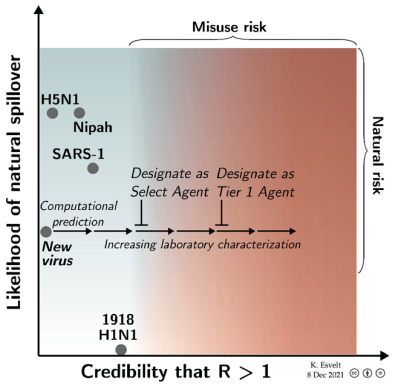
[20] The Nucleic Acid Observatory Consortium, "A Global Nucleic Acid Observatory for Biodefense and Planetary Health."
[21] "The Apollo Program for Biodefense - Winning the Race Against Biological Threats - Bipartisan Commission on Biodefense"; "American Pandemic Preparedness: Transforming Our Capabilities."
[22] **Defining pandemic-capable:** Any virus that normally circulates in a population (R~1) will cause a pandemic when introduced into a more susceptible population that lacks pre-existing immunity (R>1). This is why pandemics typically arise from viruses that spill over from other species, which spread rapidly before becoming endemic. Therefore, a virus is a credible pandemic threat if its components:

- are functionally equivalent to those of an endemic human virus of the same family
- are not recognized by the adaptive immune systems of most humans




**Assessing pandemic risks.** Pandemics may result from natural spillover, laboratory accidents, or deliberate misuse of viruses identified as credibly pandemic-capable (R>1). Designating viruses as Select Agents upon obtaining the first experimental evidence indicative of pandemic potential could preserve the hypothesized benefits of virus discovery for "universal" virus family vaccine and broad-spectrum antiviral development while reducing accident risks and deterring characterization experiments that would otherwise result in the proliferation of credible weapons of mass destruction.

This testimony reflects the personal opinions and technical expertise of Dr. Kevin M. Esvelt.
He is currently a professor at MIT, but does not speak on behalf of the Institute on this occasion.

**References**

"American Pandemic Preparedness: Transforming Our Capabilities," September 3, 2021. https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/03/fact-sheet-biden-administration-to-transform-capabilities-for-pandemic-preparedness/.

"A Spreading Plague: Lessons and Recommendations for Responding to a Deliberate Biological Event," June 13, 2019. https://www.nti.org/analysis/articles/spreading-plague-lessons-and-recommendations-responding-deliberate-biological-event/.

"Biosecurity Innovation and Risk Reduction: A Global Framework for Accessible, Safe and Secure DNA Synthesis." Accessed December 6, 2021. https://www.weforum.org/reports/biosecurity-innovation-and-risk-reduction-a-global-framework-for-accessible-safe-and-secure-dna-synthesis-582d582cd4.

Bloom, Jesse D., Yujia Alina Chan, Ralph S. Baric, Pamela J. Bjorkman, Sarah Cobey, Benjamin E. Deverman, David N. Fisman, et al. "Investigate the Origins of COVID-19." *Science* 372, no. 6543 (May 14, 2021): 694. https://doi.org/10.1126/science.abj0016.

Butler, D. "Bioweapons Treaty in Disarray as US Blocks Plans for Verification." *Nature* 414, no. 6865 (December 13, 2001): 675. https://doi.org/10.1038/414675a.

"California Legislature - AB-70 Gene Synthesis Providers." Accessed December 5, 2021. https://leginfo.legislature.ca.gov/faces/billStatusClient.xhtml?bill_id=202120220AB70.

Cello, Jeronimo, Aniko V. Paul, and Eckard Wimmer. "Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template." *Science* 297, no. 5583 (August 9, 2002): 1016–18. https://doi.org/10.1126/science.1072266.

Diggans, James, and Emily Leproust. "Next Steps for Access to Safe, Secure DNA Synthesis." *Front Bioeng Biotechnol* 7 (April 2019): 86.

Esvelt, Kevin M., Jacob C. Carlson, and David R. Liu. "A System for the Continuous Directed Evolution of Biomolecules." *Nature* 472, no. 7344 (April 2011): 499–503.

Esvelt, Kevin M., Andrea L. Smidler, Flaminia Catteruccia, and George M. Church. "Concerning RNA-Guided Gene Drives for the Alteration of Wild Populations." *eLife*, July 2014, e03401.

Gryphon Scientific. "Risk and Benefit Analysis of Gain of Function Research," April 2016. http://www.gryphonscientific.com/wp-content/uploads/2016/04/Risk-and-Benefit-Analysis-of-Gain-of-Function-Research-Final-Report.pdf.

Herfst, Sander, Eefje J. A. Schrauwen, Martin Linster, Salin Chutinimitkul, Emmie de Wit, Vincent J. Munster, Erin M. Sorrell, et al. "Airborne Transmission of Influenza A/H5N1 Virus between Ferrets." *Science* 336, no. 6088 (June 22, 2012): 1534–41. https://doi.org/10.1126/science.1213362.

Holmes, Edward C., Andrew Rambaut, and Kristian G. Andersen. "Pandemics: Spend on Surveillance, Not Prediction." *Nature* 558, no. 7709 (June 2018): 180–82. https://doi.org/10.1038/d41586-018-05373-w.

Hu, Ben, Lei-Ping Zeng, Xing-Lou Yang, Xing-Yi Ge, Wei Zhang, Bei Li, Jia-Zheng Xie, et al. "Discovery of a Rich Gene Pool of Bat SARS-Related Coronaviruses Provides New Insights into the Origin of SARS Coronavirus." *PLoS Pathogens* 13, no. 11 (November 2017): e1006698. https://doi.org/10.1371/journal.ppat.1006698.

Imai, Masaki, Tokiko Watanabe, Masato Hatta, Subash C. Das, Makoto Ozawa, Kyoko Shinya, Gongxun Zhong, et al. "Experimental Adaptation of an Influenza H5 HA Confers Respiratory Droplet Transmission to a Reassortant H5 HA/H1N1 Virus in Ferrets." *Nature* 486, no. 7403 (May 2, 2012): 420–28. https://doi.org/10.1038/nature10831.

Inglesby, Thomas V., and David A. Relman. "How Likely Is It That Biological Agents Will Be Used Deliberately to Cause Widespread Harm? Policymakers and Scientists Need to Take Seriously the Possibility That Potential Pandemic Pathogens Will Be Misused." *EMBO Reports* 17, no. 2 (February 2016): 127–30. https://doi.org/10.15252/embr.201541674.

International Gene Synthesis Consortium. "Harmonized Screening Protocol V2," 2017. https://genesynthesisconsortium.org/wp-content/uploads/IGSCHarmonizedProtocol11-21-17.pdf.

Kaczynski, T. "The Unabomber Manifesto: Industrial Society and Its Future." *The Washington Post*, September 19, 1995. https://scholar.google.ca/scholar?cluster=16262823500107443 2&hl=en&as_sdt=0,5&sciodt=0,5.

Katz, Rebecca, Ellie Graeden, Keishi Abe, Aurelia Attal-Juncqua, Matthew R. Boyce, and Stephanie Eaneff. "Mapping Stakeholders and Policies in Response to Deliberate Biological Events." *Heliyon* 4, no. 12 (December 2018): e01091. https://doi.org/10.1016/j.heliyon.2018.e01091.

Klotz, Lynn C., and Edward J. Sylvester. "The Consequences of a Lab Escape of a Potential Pandemic Pathogen." *Frontiers in Public Health* 2 (August 11, 2014): 116. https://doi.org/10.3389/fpubh.2014.00116.

Levy, L., and A. Smithson. "Ataxia: The Chemical and Biological Terrorism Threat and the US Response," October 9, 2000. https://www.stimson.org/2000/ataxia-chemical-and-biological-terrorism-threat-and-us-response/.

Lipsitch, Marc, and Thomas V. Inglesby. "Moratorium on Research Intended to Create Novel Potential Pandemic Pathogens." *mBio* 5, no. 6 (December 12, 2014). https://doi.org/10.1128/mBio.02366-14.

Manheim, David, and Gregory Lewis. "High-Risk Human-Caused Pathogen Exposure Events from 1975-2016." *F1000Research* 10, no. 752 (August 4, 2021): 752. https://doi.org/10.12688/f1000research.55114.1.

Merler, Stefano, Marco Ajelli, Laura Fumanelli, and Alessandro Vespignani. "Containing the Accidental Laboratory Escape of Potential Pandemic Influenza Viruses." *BMC Medicine* 11 (November 28, 2013): 252. https://doi.org/10.1186/1741-7015-11-252.

National Center for Science and Engineering Statistics. "Doctorate Recipients from U.S. Universities, 2019." Accessed September 6, 2021. https://ncses.nsf.gov/pubs/nsf21308/data-tables.

