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BLOOMBERG SCHOOL
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Center for Health Security

US-India Strategic Dialogue on Biosecurity

Report on the fifth dialogue session

Report Release:
October 2018

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US Air Force Institute for National Security Studies

US Defense Threat Reduction Agency

This publication results from research supported by the Project on Advanced Systems and Concepts for Countering Weapons of Mass Destruction (PASCC). The views expressed in written materials or publications, and/or made by speakers, moderators, and presenters, do not necessarily reflect the official policies of PASCC, nor does mention of trade names, commercial practices, or organizations imply endorsement by the US government.

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EXECUTIVE SUMMARY

In September 2018, the Johns Hopkins Center for Health Security hosted a dialogue on biosecurity between senior experts and leaders from the United States and the Republic of India. The purposes of this dialogue are to increase knowledge of prevention and response efforts for natural, deliberate, and accidental biological threats in India and the United States; look for new synergies and share best practices and innovations; examine opportunities for partnership and collaboration; develop and deepen relationships between dialogue participants; and identify issues that may warrant being brought to the attention of the Indian or US government.

The dialogue, which was held in Washington, DC, was organized in collaboration with the DBT-UNESCO Regional Centre for Biotechnology, an autonomous institute of the Department of Biotechnology (in the Ministry of Science and Technology, Government of India). This was the fifth meeting of the dialogue, following previous engagements in Washington, DC, in September

2016 and November 2017, and in New Delhi, India, in February 2017 and February 2018. This effort is supported by the Project on Advanced Systems and Concepts for Countering WMD (PASCC, which is sponsored by the Defense Threat Reduction Agency, DTRA) of the US Air Force Institute for National Security Studies.

The biosecurity dialogue took place on the cusp of a historic 2+2 meeting between the US Secretaries of State and Defense and their Indian counterparts in early September in New Delhi. Other recent developments between the 2 countries include: the upgrading of India to the Strategic Trade Authorisation-1 category by the United States; India's joining the Australia Group (AG), in which the United States is already a participant; and India's joining the Wassenaar Arrangement, of which the United States is also a member.

Recognizing the strategic convergence between the national security priorities of the 2 countries, the Center convened senior thought leaders, scientists, public health practitioners, and medical experts from the US and India to discuss shared biosecurity priorities, infectious disease outbreak response, biosafety and biotechnology concerns, advances in biotechnology, and possible future collaborations between the 2 countries. The diverse group of participants shared perspectives from government, academia, and industry and included subject matter experts in biosecurity, biosafety, the life sciences, medicine, and public health. In accordance with the dialogue format, participants offered insights based on personal expertise and did not represent the government of either country in an official capacity.

Members of the Indian delegation were:

- **Randeep Guleria, MD**, Director, All India Institute of Medical Science (AIIMS)
- **Indira Nath, MD**, former Head and Senior Professor, Department of Biotechnology, AIIMS Delhi; former Raja Ramanna Fellow and Emeritus Professor, NIOP, Delhi
- **S. R. Rao, PhD**, Senior Advisor, Department of Biotechnology, Ministry of Science and Technology, Government of India
- **V. Siva Reddy, PhD**, Chief Scientific Officer, Biosafety Support Unit, Government of India
- **Ambassador Rakesh Sood, PhD**, Observer Research Foundation
- **Sudhanshu Vrati, PhD**, Executive Director, Regional Centre for Biotechnology, Government of India

Members of the American delegation were:

- **David R. Franz, DVM, PhD**, former Commander, US Army Medical Research Institute for Infectious Diseases
- **Dan Hanfling, MD**, Contributing Scholar, Johns Hopkins Center for Health Security
- **Susan J. Koch, PhD**, Distinguished Research Fellow, National Defense University Center for the Study of Weapons of Mass Destruction; Senior Scholar, National Institute for Public Policy; associate faculty member, Department of Defense and Strategic Studies, Missouri State University
- **Ambassador Ronald F. Lehman II, PhD**, Counselor to the Director, Lawrence Livermore National Laboratory; Chair, US Department of Defense Threat Reduction Advisory Committee (TRAC)
- **Maureen O'Leary, PhD, MBA, CBSP**, Director, Environmental Health & Safety, Dartmouth College
- **David A. Relman, MD**, Thomas C. and Joan M. Merigan Professor in Medicine, and Microbiology & Immunology, Stanford University

Several observers from both countries also attended the meeting: **Sumit Goswami**, Counsellor (Defence Technology), Embassy of India, Washington, DC; **Angelica Lopez**, INDOPACOM Science Lead, A&AS Support to DTRA; **Cassandra Peterson**, Project Lead for India, A&AS Support to DTRA; and **Judee Allen-Close**, Senior Foreign Affairs Officer, US Department of State.

Additionally, several speakers met with the dialogue participants to discuss recent developments in biosecurity and biodefense in the US and India: **Kevin Yeskey**, Principal Deputy Assistant Secretary for Preparedness and Response, Office of the Assistant Secretary for Preparedness and Response, US Department of Health and Human Services; **Hamid Jafari**, Principal Deputy Director, Center for Global Health, US Centers for Disease Control and Prevention; and **Col. Matthew Hepburn**, Program Manager, Biological Technologies Office, Defense Advanced Research Projects Agency (DARPA). Center staff facilitating the meeting were Thomas V. Inglesby, Director; Gigi Gronvall, Senior Scholar; Anita Cicero, Deputy Director; Diane Meyer, Senior Analyst; and Andrea Lapp, Director of Events. Additionally, Eric Toner, Senior Scholar, helped facilitate a version of the Clade X tabletop exercise for the dialogue participants.

Following the dialogue sessions, the delegations visited the White House, where they met with several individuals, including: **Hillary H. Carter**, Director for Countering Biological Threats, National Security Council; **Shaun Hayeslip**, Director of Nonproliferation, National Security Council; **Karen Zimmerman**, Biosecurity

Engagement Program, US Department of State; and **Regina M. Galer**, Director for South Asia, National Security Council. There the delegations were updated on US biosecurity and biodefense policies. The delegations also discussed shared biosecurity priorities and identified and discussed next steps regarding more formal collaborative efforts that could be undertaken by the United States and India.

During the 2-day dialogue meeting, several key topics and opportunities for collaboration were identified:

- Writing a joint statement between the United States and India to highlight a bilateral commitment to biosecurity initiatives. This statement will be collaboratively drawn up by the US and Indian governments and will be made public once completed;

- Developing a joint publication between US and Indian dialogue participants that highlights important findings and key themes that have emerged throughout the 5 dialogue sessions. This would ideally be published in a peer-reviewed journal and be publicly available;

- Authoring a joint publication between US and Indian dialogue participants that compares and contrasts healthcare system preparedness and response policies and practices in each country. This would ideally be published in a peer-reviewed journal and be publicly available;

- Creating a joint laboratory exchange program between the United States and India in which scientists can visit others' laboratories to learn about their research and how they conduct biosafety practices;

- Establishing a formal partnership between the DBT-UNESCO Regional Centre for Biotechnology and the Center for Health Security to facilitate continued bilateral collaboration around studying, preventing, and mitigating biological threats of mutual concern; and

- Examining the feasibility of elevating future biosecurity dialogues to the Track I (ie, government-to-government) level. There is evidence that this is already beginning to happen, and, as of publication of this report, the 2 governments are actively exploring official joint initiatives.

The next meeting of the dialogue is tentatively scheduled for February 2018 in Hyderabad, India.

INTRODUCTION

In September 2018, the Johns Hopkins Center for Health Security hosted the fifth meeting of a dialogue (ie, a nongovernmental engagement) on biosecurity between the United States and the Republic of India. The purposes of this dialogue are to increase knowledge of prevention and response efforts for natural, deliberate, and accidental biological threats in India and the United States; look for new synergies and share best practices and innovations; examine opportunities for partnership and collaboration; develop and deepen relationships between dialogue participants; and identify issues that may warrant being brought to the attention of the Indian or US government.

The meeting was held in Washington, DC, and featured subject matter experts in biosecurity, biosafety, the life sciences and biotechnology, medicine, and public health.