Noble, Charleston, John Min, Jason Olejarz, Joanna Buchthal, Alejandro Chavez, Andrea L. Smidler, Erika A. DeBenedictis, George M. Church, Martin A. Nowak, and Kevin M. Esvelt. "Daisy-Chain Gene Drives for the Alteration of Local Populations." *Proceedings of the National Academy of Sciences of the United States of America* 116, no. 17 (April 23, 2019): 8275–82. https://doi.org/10.1073/pnas.1716358116.

OECD. "OECD: Graduates by Field." Accessed January 19, 2021. https://stats.oecd.org/Index.aspx?DataSetCode=EDU_GRAD_FIELD.

"Opportunities Exist for the National Institutes of Health To Strengthen Controls in Place To Permit and Monitor Access to Its Sensitive Data." Accessed December 5, 2021. https://oig.hhs.gov/oas/reports/region18/181809350.asp.

Sandberg, Anders, and Cassidy Nelson. "Who Should We Fear More: Biohackers, Disgruntled Postdocs, or Bad Governments? A Simple Risk Chain Model of Biorisk." *Health Security* 18, no. 3 (June 10, 2020): 155–63. https://doi.org/10.1089/hs.2019.0115.

Saylors, Karen, David J. Wolking, Emily Hagan, Stephanie Martinez, Leilani Francisco, Jason Euren, Sarah H. Olson, et al. "Socializing One Health: An Innovative Strategy to Investigate Social and Behavioral Risks of Emerging Viral Threats." *One Health Outlook* 3, no. 1 (May 14, 2021): 11. https://doi.org/10.1186/s42522-021-00036-9.

Sewell, D. L. "Laboratory-Associated Infections and Biosafety." *Clinical Microbiology Reviews* 8, no. 3 (July 1995): 389–405. https://doi.org/10.1128/CMR.8.3.389.

"STOP Spillover." Accessed December 6, 2021. https://stopspillover.tufts.edu/.

"The Apollo Program for Biodefense - Winning the Race Against Biological Threats - Bipartisan Commission on Biodefense," January 13, 2021. https://biodefensecommission.org/reports/the-apollo-program-for-biodefense-winning-the-race-against-biological-threats/.

The Nucleic Acid Observatory Consortium. "A Global Nucleic Acid Observatory for Biodefense and Planetary Health." *arXiv [q-bio.GN] http://arxiv.org/abs/2108.02678*, August 5, 2021. arXiv. http://arxiv.org/abs/2108.02678.

The SecureDNA team. "Secure DNA Project - DNA Synthesis Screening." Accessed December 6, 2021. https://www.securedna.org/main-en.

Wikipedia contributors. "James Holmes (mass Murderer)." Wikipedia, The Free Encyclopedia, December 4, 2021. https://en.wikipedia.org/w/index.php?title=James_Holmes_(mass_murderer)&oldid=1058622750.

Wille, Michelle, Jemma L. Geoghegan, and Edward C. Holmes. "How Accurately Can We Assess Zoonotic Risk?" *PLoS Biology* 19, no. 4 (April 2021): e3001135. https://doi.org/10.1371/journal.pbio.3001135.

"WSU to Lead USAID's Global Sampling Project for Discovery of Emerging Viral Zoonoses - Global Biodefense," October 14, 2021. https://globalbiodefense.com/2021/10/14/wsu-to-lead-usaids-global-sampling-project-for-discovery-of-emerging-viral-zoonoses/.

Xie, Xuping, Kumari G. Lokugamage, Xianwen Zhang, Michelle N. Vu, Antonio E. Muruato, Vineet D. Menachery, and Pei-Yong Shi. "Engineering SARS-CoV-2 Using a Reverse Genetic System." *Nature Protocols* 16, no. 3 (March 2021): 1761–84. https://doi.org/10.1038/s41596-021-00491-8.

Mr. BERA. Thank you.

Let me now recognize my good friend, the ranking member, the gentleman from Ohio, Mr. Chabot, for 5 minutes of questioning.

Mr. CHABOT. Thank you very much, Mr. Chairman, and, again, thank you for holding this, what I think is a very, very important meeting, and I want to commend all of the witnesses for their testimony this morning.

Dr. Esvelt, I am going to turn to you if I can. Since the beginning of this pandemic, I think, to a considerable degree, the American public has been misinformed, kind of misled, first of all, obviously, by the PRC but to some degree, the coverage in the media as far as the relative likelihood that a lab leak actually caused this pandemic. So I have a few questions.

First of all, it is my understanding that lab leaks, even in this country but especially in other parts across the globe, are, you know, pretty safe, but that lab leaks do happen, in fact, much more often than the general public or the media seem to appreciate. Could you comment on that, and you know, how frequently do such lab leaks actually occur?

Mr. ESVELT. That is an excellent question, Ranking Member Chabot. There is well-documented evidence that hundreds of lab leaks, involving dangerous pathogens, occur around the world. This evidence is so substantial—of course, most of them do not involve potential pandemic viruses—but nevertheless we know that the risk is nontrivial.

To the extent that we add one more to the list, whether or not we can do so, doesn't change our assessment of the risk, which is that it is definitely nontrivial. I am not saying that some of these experiments cannot be performed safely in theory, but in practice, we are all human, and humans do make mistakes.

Mr. CHABOT. Thank you. Let me ask you specifically this. How many times, for example, was there a SARS leak in the PRC, in a lab in China?

Mr. ESVELT. There were two known occasions—at least two known occasions confirmed of leaks of SARS 1 after the initial outbreak. One of them actually did lead to a chain of transmission through people associated with the laboratory members that experienced the leak.

Mr. CHABOT. Thank you. And I think, you know, much of the world, unfortunately, is woefully behind in getting their healthcare systems up to the standards that are set by the international health regulations, and that is why I have been working very closely with my Democratic colleague, Gerry Connolly, on the Global Health Security Act.

We have been working on that now for a number of years, and I would want to add that it was somewhat prescient, and I want to say, particularly on Mr. Connolly's part, because we introduced this prior to COVID. It was almost a year prior to COVID that we introduced this legislation, and then the COVID came around, you know, was facing us around the corner.

So could you talk about, right now, even, you know, if our standards are very good here in the United States, if they are not up to par in other countries across the globe, how it can affect us here at home? And obviously COVID is the best example, but why

should we care? Why should we—for example, you know, we give assistance across the globe, with all kinds of recommendation how that assistance or requirements of how that assistance is utilized.

How do things across the globe, how can they affect us here at home? Why should we care about that?

Mr. ESVELT. Well, unfortunately, a leak of a pandemic-capable virus anywhere in the world will most certainly come to affect us here in the United States unless it can be contained elsewhere. And, as noted, many countries have much less sophisticated systems for detection and containment.

It is also certainly true that, even in the United States in well regarded labs, leaks do happen. So the risk is not zero anywhere in the world, and it is arguably more severe elsewhere for certain.

So I do not mean to say that we should not support other countries in monitoring the animal-human interface, as Dr. Adalja suggested, and in assisting them in detecting threats as early as possible and containing them before they get to American shores.

But supporting other nations in directly culturing these kinds of viruses in the lab does risk lab leaks. Or what is more, if we identify a pandemic-capable virus anywhere in the world and we publish it, then a malevolent actor, anywhere in the world, could assemble it using available published protocols and deliberately release it as a weapon of mass destruction.

So that kind of research, pandemic virus prediction, simply cannot be performed safely anywhere in the world.

Mr. CHABOT. Thank you very much, Doctor.

Mr. Chairman, my time is expired, and I yield back.

Mr. BERA. Great. Thank you.

Let me now recognize the gentlelady from Nevada, Ms. Titus, for 5 minutes.

Ms. TITUS. Thank you, Mr. Chairman, and thank our witnesses. I am glad that Dr. Esvelt made it back. I had a question for him. And I know he is an expert on this, and if we didn't know it from his resume, we could tell it from the white board behind him. It is very impressive.

We have talked a lot about what happens in the lab, but I would like to extend that and talk about the relationship between biosecurity and climate change. Climate change leads to demographic changes. People move, animals move, the weather changes, patterns that affect growth of crops.

All of those things seem to be related in some way to biosecurity, and I wonder if you could address that relationship and how we might look at this bigger picture, not just the labs.

Mr. ESVELT. Thank you, Congresswoman. So the idea you have so well articulated is often called One Health, and the idea is that the health of animals and the environment and people is all connected, most obviously because viruses and other pathogens can spread between animals and people. And, as we have seen with SARS 2, that can even occur back, and possibly back and forth. We are not certain.