Previous dialogue meetings were held in Washington, DC, in September 2016 and November 2017 and in New Delhi, India, in

February 2017 and February 2018.[1-4] Each meeting was sponsored by the Project on Advanced Systems and Concepts for Countering WMD (PASCC, sponsored by the Defense Threat Reduction Agency, DTRA). The Department of Biotechnology of the Government of India's Ministry of Science and Technology has been an important collaborative partner in this effort, having expanded participation in the dialogue and assisted in developing content for meetings.

The biosecurity dialogue took place in the days immediately following a historic meeting between the US Secretaries of State and Defense and their Indian counterparts in early September in New Delhi. The success of this highly anticipated joint meeting signifies growing bilateral ties between the 2 nations and included the signing of the Communications Compatibility and Security Agreement, a major military communications agreement.[5] The United States also recently upgraded India to the Strategic Trade Authorisation-1 category, which will help increase technology collaboration and trade between the 2 countries.[6] However, some challenges do remain, including concerns about the US Countering America's Adversaries Through Sanctions Act (CAATSA).[7,8]

There have also been numerous advances in the past year that demonstrate the commitment of both India and the United States to biosecurity. In early 2018, India joined the Australia Group (AG), in which the United States is already a participant. The AG, which was established in 1985, is an informal group of countries that share a commitment to chemical and biological weapon nonproliferation through export control measures.[9] India also recently joined the United States as a member of the Wassenaar Arrangement, another export control regime that seeks "greater responsibility in transfers of conventional arms and dual-use goods and technologies."[10]

The meeting consisted of 6 sessions, each preceded by brief opening remarks delivered by selected participants from each country; these remarks, in turn, set the stage for subsequent group dialogue. Topics of discussion included shared biosecurity priorities and the evolving geopolitical climate, medical care delivery during an infectious disease outbreak, previous biosafety events and lessons learned, future concerns in emerging biotechnology, new technologies, and next steps and possibilities for US-India collaboration. Guest presentations discussed the US healthcare system's response to infectious disease emergencies, global health security priorities from a US perspective, and the Defense Advanced Research Projects Agency's (DARPA) investments in biotechnology for national security. Participants also took part in a 2-hour tabletop exercise adapted from the Center's May 2018 Clade X exercise.

In addition to the invited participants and the Johns Hopkins Center for Health Security staff, several observers also attended the dialogue: **Sumit Goswami**, Counsellor (Defence Technology), Embassy of India, Washington, DC; **Angelica Lopez**, INDOPACOM Science Lead, A&AS Support to DTRA; **Cassandra Peterson**, Project Lead for India, A&AS Support to DTRA; and **Judee Allen-Close**, Senior Foreign Affairs Officer, US Department of State.

Indian and US participants in the dialogue

MEETING OVERVIEW

Shared Priorities and the Evolving Geopolitical Climate

The first session of the dialogue discussed shared biosecurity priorities between the United States and India in the current and evolving geopolitical climate. Participants discussed recent diplomatic developments between the US and India, including the elevation of India by the United States to the Strategic Trade Authorisation-1 category and, perhaps most important, the successful completion of the first-ever 2+2 meeting between the US Secretaries of State and Defense and their Indian counterparts. Other important developments include India's recent joining of both the AG and the Wassenaar Arrangement, of which the United States is already a member. Each of these milestones highlights increasing diplomatic ties between the 2 nations, as well as a shared commitment to biosecurity. However, participants did note that heightened tensions in some areas in Asia, including in Iran, Syria, and the Persian Gulf, as well as current US relations with China and Russia, could potentially detract

from diplomatic gains made between the 2 countries. Participants also noted concerns about CAATSA.

Participants highlighted several shared areas of concern and priorities for future engagement. These included:

- *Supply chains*: Participants stressed that the public health and health security implications are often not considered when tariffs are imposed, but tariffs could have dramatic consequences for medical supply availability. Participants also highlighted concerns that access to medical devices could suffer under trade and travel restrictions.

- *Responsible life sciences research*: Recent emphasis on biosafety has been focused on the research itself (eg, dual-use research of concern, or DURC), with less emphasis on the scientists conducting the research. Participants noted the need to instill responsible codes of conduct in the research community to help ensure that biosafety practices are adhered to.

- *Vaccines*: Both India and the United States have vaccine development and manufacturing capabilities. For example, the first rotavirus vaccine to be developed and manufactured in India, ROTAVAC, was launched in 2015 and was phased in to India's national immunization program starting in 2016.[11,12] The vaccine also reached WHO prequalification status earlier this year and is now accessible to the UN and Gavi, the Vaccine Alliance.[12] The participants highlighted potential opportunities for US-India collaboration, given India's growing advancement in vaccine development and manufacturing, but had concerns about the affordability of a vaccine if it is made in the United States.

- *Healthcare access and costs*: The costs of health care have grown dramatically, and, even with universal health coverage, there will always be services that are out of reach for certain populations. Thus, bioethics will become increasingly important as biotechnology advances and new, potentially life-saving drugs are developed and introduced into the market. Participants mentioned cancer therapeutics as being particularly

Left to Right: Anita Cicero, Ambassador Rakesh Sood, Dave Franz, and Indira Nath

troublesome, as they are extremely costly and inaccessible to most of the population.

- *The erosion of norms*: The use of the nerve agent Novichok against a former Russian spy and his daughter in Salisbury, England, in May 2018 raised concerns about the adherence to international norms against the use of chemical weapons. Participants feared that erosion of these norms could lead to the use of other nonconventional weapons, including biological materials.

Remarks by Hamid Jafari, Principal Deputy Director, Center for Global Health, US Centers for Disease Control and Prevention

The delegates engaged in an informative discussion with Dr. Jafari about global health security priorities and biosecurity in India. Dr. Jafari's presentation centered around why the US Centers for Disease Control and Prevention (US CDC) invests in global health and highlighted the continued commitment of the United States to the Global Health Security Agenda (GHSA). The GHSA, which was first launched in 2014, is a growing partnership of more than 64 nations (including the United States and India) that are working to strengthen the capacity to prevent, detect, and respond to infectious disease outbreaks, both at a national and a global scale.[13] Dr. Jafari noted that the US CDC has supported numerous GHSA initiatives in India, including emergency management, lab capacity development, and BSL-2/BSL-3 laboratory technical assistance. They have also worked with India to promote biosafety and biosecurity through collaborative training and workshops.

Medical Care Delivery During an Infectious Disease Outbreak

During this session, participants discussed a number of topics related to medical care delivery during an infectious disease outbreak, including detection of the outbreak itself. Speakers from both countries noted the challenges of disease surveillance that might impede the early detection of and response to an outbreak. These include manual surveillance systems that are cumbersome and time-consuming to use, and electronic reporting systems that are not well integrated in a country's healthcare system or across borders. These issues can lead to poor situational awareness that increases the vulnerability of the healthcare system to large disease outbreaks.

Participants discussed the extent to which emerging technologies, such as using social media platforms for syndromic surveillance, might be able to bridge some of these surveillance gaps, as well as how the lack of point-of-care tests for many infectious diseases prohibits early diagnosis and can facilitate the spread of disease. Participants

spoke of the need to increase awareness among front-line healthcare practitioners (eg, physicians, nurses) of worrisome clinical signs and symptoms and travel histories that might indicate infection with a highly contagious pathogen such as Ebolavirus. In both countries, clinicians need to be trained to recognize these diseases and to quickly isolate those who they suspect may have a serious contagious infectious disease.

Left to right: V. Siva Reddy, Dan Hanfling, and Randeep Guleria

Outbreak response was also discussed, including the medical management and quarantine of suspected and confirmed cases, and whether there was enough surge capacity in the healthcare system to support a large outbreak response. One participant noted that since many of the healthcare systems in the United States are private, it is very difficult to fully assess the systems' surge capacity, particularly as more health care is delivered in outpatient settings. Many participants noted that their respective healthcare systems lack the manpower needed to surge the system during a response, and there is concern about their ability to provide advanced critical care (eg, ventilation, ICU care) to acutely ill patients. The ethics of quarantining infectious patients was also raised, including potential legal issues that may arise and how best to respect citizens' rights while still protecting the larger public. To better prepare for these challenges, participants underscored the importance of regular drills that can exercise response policies and skill sets needed to combat large outbreaks. Additionally, creating a global "brain trust" of individuals skilled in infectious disease outbreak preparedness and response that could be mobilized during a response could be beneficial.