So monitoring the health of the environment and animals and detecting animal outbreaks could potentially allow us to anticipate threats to humans. Whether the risk of natural pandemics resulting from spillover from animals to humans is greater now than be-

fore is—has been advanced as a hypothesis. There isn't a lot of data to support that one way or another.

To the extent that we are forcing wild animals into contact with humans as we advance into the environment, that should increase the risk.

On the other hand, more people now live in cities than before, which might imply fewer people in direct contact with those animals.

But it is certainly true that the impacts on the environment can come back to affect our health in direct ways. So I fully support the sorts of monitoring programs that examine the animal-human interface, as those really could detect nascent pandemics before they actually spread out of control.

That is very distinct from surveying for animal viruses, the vast majority of which will never actually come in contact with humans but, if identified, could be deliberately assembled and released as a weapon.

Ms. TITUS. Well, thank you for that answer. It kind of confirms what I just suspected on an informal level, and I would like it if we could look into that, Mr. Chairman, see if there is some way we can be supportive of that kind of research.

Thank you, Doctor.

I would ask Dr. Yassif, we have had different responses to the COVID. Different States have different degrees of prevention or cure. Different countries have come on earlier, later.

Do you think it is better for us to have universal standards that everybody follows so we are all on the same page, or is it better to respond individually with circumstances that differ how we can meet those as opposed to being bound by one set of rules?

Dr. YASSIF. Well, thank you so much for that really important and timely question. I think the challenge of finding a way for every country to lead its own pandemic responses and mitigation efforts while having an integrated global response is not trivial, but it is important to get it right.

I think the short answer is it is sort of a balance between the two sort of poles that you are talking about. One is having a shared global standard while still allowing countries the flexibility to respond, as appropriate, based on their needs and capabilities. And I think this has got a few pieces.

So, first, I think at the international level what we really need is a more integrated and effective early warning system associated with the WHO sort of alert and warning system, the Public Health Emergency of International Concern declaration.

That needs to be strengthened, and we at NTI have recommended that it shift from a binary sort of yes/no signal to something that is more—to something that has multiple grades so that it provides information to countries about how bad an emerging pandemic risk might be.

So we just need to strengthen that system so countries have better sense of what the risk is over the horizon even, perhaps, before it might have materialized. And I think to make that really—you can think about the early stages of COVID, perhaps in February and March 2020, when we saw it start to break out in certain parts of the world, but we weren't really sure how serious it was. And

we need to really do better in terms of early intelligence—epidemic intelligence in sort of thinking about the emerging risks of a new pandemic.

Second I would offer is that countries—you know, I think the shared approach that countries should offer is proactive response, that is, you know, triggered early response to emerging pandemics, not wait for mounting case counts and fatality because then it is too late.

But, fundamentally, countries around the world have different populations and different capabilities, and so they will have to have flexibility within that system to respond effectively. Thank you.

Ms. TITUS. Thank you.

I yield back, Mr. Chairman. Thank you.

Mr. BERA. Great. Thank you. Let me now recognize the gentlelady from Pennsylvania, Ms. Houlahan, for 5 minutes of questioning.

Ms. HOULAHAN. Hi all, and thank you so much for the conversation. It has been riveting and terrifying all at the same time. And I have been trying to compose my questions, and I have so many of them and no real good way to articulate them into one cogent question.

Dr. Esvelt, I think your testimony was perhaps the most devastating, and so, at the same time, I hear optimism coming that we will be able to manage and control future pandemics, but I am concerned and confused where the advice is, you know, basically, not to make it too exaggerated, but we should stick our heads in the collective sand and not look up or around because of the implications that bad actors would have if we were to be able to understand what the threats are.

So I also look at the response that the Nation took and the world has taken to COVID–19—and this has something to do with Representative Titus' line of questions—which is, we have done horribly as a collective in terms of managing what happened with COVID–19.

And even had we had advance warning and a couple weeks of warning, I am not certain that we would end up in much of a different place than we are. And so here we are, optimism coming from you all and advice to, you know, not look around, but we really have mismanaged this one.

How can we possibly do this better, and what is your prescription for the average person, citizen, to be able to prevent this from happening and for it to, you know—I am just trying to figure out, like, what do we do to prevent another pandemic from happening if we are not going to look around and understand what it is, if we are not going to develop cures or techniques to address those issues, and if we have got a population that is uncompliant? And I would love to turn that over to my fellow MIT person, Dr. Esvelt.

Mr. ESVELT. Thank you for that very difficult question. So I think, to be blunt, we are in a very bad place, and even with very substantial investments, we will still struggle against a truly nasty pandemic.

In my assessment, something deliberate could be much worse than anything that is natural, simply because something that is natural is a single point of spillover and involves a single virus,

where something deliberate could be multiple points in travel hubs with multiple viruses. So that is why I say deliberate would be worse.

Also, engineered would be worse, but that is something that I really would prefer that we not discuss today.

If we want to be actually immune to future pandemics, as The Honorable Andy Weber has indicated, I think we need early warning, metagenomic sequencing systems, especially in travel hubs, so we know what it is.

Once we know what it is, then we can figure out where it is with diagnostics.

But then we need to ensure that food distribution, water distribution, and power all stay on, healthcare remains operational in the teeth of a 30 percent-plus lethality pandemic.

And I think that can only be done by investing in new personal protective equipment. Make it comfortable, as good as a powered air purifying respirator today. And it needs to be reliable enough that all essential workers can be confident going out there in that kind of a pandemic and keeping our civilization intact.

If we do that, then I think we will be resistant to just about any kind of pandemic. I am not confident in our ability to reliably come up with vaccines or any kind of countermeasure against every kind of threat.

Note that we still do not have an HIV vaccine. Note how long it took us to get Paxlovid, although I would love to see that approved immediately. These things are amazing when you can get them, but we should not assume they are possible.

Whereas gear that can prevent Americans from getting infected in the first place, that will always work. And I am not saying stick our heads in the sand on this. I am saying build a network to ensure that whatever it is, we can see it when it comes. But that the vast majority of pandemic-capable viruses out there, whether they are in nature or whether they do not exist yet and scientists are trying to evolve them, the vast majority of those would never hit us anyway.

Even if we had advance warning of a particular one, mRNA vaccine design can be done in a day now. So, if we can get a virus, we are going to have it almost immediately. And so advance knowledge of a particular virus out there that is going to come and bite us actually doesn't save us any time, as long as we are willing to combine Phase 1 and Phase 2 trials, which I would like to think we would certainly do in a pandemic.

So that is why I say I do not think knowing a particular virus as a threat is going to help us respond, and I also do not think we are really going to invest the kind of money needed to develop vaccines for what are probably hundreds of existing pandemic-capable viruses out there in nature. That just doesn't seem practical to me.

So I would prefer to work on preparedness plans that would work for everything across the board.

Ms. HOULAHAN. And so these detection systems that you are talking about that are at airports, et cetera, I am assuming that these are some sort of passive detection systems, that they do not require anybody participating in them in any way, shape, or form?

And, you know, help me understand as a layperson, how would a passive detection system, where you do not have a cataloguing of what it is that you are looking for, do you even know that you have seen something? If that makes any sense.

Mr. ESVELT. That is a great question, and briefly, the answer is, any serious biological threat must be growing exponentially. So, if we sequence all the nucleic acids out there, all of the RNA and DNA, because viruses can come in either form, and we just look for the sequence fragments that are growing rapidly in abundance, that is a biological threat. And every biological threat will display that signature. And we think that by looking for it, we can reliably find anything of that variety.

So that is when I say, even if an adversary designs something to be undetectable by targeted probes, looking for the kinds of viruses we know are threats, we will still be able to detect it using metagenomic sequencing in that way.

Ms. HOULAHAN. Thank you, Doctor.

Is my time out?

Mr. BERA. The gentlelady's time has expired.

Ms. HOULAHAN. Thank you, Mr. Chair.

Mr. BERA. Let me go ahead and recognize the gentleman from California, Mr. Lieu, for 5 minutes of questioning.

Mr. LIEU. Thank you, Chair Bera, for holding this important hearing.

My first question goes to Dr. Adalja. I saw that in your biography, you previously worked on the anthrax issue.

I note that I was vaccinated for anthrax when I served on Active Duty in the military. I served overseas, and my question to you is about vaccines. Would you agree with me that vaccines are one of the best ways to mitigate pandemics?

Dr. ADALJA. Thank you for that question. Yes. I think when it comes to any infectious disease, prevention is always better than treatment, especially if you have a safe and effective vaccine. So vaccines have to be a cornerstone of our medical countermeasure policy because that is what takes a threat off the table, that is what reduces severity from illness, and that ultimately is what we have to aim for by looking at what is out there in the threatscape that we know can cause infection and starting to work toward vaccines. Even if it may not be the exact vaccines that is used during an epidemic or a pandemic, making those steps down the road will get us a much faster response. The work that people did on the first SARS and Middle East Respiratory Syndrome, MERS, made it much easier to develop a vaccine for SARS-CoV–2 because they already knew, for example, that the spike protein was an important target for immunity.