During this session, concerns about medical countermeasure (MCM) manufacturing, stockpiling, and distribution arose. Participants noted that it can be difficult to incentivize pharmaceutical companies to produce stockpiled vaccines for diseases such as pandemic flu, as there is no perceived profit. Procuring and maintaining government funding for these stockpiles is also problematic, and, since it is difficult to know which infectious disease will strike next, countries must prioritize what vaccines to stockpile.

Participants noted that, in the absence of stockpiled vaccines, countries must come up with a global approach to quickly ramp up vaccine production during an outbreak. This might include vaccine manufacturers that can quickly shift production capabilities to the disease at hand (eg, "surge manufacturing"). Participants also emphasized the need for continued sample sharing among countries but stressed that any vaccine produced

from those samples must be available to all, and not just the countries wealthy enough to develop and manufacture them. For example, the WHO's Pandemic Influenza Preparedness Framework ("PIP framework") aims to improve and strengthen the WHO's Global Influenza Surveillance and Response System so that it is "more fair, transparent, equitable, efficient, and effective in facilitating the sharing of influenza viruses with pandemic potential and increasing the access to pandemic influenza vaccines."[14] However, despite adoption of the PIP framework, participants noted that there are still concerns about equal access to vaccines.

Remarks by Kevin Yeskey, Principal Deputy Assistant Secretary for Preparedness and Response, Office of the Assistant Secretary for Preparedness and Response, US Department of Health and Human Services

Dr. Yeskey highlighted a number of US infectious disease response capabilities and functions, including the roles of the Assistant Secretary for Preparedness and Response (ASPR), the Medical Reserve Corps, Disaster Medical Assistance Teams, and Healthcare Coalitions (HCC). This included a discussion of ASPR's planned regional disaster health response system, which "will be a tiered system that emphasizes the use of local healthcare coalitions and trauma centers that integrate their medical response capabilities with federal facilities and local emergency medical services."[15] He also spoke of the need to increase surge capacity for infectious disease outbreaks, citing that, while the United States does have 10 regional treatment centers for highly infectious patients, more will be needed for the isolation of patients during a large outbreak. Finally, he spoke of the growing number of outpatient services being provided in homes and emphasized the need to take these into consideration during preparedness and response planning.

Biosafety Case Studies

During this dialogue session, a representative from each country was invited to share recent biosafety incidents that had occurred in their country. This was followed by a discussion of how each country approaches these types of events and how they can be prevented in the future. Some of the biosafety incidents shared were:

- The illegal cultivation of herbicide tolerant cotton in India
- Texas A&M 2006 brucellosis and Q-fever exposures
- Boston University 2005 tularemia exposures
- 2014 exposure to improperly inactivated Bacillus anthracis at the US CDC

- 2015 US Army Dugway Proving Ground shipment of live anthrax to centers not prepared (or registered) to work with it
- Discovery of smallpox virus in a National Institutes of Health building in 2014

V. Siva Reddy

These incidents have spurred numerous investigations, recommendations, and policy changes. For example, in the United States, these lapses led to changes in the federal Select Agent Program, which oversees the transport and use of a select group of biological agents and toxins.[16]

Participants agreed that to avoid future biosafety incidents, there needs to be consistent biosafety policies that are broadly applicable and enhanced investments in biosafety practices that occur before an incident. This should include well-established incident command systems that support timely reporting and response, and perhaps a biosafety office at the national level that can help researchers conduct safe science.

Future Concerns in Emerging Biotechnology

During this dialogue session, participants discussed the concerns they had about the evolving biotechnology landscape and ways that the global community can work together to mitigate misuse of biotechnology. A widely agreed upon concern among participants from both nations was the production of biotechnologies that could have an impact on agriculture and the wider ecosystem. For example, the use of gene drives to limit insect pest populations is an emerging biotechnology that could help increase agricultural yields and stop some vector-borne diseases, such as malaria and dengue. However, regulatory and ethical questions have come into play with the development of this technology, which genetically engineers insects to have certain heritable traits—for example, the potential unknown impacts on the ecosystem, which are hard to estimate and quantify, and potential cross-breeding that could allow the trait to persist in other populations.[17] Additionally, the biodiversity of food crops has decreased dramatically with the use of monoculture, increasing the vulnerability of the food supply system. Another concern was the development of nanotechnology, which could unknowingly deliver drugs, chemicals, and infectious agents, and manipulation of the human microbiome, which could have long-term, unintended side effects.

To counter the misuse of these biotechnologies, participants noted the importance of establishing a global consensus on oversight policies for genome editing, gene drives, synthetic biology, and other technologies that might emerge in the future. The policies should include the need for transparency, as science can be driven by proprietary interests, and should be ethically sound, taking into account the impact that new technologies may have on humans and the larger ecosystem. Participants noted that these policies should not be driven by certain technologies that exist today (eg, CRISPR), because these will certainly be replaced by even newer technologies. The policies should, instead, establish a set of norms and guidelines that researchers, and the agencies that fund them, follow. However, the need to prevent the grave consequences of misuse with the desire to advance science must be balanced, requiring a collaborative effort between the scientists conducting the research and the policymakers who set policy.

Left to right: Ambassador Rakesh Sood, Dave Franz, Indira Nath, and Susan Koch

New Technologies

In this dialogue session, participants discussed a variety of new technologies needed to ensure biosecurity in the ever-changing threat landscape and the need for government buy-in and international collaboration to bring these new technologies to fruition. Participants noted that the best preventive technology we currently have is vaccines, and they emphasized the importance of working with alliances such as the Coalition for Epidemic Preparedness Innovations (CEPI), of which India is a founding member. Through alliances such as CEPI, which aims to "finance and coordinate the development of new vaccines to prevent and contain infectious disease epidemics," countries can work collaboratively with public, private, civil, and philanthropic organizations to prevent future epidemics.[18] In addition to vaccines, participants also highlighted the importance of robust and reliable diagnostics, particularly those that can be deployed in the field at the point of care. Participants also spoke of emerging technologies that would allow for the prediction of what types of pathogens might lead to the next epidemic. This included efforts to catalog all viruses that could potentially infect humans and the use of algorithms to predict the evolution of viruses. While participants stressed that predicting pandemics with 100% certainty is not possible, efforts can be made to better prepare for them.

While the case for the development of new technologies to prevent epidemics can be easily made, it can be difficult to get government buy-in. Participants noted that the government currently lacks the scientific expertise to adequately address biological threats, and that this lack of expertise leads to policy gaps that undermine the support and regulation of new technologies. Additionally, there is lack of coordination among government agencies, private industries, and laboratories, as well as a significant lack in funding, which further hinders the development of new technologies that are needed to address the ever-changing threat landscape.

Left to right: Susan Koch, Sudhanshu Vrati, and Maureen O'Leary

Col. Matthew Hepburn, Program Manager, Biological Technologies Office, Defense Advanced Research Projects Agency (DARPA)

Col. Hepburn provided a brief overview of DARPA and its investments in biotechnology for national security. Projects discussed included a technology to predict whether someone who has been exposed to an infectious agent will get sick, thus allowing interventions to be made before the person becomes contagious; technology to deliver medical countermeasures in less than 60 days after outbreak onset; and injecting genetic imprints of antibodies for long-term protection against disease.'

Modified Clade-X Tabletop Exercise

In May 2018, the Center for Health Security conducted a day-long pandemic exercise in Washington, DC, called Clade X.[19] The scenario centered around the deliberate release of a genetically engineered virus and its impact on national and global public health and economic and political security. The exercise simulated a series of meetings convened by the National Security Council and attended by US government leaders, who were played by individuals prominent in the fields of national security or epidemic response. The purpose of the exercise was to illustrate high-level strategic decisions and policies that the United States and the world would need to pursue in order to prevent a pandemic or diminish its consequences should prevention fail.

A modified exercise was conducted with the dialogue participants to elicit their thoughts on a variety of different challenges and issues that might emerge during a

novel pandemic like Clade X, and to identify how India's response to the same type of scenario would differ from that of the United States. The challenges and issues that were posed are listed below, along with a brief summary of the discussion that followed.

Should air travel be suspended from countries affected by the outbreak?

The participants agreed that air travel should not be suspended from countries affected by the outbreak, because people could easily cross borders into unaffected countries and travel from there instead. Instead of restricting transmission, such a measure would simply hinder travel and trade. Additionally, the government could not strand citizens who had been traveling abroad, as they could be indefinitely stuck in the country experiencing the outbreak or require special travel arrangements to bring them home (eg, privately chartered flights). They instead stressed the importance of strong screening measures and of discouraging travel to affected countries.