So, yes, vaccines are always going to be one of the cornerstones for medical countermeasures.

Mr. LIEU. And it also turns out that our immune system is pretty smart. So, when we put vaccines in and train our immune system, even with the variants, our immune system still sort of figures it out, that, oh, maybe, this is something we need to take care of. So, while the vaccines may not be a hundred percent effective, they are still somewhat effective at making the immune system better against even a variants. Isn't that correct?

Dr. ADALJA. Right. If you have an effective vaccine, it is very hard for a variant or a mutation to erase all the protection the vaccine gives you. Vaccines are not all or none. It is not an on-or-off switch. It is a spectrum of protection.

So, even if a vaccine may allow you to get infected, other arms of the immune system, other than the antibodies, may protect you against the severe consequences. So, even when you have a vaccine that is not 100 percent, that is not a magic bug zapper, you still get benefits from them, and they are beneficial.

This underscores what we do with the influenza vaccine every year. We know it is much more protective against severe disease than it is protection against mild disease, and that is also true for the COVID–19 vaccines.

Mr. LIEU. Thank you. This question is for Dr. Esvelt. You said something interesting about combining Phase 1 and Phase 2 trials. Can you explain the difference between Phase 1 and Phase 2 trials for vaccine development?

Mr. ESVELT. Thank you, Representative. Yes. A Phase 1 trial normally seeks to establish the safe dosage and doesn't try to figure out whether or not a vaccine actually is effective against the given pathogen.

Phase 2 is when we give it to enough people, some of whom we know will become infected, that we will be able to tell how effective the vaccine actually is.

So, when I suggest combining Phase 1 and Phase 2, if there is a pandemic there is very high lethality, much higher than SARS 2, then, in all likelihood, we would want to get shots into arms sooner rather than later, if necessary, trying multiple different doses of the same vaccine in different cohorts.

Honestly, if we are serious about it, we would actually run challenge trials in which we take volunteer cohorts, guarantee them the best medical care and deliberately infect them, some of whom would have vaccinated with different vaccines in different amounts.

Mr. LIEU. In a high-lethality pandemic, would the FDA have authority to do this, or would there need to be a change to a law for them to combine the trials and speed things up?

Mr. ESVELT. That is an excellent question. I am afraid I do not know. I suspect Dr. Adalja may know.

Mr. LIEU. Does anyone on the panel know?

Dr. ADALJA. If I can, sir, I do think that this is something that has been—that is in the public health authority laws of the FDA. I do not know that for sure, but I do think there has been a lot of discussion about running Phase 1 and Phase 2 simultaneously. And I think that there is not any obstacle to doing so, and it would be necessary during a pandemic to get the vaccine as quickly as possible to meet these hundred-day goals that we hear talked about.

Mr. LIEU. Thank you.

And now let me speak to my Republican colleagues across the aisle. We need your help to counter vaccine disinformation. As you have just heard, vaccines are one of the most effective ways to mitigate a pandemic, and yet we have lots of folks believing that these vaccines have microchips in them or that they cause autism or that

they are going to give you COVID or other crazy things, and all of that is false.

And so we simply need Republican colleagues to step up and, when they go on Fox News, just push back on their hosts who are saying crazy stuff about these vaccines because that is how we can beat this pandemic by getting as many people vaccinated as quickly as possible.

With that, I yield back.

Mr. BERA. Great. Thank you.

Let me now recognize the gentlelady from Virginia, Ms. Spanberger, for 5 minutes of questioning.

Ms. SPANBERGER. Thank you very much, Mr. Chairman, and to our witnesses today, thank you so much for being here. This has been extraordinarily interesting, frightening, but I believe that the way that we prepare ourselves for the threats that exist is by facing them head on. So I truly appreciate your honest assessments and the information you shared.

I also am thankful that the chair and the ranking member included the term "deterrence" in the title of today's hearing, because, you know, frankly the best defense against future biothreats is our ability to quickly mitigate the spread of them and the effects of any biological agent.

And a critical part of any biosecurity deterrence strategy is ensure that the United States has the manufacturing capacity to quickly ramp up our production, if necessary, medical countermeasures in the event of an emergency.

And I am sure all of our witnesses know, active pharmaceutical ingredients are the base ingredients for producing essential generic medicines, but, unfortunately, 87 percent of facilities that produce APIs are overseas.

Our healthcare system suffers routine shortages, even outside of emergencies, and our reliance on foreign suppliers really jeopardizes our ability to keep Americans healthy.

For example, the U.S. has lost the capacity to produce penicillin here at home. That should be kind of a flashing warning sign to those who are focused on how prepared we may be into the future to ultimately deter or respond to future biosecurity threats or even supply chain challenges.

I introduced a bill called the PREPARE Act. It is a bipartisan piece of legislation to identify the essential generic medicines that are necessary for us to have, as a Nation, available at all times and to authorize the creation of a stockpile of active pharmaceutical ingredients so that we can ensure that our pharmaceutical supply chain is always able to produce the essential medicines that we need in the event of an emergency.

Certainly my district in central Virginia is leading the way in ensuring robust domestic supply of essential medicines, which is why I am so focused on this issue.

The bipartisan PREPARE Act would provide statutory authorization for this important Federal effort and would create thousands of well-paid jobs, improve patients' access to medicines, and bolster our national biosecurity.

And all of this kind of preface leads me to my question. Either for Mr. Weber or for Dr. Adalja, how does strengthening the domes-

tic production capacity of essential medicines and other medical countermeasures improve our Nation's ability to deter biosecurity threats?

Again, assuming you agree with that assertion, if you could comment on that.

Mr. WEBER. Yes, yes, thank you for your leadership in this area. It is very important, and I will just give you one example. Smallpox. We vaccinate our forces against smallpox. We have a stockpile of enough for every American in our Strategic National Stockpile, and I think just that fact is deterrence.

It tells our adversaries that smallpox would not be successful as a weapon against the United States and its citizens.

So that kind of preparedness deterrence, by having those capacities to respond, I think, are key. And onshoring those capabilities here in the United States to surge and rapidly manufacture all of these medical countermeasures is vital to not just public health but to U.S. national security.

Ms. SPANBERGER. Thank you, Mr. Weber.

Dr. Adalja, would you add anything to that?

Dr. ADALJA. I completely agree. I liken medical countermeasures to almost an anti-ballistic missile defense system, that the more prepared we are for these threats, natural or deliberate, the less likely they are to be used. And I think the smallpox example is a great one, and I think—and I applaud your leadership on the PREPARE Act because I have worked on this issue in the past, where we know that there are many active pharmaceutical ingredients that all trace back to one place. And, if there is a supply chain disruption, it becomes really disastrous.

And I think we need a lot more redundancy when it comes to certain medical countermeasures that should be thought of as part of national security.

Ms. SPANBERGER. So, Dr. Adalja, just following up briefly on that point, you know, the World Health Organization maintains the list of essential medicines since I guess at least 2007, but only in 2020 did FDA publish its first list of essential medicines.

As new pathogens and biothreats emerge, how can the government identify the essential medicines and medical countermeasures for the threats that exist, that we, as a Nation, will want to have to protect our people and our servicemembers?

Dr. ADALJA. It will have to have a lot of clinical read-in to what is actually effective, what drugs are being used, which ones are in trials, which ones are promising but not yet approved.

All of those should be on the radar of people that are trying to figure out how to augment the Strategic National Stockpile and how to think about what needs to have redundancy in supply chains.

Ms. SPANBERGER. Excellent.

Mr. Chairman, I yield back.

Again, to our witnesses, thank you so much for your time today. It is extraordinarily helpful as we think about what Congress' role should be in making sure we are protecting our people.

Mr. BERA. Great. Thank you.

Let me now recognize the gentlelady from North Carolina, Ms. Manning, for 5 minutes of questioning.

Ms. MANNING. Thank you, Mr. Chair, and thank you to our witnesses for being with us today on this important topic.

Mr. Weber, I am interested in what you started talking about at the beginning of your testimony about the strategy of deterrence of denial.

And I am wondering what exactly that would have meant, how could it have been used to prevent COVID from becoming international? What systems did we not have in place, and why?

Mr. WEBER. Well, we didn't have a system of early warning rapid detection—a global system. This pandemic could have been stopped in its tracks in China if they had had a robust system of early warning.