How would the response to an outbreak caused by a human-engineered pathogen be different from the reponse to a natural outbreak?

Since more attacks could happen around the globe, containment of the pathogen is no longer a priority, as it would be during a naturally caused outbreak. Instead, the focus would need to shift to identifying the perpetrators, particularly if they had developed their own MCMs to protect themselves. Additionally, it would be important to look at vaccines that have been developed for related pathogens and to evaluate their potential effectiveness against the novel pathogen.

Does the US government have the authority to impose and enforce large-scale quarantines?

Participants felt that if a quarantine were implemented in one location, it would need to be implemented in each location where new cases were identified. They felt that the emphasis should instead be on self-isolation, social distancing (vs large-scale quarantines), and MCM development. They also noted that incentives could be used to encourage self-isolation, including preferential access to MCMs once they become available. Additionally, participants strongly advised against the use of the military to enforce quarantines, as such an order could lead to widespread civil unrest.

What are the best practices for effectively communicating with the public during public health emergencies?

Participants were asked whether models predicting a global pandemic with millions of deaths should be shared with the public. While it was noted that there was little benefit in sharing this information, and that it might lead to widespread panic, participants noted that not all models will be created in government institutions and thus will be released anyway. They recommended that the model be released, but only if it is paired with a discussion on how the government intends to respond to the outbreak.

Who should be prioritized to receive newly developed medical countermeasures such as vaccines?

Most participants believed that, to ensure continuity of government, business, and essential services, government officials, those who work in critical infrastructure, and business leaders should be prioritized, in addition to healthcare workers and scientists studying the pathogen. However, they also believed that some MCMs should be available to the public via a lottery system, which would randomly select individuals to receive the vaccine.

Identifying Next Steps and Possibilities for US-India Collaboration

Both delegations expressed strong support for continued bilateral engagement on biosecurity issues. As such, the sixth meeting of the dialogue is tentatively scheduled to be held in Hyderabad, India, in February 2019. The dialogue participants have already identified several topics meriting continued discussion and various opportunities for continued collaboration. These include, but are not limited to:

- Writing a joint statement between the United States and India to highlight a bilateral commitment to biosecurity initiatives. This statement will be collaboratively drawn up by the US and Indian governments and will be made public once completed.
- Developing a joint publication between US and Indian dialogue participants that highlights important findings and key themes that have emerged throughout the 5 dialogue sessions. This would ideally be published in a peer-reviewed journal and be publicly available.
- Authoring a joint publication by US and Indian dialogue participants that compares and contrasts healthcare system preparedness and response policies and practices in each country. This would ideally be published in a peer-reviewed journal and be publicly available.

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- Creating a joint laboratory exchange program between the United States and India in which scientists can visit others' laboratories to learn about their research and how they conduct biosafety practices.
- Establishing a formal partnership between the DBT-UNESCO Regional Centre for Biotechnology and the Center for Health Security to facilitate continued bilateral collaboration around studying, preventing, and mitigating biological threats of mutual concern.
- Examining the feasibility of elevating future biosecurity dialogues to the Track I (ie, government-to-government) level. There is evidence that this is already beginning to happen, and. as of publication of this report, the 2 governments are actively exploring official joint initiatives.

Prior to the conclusion of the dialogue meeting, the delegates visited the White House, where they met with several individuals, including: Dr. Hillary H. Carter, Director for Countering Biological Threats, National Security Council; Shaun Hayeslip, Director of Nonproliferation, National Security Council; Karen Zimmerman, Biosecurity Engagement Program, US Department of State; and Regina M. Galer, Director for South Asia, National Security Council. There the delegations were updated on US biosecurity and biodefense policies, including the imminent release of the US National Biodefense Strategy. The delegations also discussed shared biosecurity priorities, particularly focusing on emerging technologies and their potential for misuse, and opportunities for further collaboration. Importantly, both countries have agreed to author a joint statement that highlights a bilateral commitment to biosecurity initiatives. This statement will be collaboratively drawn up by the US and Indian governments and will be made public once completed. The writing of this joint statement is evidence of the importance of continued engagement in these biosecurity dialogues, of the strengthening relationship between its members, and of the potential for these dialogues to move to the Track I level.