And then the other part is rapid diagnostics, testing, and contact tracing, and then countermeasures like platform—programmable platforms like the mRNA vaccine. If we could have had that not in 10 months but in a hundred days or even less, that would give us tools to respond to any biological threat, whether it is engineered as a biological weapon or naturally occurring.

So it is that system; it is all about time, time to detect, to know there is a problem, and then to isolate it and have those rapid countermeasures available so we can prevent them from spreading from the source to different places around the world.

Ms. MANNING. So would that have required cooperation or first steps by the Chinese, or could we have had people in place who could have instigated that kind of a deterrence-by-denial system?

Mr. WEBER. Well, the deterrence-by-denial strategy that I laid out is primarily to prevent the deliberate use of biological weapons against the United States, its partners, and its allies around the world.

Pandemic prevention is a subset of that, I believe, and yes, we could have had in place a system of information-sharing and metagenomic testing that would have given the Chinese a better capability and prepared us better for a possible spread to this country. But we didn't have——

Ms. MANNING. I am sorry. We didn't have?

Mr. WEBER. We didn't have those systems in place.

And it is going to require a sustained investment. I do not want to say this is going to be easy.

[inaudible.]

Ms. MANNING. OK. All right. Thank you.

Mr. Adalja, I appreciated your answer to Mr. Lieu that vaccines are a critically important first line of defense against a pandemic, and I certainly echo Mr. Lieu's comments to our colleagues, because we have seen an almost unimaginable level of vaccine hesitancy and an anti-vax movement that has dramatically harmed our effort to prevent the spread of COVID.

I would like your thoughts, Dr. Adalja, about what steps we could take to get ahead of this problem the next time around, and by "this problem," I mean vaccine hesitancy or an anti-vax movement.

How can we develop our population in a way that the people are not just willing but anxious to get vaccinated to prevent the spread of a future pandemic?

Dr. ADALJA. Thank you for that question. I think this is one of the most important aspects of the pandemic that we did to think about and reflect on to get us prepared for the next pandemic, because vaccine hesitancy is a major threat.

No one imagined that we would, in the United States, still be facing the onslaught of this pandemic, not because we didn't have a vaccine but because people chose not to take the vaccine.

And I think that this self-inflicted wound is really something that is going to make us all think about how to make us—how we make ourselves more resilient, even if we have these great tools, if no one wants to utilize them.

So I think that we, as a medical community, and I am an infectious disease physician, have to be very proactive. The vaccine hesitancy movement has been something that has been coming at us for some time, basically since the dawn of vaccines.

But, with measles, mumps, rubella, with Gardasil, they continually meet each new vaccine with misinformation, and I think we have to really call it out as something that takes lives, and we can't be passive and try and debunk them only after they bring these things up.

We have to have a tool kit to talk to people, to train physicians, train healthcare providers to be able to almost vaccinate people against the anti-vaccine movement by showing them how to think about this data and allowing them to really actually just open their eyes and see the benefits of vaccines, the fact that decades have been added to all of our lives because of vaccines, hundreds of thousands of lives saved.

And to me it is mind-boggling, and it is frustrating. It is almost as if it is the voice of the Dark Ages that has gained access to internet technology and has allowed itself to spread so much bad information out there.

But this is—I do not think it is going to be one single solution. It really has to be the whole healthcare community, the whole medical community, scientific community, as well as policymakers that call this out for dangerous it is and take the fight to them, instead of being merely reactive.

Ms. MANNING. Thank you.

My time has expired. I yield back.

Mr. BERA. Great. Thank you. Let me recognize the gentlelady from Missouri, Mrs. Wagner, for 5 minutes of questioning.

Mrs. WAGNER. I thank the chair very much, and I think our witnesses for their time today.

The COVID–19 pandemic has caused immense suffering, and we grieve the millions of victims who have lost their lives.

As we continue to combat COVID–19, we must acknowledge that, right from the outset of this devastating crisis, the Chinese Communist Party, the CCP, suppressed, misrepresented, and falsified information necessary to prevent a pandemic in clear violation of the international health regulations.

Holding the CCP accountable is the only way to deter the release of another deadly virus on the global community in the future and ensure that the Communist Party stops violating international laws.

That is why I introduced the Compensation for Americans Act, which will establish a compensation fund for those affected and allow the President to freeze Chinese assets to bring the Communist Party to the negotiating table and give the United States a comprehensive toolbox of punitive measures to further incentivize China's cooperation.

However, the United States must also lead efforts to reform the international organizations and laws governing pandemic prevention and response to ensure there are real consequences for putting all nations at risk of a deadly outbreak.

The United States alone cannot prevent the next pandemic. Every member of the international community must honor their legal obligations to defend against emerging biothreats.

And the World Health Organization's failure to combat China's coronavirus-related misinformation campaign in the early days of the pandemic cost the international community precious time it needed to avert a crisis.

And the WHO remains a deeply flawed institution and is highly susceptible to China's malign influence.

Assist Secretary Weber, what reforms to the WHO are needed to prevent authoritarian States like China from co-opting global health policy to serve their interests? What leverage, I would say, does the United States have to secure these badly needed reforms?

Mr. WEBER. Well, I think the first thing that was unfortunate was several years ago we pulled out of the WHO and lost our influence there.

It is great that the United States is back at the table and using our influence, but we need to strengthen the international health regulations.

We need to support this new pandemic treaty initiative that will close some of the gaps that exist in the IHRs, and we need to make this a priority.

But it should be in the interest of all nations to work together against what is clearly a global and increasing threat of pandemics and biological weapons.

And I think it is very important that this hearing is being held by the House Foreign Affairs Committee, because it is a global problem, and there is no, you know, single-nation solution to it.

We have to work with partners around the world, even difficult partners, if we are going to get ahead of this problem.

Mrs. WAGNER. Dr. Esvelt, the State Department's 2021 arms control report States that the People's Republic of China has been, quote, engaged in activities with dual-use applications and that the U.S. does not have sufficient information to determine whether China eliminated its biological weapons program.

Can you tell me what type of dual-use activities are scientists in the PRC engaged in, and do you believe the PRC is complying with its obligations under the Biological Weapons Convention? Dr. Esvelt?

Mr. ESVELT. Thank you for the questions. The scientists in China, like those elsewhere in the world, have definitely been attempting to identify pandemic-capable pathogens.

They have, additionally, in pursuit of that goal, been exploring whether combinations of potentially risky viruses are more infectious and more transmissible than the natural wild versions.

Whether that is a violation of the Biological Weapons Convention is very much a legal and international question. If it is, then many nations would need to change their behavior on this.

But whether or not it is true, pandemic virus prediction definitely contributes to proliferation of weapons of mass destruction and undermines our national security.

Mrs. WAGNER. I am very concerned about these dual-use applications.

My time has expired. I would like to explore this further, and I thank the chairman for this very important hearing. Thank you.

Mr. BERA. Great. Thank you. I am going to take chairman's prerogative, if I can, and ask an additional question. And I am told Mr. Levin may be joining us shortly.

You know, we talked a little bit about countermeasures as one of our best strategies for deterrence. I think it is quite remarkable that we were able to come up with a vaccine within 10 months' time.

I have heard several of you suggest that if we can narrow that down to a hundred days, that would—obviously the shortest possible time. My sense is, with the mRNA technology, we can achieve that hundred-day goal. Is that the right target at this point that we should be thinking about, Dr. Adalja, or any of the witnesses?

Dr. ADALJA. Thanks for that question. I think 100 days is what has been articulated, and I think that is something to aim for. Whether it is a hundred days or 180 days or 150 days I think doesn't matter so much. The point is that we have the technology to speed vaccine development, and even just a week faster would have saved lives in the United States, for example, if the Pfizer vaccine was available a week later.

So we do have to be much more innovative harnessing these vaccine technologies at the same time, but we also have to be cognizant of the fact that the vaccine hesitancy movement is going to say this happened even faster, and that may end up becoming a problem.

But I do think that it is not a scientific problem now to get vaccines faster, and I think we have to really incentivize companies to move quickly and rapidly characterize these threats and develop vaccines, and I think it can be done.

Mr. BERA. So the scientific component of it might be easiest component, looking at the regulatory process of having Phase 1 and Phase 2 trials ready to go in a pandemic, and then obviously the faster they are, how we market those vaccines and address the hesitancy.

I have got one last question, then I will turn it back over to Mr. Levin and recognize Mr. Levin.

We have also talked about surveillance a little bit. Something I have explored and talked to some of our technology companies is how we use technology, you know, search terms, et cetera, as a form of surveillance.

And, you know, I would be curious if, you know, any of the experts that we have on as witnesses have any thoughts on that. You

know, if all of a sudden a certain area people are searching "fever," searching particular search terms, is that an area that we should explore in terms of biosurveillance, how we work with the tech sector? Maybe Dr. Yassif.

Dr. YASSIF. Thank you, Chairman Bera. I really appreciate that question. I do think that we need to think creatively about using all the different and emerging new technologies that are at our disposal to take creative approaches to biosurveillance.

So the kind of Google search and base strategy that you are describing is something that, you know, Google and others have tried to do in the past I think with some success, but you know, in some ways, mixed results.

But I think over time we are seeing more and more different types of data streams come online that we could think about integrating into a 21st century strategy for biosurveillance.

And I think that could be really useful for early detection of emerging infectious disease outbreaks so that we can stop outbreaks at the source, which is critical as the other witnesses have shared.

And it may also perhaps yield other types of information that could help us more reliably attribute the source of outbreaks in the event that we are not sure if they were natural or not, and we are thinking about that in the context of our joint assessment mechanism that I discussed in my testimony.

And, if I may, I just wanted to offer one more thought about the role of vaccines and the other capabilities for ensuring that the United States and the globe can respond effectively to pandemics.

And I absolutely agree with all the comments that have been made about the critical importance of vaccines and the critical importance of platform technologies and that the most robust thing we can do is to be prepared to be surprised and that we shouldn't assume that we will know in advance where the next pandemic threat will emerge from, and we absolutely need to have a flexible and adaptable response, and it has to be quick. I could not agree more.

But I would also offer that we need nonpharmaceutical interventions in the interim. So, when we saw with COVID it took us well over a year and actually quite a lot longer to have a vaccine that was developed, tested, and ready to go. And we should absolutely accelerate those timelines. I think that is a high priority.

But we need to acknowledge that there is going to be a lag time, and in that interim, the virus will spread, and lives will be lost, and economies will be damaged.

And social distancing and nonpharmaceutical interventions can be incredibly valuable for slowing the chains of transmission and saving lives during a public health emergency of international concern.

And we shouldn't be winging it during a pandemic. We should have plans in place. We should have—national governments around the world should have response plans in place for a high-consequence biological event where you are triggering proactive early response that incorporates these kinds of provisions for national and global response in addition to all the other important

medical countermeasures and other provisions that we have been discussing. Thank you.

Mr. BERA. Great. Thank you.

Let me now recognize the gentleman from Michigan, Mr. Levin, for 5 minutes of questioning.

Mr. LEVIN. Thank you so much, Chairman Bera, for holding this really important hearing and for your leadership on these issues.

I want to talk about arms control and its relationship with biothreats.

You know, the COVID pandemic has made the importance of international cooperation in the face of emerging biothreats abundantly clear, and it appears that all the witnesses before the subcommittee today would agree that we have to improve international cooperation among national governments and international organizations on biosecurity issues if we hope to prevent more severe threats in the future.

Despite the U.S. and Russia being in communication on arms control, which is certainly an improvement from the last 4 years, it is my sense that real progress toward another major arms control agreement is stalled.

So I am curious whether you think that investing in international cooperation and negotiations with other governments on biosecurity would also yield benefits for broader arms control efforts.

For instance, could the U.S. leverage cooperation on biosecurity as we seek to address the arsenals of other nuclear powers?

Now, Mr. Weber, you Stated in your testimony that we could more effectively deter the use of bioweapons if U.S. policy were explicitly to State that U.S. nuclear weapons' sole purpose was to deter the use of nuclear weapons.

Why is the threat of nuclear use not credible in deterring biological attacks? Could you explain that?

Mr. WEBER. Yes. And I certainly support what Candidate Biden said, that we should adopt a sole-purpose strategy, that nuclear weapons are for deterring nuclear weapons.

Traditionally, we have included biothreats, Big Cyber threats, chemical threats, as something that we think that nuclear weapons are useful in deterring. But the truth is they are just not credible. No nation thinks that we would actually use nuclear weapons in response to a biological attack. They are not credible.

And that is why we are favoring a deterrence-by-denial strategy by having such good early warning and defenses against infectious disease—afterall, biological weapons are infectious disease—that our adversaries will decide that it is not worth pursuing biological weapons because they won't be very effective.

So that is the approach that we are recommending, is investing in our biodefenses to make these threats obsolete as weapons of mass destruction.

And we also need to support the efforts to strengthen the Biological and Toxin Weapons Convention, which bans biological weapons. These activities that are happening in North Korea and Russia are already prohibited by the international community, and we need to work harder to find mechanisms to strengthen that international

convention against the development and stockpiling of biological weapons.

Mr. LEVIN. All right. Well, thanks, and hopefully we can, you know, in tandem, improve our, you know, cooperation on biological weapons with a revamped effort on arms control in terms of nuclear weapons.

Now, COVID–19 has proved that we can't prevent future pandemics alone. It has just blown up the idea of a go-alone strategy on foreign policy generally and that expanding health capabilities around the globe requires sharing financial resources and making strategic investments.

I understand that Dr. Yassif, in her testimony, has recommended that the United States invest in a new multilateral financing mechanism for pandemic preparedness that would incentivize other governments to invest in their own readiness to respond to future pandemics.

And you were just touching on this, so Dr. Yassif, how can we ensure that U.S. investments in international pandemic preparedness efforts are targeted effectively?

Dr. YASSIF. Well, thank you, Representative. The issue of financing is absolutely critically important, and thank you for raising the multilateral pandemic preparedness financing mechanism that we have been advocating for.

And I would also thank the House for being so proactive and forward leaning on this issue. We are hoping that Congress can really advance this important initiative and get it across the finish line, understanding that it is currently the matter of active discussion.

And, you know, we are advocating for this financing mechanism because everything we have had in place so far hasn't worked. You know, we have seen a cycle of panic and neglect in the runup to COVID that has left us woefully unprepared and has really led the U.S., and the globe I think, to inadequately respond. And so we need a better approach.

We do not think the United States can or should do it alone. We absolutely think other governments should step up and put their money on the table and contribute to their own pandemic preparedness.

But absolutely it should be targeted, and it shouldn't just be based on the fashion of the day. We should move money to the most—to the places where it is most needed and where it can have the greatest impact on reducing global biological risks. You know, there are a number of tools at our disposal to figure out what that is.

I will share that today NTI, in partnership with the Johns Hopkins Center for Health Security, we released 2021 Global Health Security Index, which it has a lot of data about pandemic preparedness and biosecurity capabilities in countries around the world, including gaps and where there is room for improvement.

We put that forward as a tool to help funders within government and in the private sector to think about how they can most effectively invest their resources to target the areas that need the most investment.

As part of our financing mechanism, the other provision that we are thinking about is that countries should absolutely be part of

the discussion to think about what their own internal priorities should be and where they need the greatest investment to shore up their vulnerabilities.

So appreciate the question about targeted financing, I couldn't agree more, and fortunately we have at our disposal a number of tools that can help make that effective. Thank you.

Mr. LEVIN. Thanks. Well, Mr. Chairman, it looks like my time is expired, but I will just say, in closing, if I am not able to ask this as a further question, that, you know, clearly we need to—a multilateral financing mechanism like this would need to incentivize efforts to improve transparency and data-sharing and support countries in doing that as we prepare for future biosecurity threats because the kind of idea that South Africa and other countries did such a great job in sharing and then they seem to be penalized for it, you know, we have to figure out ways to get beyond that.

So thanks, Mr. Chairman. I appreciate it.

Mr. BERA. Thank you.

And, you know, I think, with that, we have asked all the questions. It doesn't look like the ranking member, Mr. Chabot, has a closing statement.

So I want to, you know, commend, you know, each of the witnesses for your testimony and look forward to working with the other members on this subcommittee, full committee, and Congress, to address some of the issues that were raised and again defeat COVID–19 but, at the same time, make sure we are prepared for the next pandemic or any other biothreats.

So, again, thank you for the testimony. It was timely.

And, with that, I will go ahead and bang the gavel, and the hearing is adjourned. Thank you.

[Whereupon, at 11:40 a.m., the subcommittee was adjourned.]

# APPENDIX

**SUBCOMMITTEE HEARING NOTICE**
**COMMITTEE ON FOREIGN AFFAIRS**
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515-6128

**Subcommittee on Asia, the Pacific, Central Asia, and Nonproliferation**

**Ami Bera (D-CA), Chair**

December 3, 2021

**TO: MEMBERS OF THE COMMITTEE ON FOREIGN AFFAIRS**

You are respectfully requested to attend an OPEN hearing of the Committee on Foreign Affairs, to be held virtually by the Subcommittee on Asia, the Pacific, Central Asia, and Nonproliferation via Cisco WebEx (and available by live webcast on the Committee website at https://foreignaffairs.house.gov/):

**DATE:** Wednesday, December 8, 2021

**TIME:** 10:00 a.m., EST

**SUBJECT:** Biosecurity for the Future: Strengthening Deterrence and Detection

**WITNESS:** The Honorable Andy Weber
Senior Fellow
Council on Strategic Risks

Jaime Yassif, Ph.D.
Senior Fellow
Global Biological Policy and Programs, Nuclear Threat Initiative

Amesh Adalja, Ph.D.
Senior Scholar
Center for Health Security, Johns Hopkins University Bloomberg School of Public Health

Kevin Esvelt, Ph.D.
Director
Sculpting Evolution Group, Massachusetts Institute of Technology

**By Direction of the Chair**

To fill out this form online: Either use the tab key to travel through each field or mouse click each line or within blue box. Type in information.

# COMMITTEE ON FOREIGN AFFAIRS

Note: Red boxes with red type will NOT print.

MINUTES OF SUBCOMMITTEE ON *Asia, the Pacific, Central Asia, and Nonproliferation* HEARING

**Day** *Wednesday* **Date** *December 8, 2021* **Room** *Cisco WebEx*

**Starting Time** *10:08 am* **Ending Time** *12:04 pm*

**Recesses** *0* (____to ____) (____to ____) (____to ____) (____to ____) (____to ____) (____to ____)

**Presiding Member(s)**

*Chairman Ami Bera*

*Check all of the following that apply:*

**Open Session** ☑
**Executive (closed) Session** ☐
**Televised** ☑

**Electronically Recorded (taped)** ☑
**Stenographic Record** ☑

To select a box, mouse click it, or tab to it and use the enter key to select. Another click on the same box will deselect it.

**TITLE OF HEARING:**

*Biosecurity for the Future: Strengthening Deterrence and Detection*

**SUBCOMMITTEE MEMBERS PRESENT:**

*Chairman Bera, Ranking Member Chabot, Rep. Sherman, A. Levin, Connolly, A. Kim, Lieu, Spanberger, Manning, Perry, Wagner, Buck, Burchett, Barr, Y. Kim*

**NON-SUBCOMMITTEE MEMBERS PRESENT:** *(Mark with an * if they are not members of full committee.)*

**HEARING WITNESSES: Same as meeting notice attached? Yes** ☑ **No** ☐
*(If "no", please list below and include title, agency, department, or organization.)*

**STATEMENTS FOR THE RECORD:** *(List any statements submitted for the record.)*

***QFR - Young Kim***
***SFR - Connolly***

**TIME SCHEDULED TO RECONVENE** _____
**or**
**TIME ADJOURNED** *12:04pm*

Clear Form

Note: If listing additional witnesses not included on hearing notice, be sure to include title, agency, etc.

**Subcommittee Staff Associate**

WHEN COMPLETED: Please print for subcommittee staff director's signature and make at least one copy of the signed form. A signed copy is to be included with the hearing/markup transcript when ready for printing along with a copy of the final meeting notice (both will go into the appendix). The signed original, with a copy of the final meeting notice attached, goes to full committee. An electronic copy of this PDF file may be saved to your hearing folder, if desired.

**HOUSE COMMITTEE ON FOREIGN AFFAIRS**

*SUBCOMMITTEE ON ASIA, THE PACIFIC, CENTRAL ASIA, AND NONPROLIFERATION*

*ATTENDANCE*

| *PRESENT* | *MEMBER* |
|---|---|
| **X** | Ami Bera, CA |
| **X** | Brad Sherman, CA |
| | Dina Titus, NV |
| **X** | Andy Levin, MI |
| | Chrissy Houlahan, PA |
| **X** | Andy Kim, NJ |
| **X** | Gerald E. Connolly, VA |
| **X** | Ted Lieu, CA |
| **X** | Abigail Spanberger, VA |
| **X** | Kathy Manning, NC |

| *PRESENT* | *MEMBER* |
|---|---|
| **X** | Steve Chabot, OH |
| X | Scott Perry, PA |
| X | Ann Wagner, MO |
| X | Ken Buck, CO |
| X | Tim Burchett, TN |
| | Mark Green, TN |
| X | Andy Barr, KY |
| X | Young Kim, CA |

# STATEMENT FOR THE RECORD

**"Biosecurity for the Future: Strengthening Deterrence and Detection"**
**House Foreign Affairs Subcommittee on Asia, the Pacific, and Nonproliferation**
**Hearing**
**10:00 AM, December 8, 2021**
**Rep. Gerald E. Connolly (D-VA)**

Thank you, Chairman Bera and Ranking Member Chabot for calling this important hearing on biosecurity and how the United States can better address and detect risks to the lives and health of the American people.

In March 2020, when COVID-19 was declared a global pandemic, the United States was grievously underprepared to detect, prevent, and respond to a global pandemic. No further proof is needed than the 15,000 Virginians and 788,000 Americans that have sadly lost their lives to the virus.

While COVID-19 has assuredly led to the greatest biosecurity vulnerability in a century, our need to bolster our own deterrence and detection capabilities were known prior to the pandemic.

In 2001, a week after the 9/11 attacks, the United States was sent into a frenzy when letters containing anthrax were sent to U.S. Senators and members of the media, killing five people. For the first time, an intentional bioweapon was deployed in the United States right and it targeted this institution. The H1N1 flu that ignited an epidemic in 2009 luckily retained a less severe mortality rate in comparison to previous pandemic influenza.

In 2015, the Zika virus infected millions in the Western Hemisphere causing birth defects in thousands of children.

According to the World Health Organization (WHO) the Ebola epidemic was the "largest, most severe and most complex Ebola epidemic" in history, killing over 11,000 people and infecting thousands more.

COVID-19 was not the first biosecurity threat the United States has faced and it most certainly will not be the last.

In October 2015, the Bipartisan Commission on Biodefense published a report, "A National Blueprint for Biodefense" which laid out 33 recommendations to prepare for biological attacks and vulnerabilities. We did not listen then, but we must listen now.

What was required after anthrax, H1N1, Zika, Ebola, and is now required amidst COVID-19 is for our government to take a step back and reassess how the United States can deter the use and propagation of bioweapons and detect and prevent highly infectious diseases before they reach widespread contagion.

First, the United States must establish and fund a unified public health and biosecurity infrastructure to forestall the next pandemic.

We cannot irregularly fund disjointed preparedness efforts across myriad agencies and institutions with the expectation that those entities will seamlessly work together without miscommunication or confusion. Though these institutions and agencies are filled with some of the brightest and most dedicated public servants and scientists our country has to offer, the structure of our pandemic response disincentivizes thorough communication, information sharing, adequate systems for surveillance, and international exchange of information.

This was why in 2018, with Ranking Member Chabot, I introduced the Global Health Security Act (H.R. 391), to create a U.S. Coordinator for Global Health Security in the National Security Council, where the Executive Branch can coordinate the interagency response with a unified and authoritative voice at the highest level of government.

We have since worked in a bipartisan basis to incorporate lessons learned from the pandemic and expand the scope of the bill to include a more robust interagency process and whole-of-government global health security strategy as well as establish a multilateral fund for global health security as envisioned by the Administration's pandemic response plan.

The Global Health Security Act was reported out of this Committee on a voice vote, it passed the House on suspension, and was included in the House-passed FY2022 National Defense Authorization Act with broad bipartisan support. However, one Senator was able to object to the provision and have it excluded from the recently released NDAA Conference Report. This was done despite the willingness on the part of the House to accept an extraordinary number of Senate provisions into the NDAA text in order to reach a compromise on this urgent priority. It my hope this Committee will continue to work to insist on Congressional action on this global health security legislation.

Second, the United States cannot improve its biosecurity preparedness if it acts alone. Constructive engagement with the WHO, the Pan American Health Organization, and the Global Health Security Agenda offer pragmatic opportunities to strengthen detection and prevention efforts worldwide. By including technology-sharing, scientific exchanges, and regular communication in this framework, governments and institutions can prepare in advance for a wide range of possible biosecurity threats.

We must work with our allies and partners at the United Nations to revamp the Biological Weapons Convention to include updated language that includes the challenges of today. This includes addressing threats related to the proliferation of potentially dangerous bioweapons to non-state actors. It is of the utmost importance that the United States engage its allies and adversaries to stop certain biotechnology from falling into the wrong hands.

Third, we must continue to invest in the general health and well-being of the American people so that we are better positioned to respond to public health emergencies. Further digitizing and expanding healthcare information technologies will enhance communication and information exchange within the medical community to more adequately detect prevent and treat widespread viral infection.

By passing the Build Back Better act through both chambers, we will improve nutrition for children, lower drug costs, and expand affordable healthcare for millions of Americans. When we improve access to health care and ensure those at elevated risk from COVID-19 or other health care emergencies, we become more resilient against future pandemics and bioweapons.

Finally, we must support robust biosecurity infrastructure over the long run. This is a vital national security item that Congress can support.

From Fiscal Years 2015 to 2019, the five years before the COVID-19 pandemic, the United States appropriated an average of $218.34 million per year towards U.S. Bilateral Global Health Security Funding. This accounted for .035 percent of the total defense budget. With sporadic funding injections to combat Ebola or COVID, we may be able to resolve these biosecurity threats in the short run, but we will remain woefully unprepared in the long run. We must design and securely fund a unified public health and biosecurity infrastructure, for the current pandemic and ones to come.

# RESPONSES TO QUESTIONS SUBMITTED FOR THE RECORD

**Questions for the Record from Representative Young Kim**
**House Foreign Affairs Subcommittee on Asia, the Pacific, Central Asia, and Nonproliferation**
**"Biosecurity for the Future: Strengthening Deterrence and Detection"**
**December 8, 2021**

**Question: Adversary Threat Capabilities**
"Dr. Esvelt, can you provide this Subcommittee with any insight you have on whether there are any new technologies to enter the market or threat capabilities acquired by our adversaries expected over the next 5 to 10 years that could pose a national security risk?"

**Answer**
**Dr. Esvelt:** Recent and likely future technological advances related to pandemic viruses have combined to create a proliferation risk considerably greater than that of nuclear weapons.

Between 10,000 and 40,000 individuals are currently capable of assembling an influenza virus or a coronavirus from a genome sequence and synthetic DNA at an affordable cost for an upper-middle class individual. Over the next 5-15 years, the cost of access to viruses will continue to decrease with the price of synthetic DNA, and more individuals will gain the necessary skills as more life scientists are trained and superior virus assembly protocols are published.

However, none of those actors knows which viruses would cause pandemics. Very few of them can perform the necessary experiments to credibly identify pandemic viruses on their own, and none would be believed if they claimed to have a pandemic weapon and tried to use it to threaten or deter the United States. Since any data they produced in support of their claim could easily be fabricated, only independent laboratories can identify credible pandemic weapons.

Therefore, the proliferation and national security risk posed by the deliberate assembly and release of pandemic viruses is nascent: it does not yet exist. But as soon as the international scientific community credibly identifies one or more pandemic-capable viruses, the number of actors with access to weapons capable of killing at least a million people will increase by a factor of a thousand.

Today, multiple well-meaning funding programs seeking to prevent natural pandemics, most notably the DEEP VZN program of USAID, aim to identify new pandemic viruses and share them in a public list. The original versions of these programs were created over a decade ago, when very few actors could assemble viruses from synthetic DNA, and those currently responsible for overseeing these programs were not aware of the emerging proliferation risk posed by the new techniques until very recently alerted.

To reduce the nascent proliferation risk and national security threat from pandemic biology, I recommend:

1. Delaying the identification of pandemic viruses by redirecting funds currently allocated to pandemic virus identification by USAID's DEEP VZN program to the other goals of that program, namely monitoring the animal-human interface and minimizing contact with animal reservoirs in ways consistent with the One Health approach, and doing the same for

any other government programs that would identify novel pandemic-capable viruses for any reason.

2. Updating the Federal Select Agent and Toxin program to automatically add any virus with at least one experimental data point indicative of pandemic capability, and ensuring that any functional equivalents of Select Agent components generated through design processes such as combining different viruses, directing their evolution, or applying machine learning tools are themselves regulated as Select Agents.

3. Passing federal legislation similar to CA AB-70 to require a minimum level of DNA synthesis screening within the U.S., and directing the State Department to encourage other nations to require screening in order to fulfill their obligations as signatories of the Biological Weapons Convention, Article IV of which requires them to take any national measures necessary to prevent the production or acquisition of biological weapons within their territory.

**Question: International Financing for Pandemic Prevention**
"There is an ongoing debate about the need for an international financial institution to fund pandemic preparedness work. Dr. Esvelt, do you believe such an institution would be helpful from a biosecurity point of view?"

**Answer**
**Dr. Esvelt:** Additional support for pandemic preparedness work overseas could help contain nascent natural or accidental pandemics before they reach our shores, although any increase in the rate of collection of potential pandemic viruses or the number of laboratories studying potential pandemic agents will increase the risk of accidents and deliberate misuse and should be avoided on security grounds.

International funds for pandemic preparedness are highly unlikely to prevent or mitigate the deliberate misuse of pandemic viruses as weapons, which we must assume will be distributed in multiple travel hubs, possibly within the United States.

As I am not an expert on financing, I cannot advise on whether an international financial institution would be more useful than direct funding of international work by agencies such as USAID.

**Question: Preparedness for Bio-Attacks and Bioterrorism**
"Dr. Esvelt, do you believe the global impact of COVID-19 makes it more or less likely that non-state actors will pursue biological weapons in the future? What does the global response to the COVID-19 pandemic reveal about U.S. and international partners' preparedness for an act of bioterrorism and how could this be improved?"

**Answer**
**Dr. Esvelt**: COVID-19 has demonstrated that the United States is highly vulnerable to pandemic agents, which can kill more people and cause more economic damage than any nuclear

detonation. Whether or not SARS-CoV-2 was connected with laboratories in Wuhan in any way, the world clearly accepts that laboratories can plausibly generate pandemics. Together, these factors have greatly increased awareness of the potential of pandemic-class weapons. We should assume this has piqued the interest of non-state actors.

With respect to future vulnerability, if SARS-CoV-3 were introduced today, with comparable epidemiological traits to the Omicron variant of SARS-CoV-2, we would be unable to contain it. The same would be true of a suitably infectious influenza virus, vaccine-evading measles, or any other highly contagious pandemic virus. I am not aware of any current or planned investments that would change this situation.

Current plans aim to ensure that we will have an approved mRNA vaccine within 100 days. That is too long to respond to a natural pandemic, let alone one deliberately released at several travel hubs simultaneously, let alone multiple deliberately released pandemic viruses. Any remotely competent adversary intending to release pandemic weapons would arrange to do both. Moreover, we still lack a vaccine for HIV, and should not assume that it will always be possible to develop a vaccine for every pandemic virus. Preparing for future pandemics by focusing primarily on vaccines and other medical countermeasures is not even preparing to fight the last war: it's preparing to fight a public health crisis, not defend against a deliberate attack.

If a virus responsible for a future pandemic is as contagious as Omicron and exhibits a lethality rate greater than 30%, it is possible that we would see widespread societal breakdown as too many essential workers refuse to venture out, causing disruptions in the delivery of food, water, and electricity. This could plausibly occur even if we could develop mRNA vaccines for all of the pathogens within 100 days of identification if the agents are in multiple American cities within the first week.

Therefore, while investments in rapid mRNA vaccine manufacturing are important, biodefense measures against deliberate threats should focus on reliable methods of preventing Americans from becoming infected.

The minimum set of defensive capabilities needed to withstand a truly serious pandemic include:

1. An observatory system based on untargeted metagenomic sequencing that can reliably detect any pandemic agent and warn us to take precautions, and
2. Personal protective equipment for our essential workers that is believably good enough to keep them safe in the teeth of a 30%+ lethality pandemic, thereby keeping our food, water, power, and healthcare distribution systems operational.
3. A comprehensive plan to use the protective equipment when necessary.

Other measures such as scalably mass-produced rapid diagnostics and infrastructure investments to reduce transmission would be highly cost-effective, but not mandatory.

We estimate that a basic nucleic acid observatory capable of reliably detecting any pandemic-class weapon could be constructed and operated for less than a billion dollars a year. Even at today's prices, a bulk purchase of powered air-purifying respirators for all essential workers in the United States would cost around $50 billion; research and development could substantially

reduce this figure and make the equipment much more comfortable. A warning system and sufficient protective equipment could extinguish virtually any pandemic within our borders despite adversaries' best efforts.

Until such a defensive system is in place, it is imperative that we prevent the public disclosure of viruses capable of causing new pandemics. Failing to build such a system will render us increasingly vulnerable, as multiple independent fields are advancing in ways that will make it possible to build increasing numbers of novel pandemic-class agents. I do not think it likely that these advances can be forestalled for more than a decade even if they are not made publicly available; the unrelated beneficial and commercial applications are too great.

Since it will always be easier for an adversary to synthesize and release a pandemic virus than for us to develop, approve, manufacture, and distribute a vaccine – if we can successfully do so at all – a world in which many pandemic-capable agents are known is a world in which many small-scale actors can unilaterally bring the United States to its knees. With a suitable early warning system, adequate protective equipment, and comprehensive plans to use it when necessary, we will be able to reliably defend ourselves against both natural pandemics and deliberate weapons.