APPENDIX A: REFERENCES

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APPENDIX B: DIALOGUE PARTICIPANTS' BIOGRAPHIES

Anita Cicero, JD

Anita Cicero directs operations and is the deputy director at the Johns Hopkins Center for Health Security. She is a lawyer with over 25 years of experience. Ms. Cicero works closely with the director to lead strategic and budget planning and program development at the Center. She is also an associate editor of the journal *Health Security*, the leading peer-reviewed journal in this field.

Ms. Cicero has greatly expanded the Center's efforts in epidemic preparedness, nuclear resilience, and international programs and has provided leadership on the Center's health security preparedness work for the country of Taiwan. In working to engage the Center in valuable new exchanges, Ms. Cicero has also launched a number of initiatives to improve mutual understanding and collaboration with countries including China, Kuwait, the Kingdom of Saudi Arabia, Singapore, Malaysia, and Indonesia.

Ms. Cicero has authored or co-authored a number of widely cited articles and reports on biosecurity policy, pandemic preparedness, nuclear and radiological consequence management, biosurveillance, international disease surveillance, and public health law.

Before joining the Center, Ms. Cicero spent nearly 2 decades as a practicing attorney in both the US federal government and the private sector. She was managing partner in charge of the Washington, DC, office of Drinker, Biddle & Reath, LLP, where she was responsible for more than 300 lawyers and staff. In her legal work, she created and managed a number of pharmaceutical consortia, with a particular focus on clinical research and regulatory compliance. Ms. Cicero's work required constructive engagement with members of Congress; the World Health Organization; the European Commission; the US Food and Drug Administration; the US Departments of State, Defense, and Health and Human Services; and the Environmental Protection Agency.

Before entering private practice, Ms. Cicero focused on environmental litigation and counseling. She began her career as a trial attorney in the Honors Program at the US Department of Justice, Environmental Enforcement Section. Ms. Cicero is a graduate of the Yale Law School and Oberlin College.

David R. Franz, DVM, PhD

David Franz served in the US Army Medical Research and Materiel Command for 23 of 27 years on active duty and retired as a colonel. He served as commander of the US Army Medical Research Institute of Infectious Diseases (USAMRIID) and as

deputy commander of the Medical Research and Materiel Command. Prior to joining the command, he served as group veterinarian for the 10th Special Forces Group (Airborne).

Dr. Franz served as a committee member for the National Academy of Sciences study *Biotechnology Research in an Age of Terrorism* (the Fink Report) and as a charter member of the National Science Advisory Board for Biosecurity (NSABB). He co-chaired the NAS study Global Security Engagement (CTR 2.0) in 2009 and continues to chair the bio subgroup of the NAS Committee for International Security and Arms Control (CISAC). He holds an adjunct professorship, Department of Diagnostic Medicine and Pathobiology, College of Veterinary Medicine, Kansas State University.

The current focus of his interest relates to the role of international engagement in public health and the life sciences as a component of global biosecurity policy. Domestically, he continues to encourage thoughtfulness when regulating research in the name of security, thereby minimizing negative impacts on progress in the life sciences. Dr. Franz holds a DVM from Kansas State University and a PhD in physiology from Baylor College of Medicine.

Gigi Gronvall, PhD

Gigi Gronvall is a senior scholar at the Johns Hopkins Center for Health Security and an associate professor in the Department of Environmental Health and Engineering at the Johns Hopkins Bloomberg School of Public Health. She is an immunologist by training.

Dr. Gronvall's work at the Center addresses the role of scientists in health security—how they can contribute to an effective technical response against a biological weapon or a natural epidemic. She is particularly interested in developing policies that will boost the safety and security of biological science activities while allowing beneficial research to flourish.

Dr. Gronvall is the author of the book *Synthetic Biology: Safety, Security, and Promise* (2016, Health Security Press). While the synthetic biology discipline is poised to revolutionize important sectors for national security, there are technical and social risks. Dr. Gronvall describes what can be done to minimize risks and maximize the benefits of synthetic biology, focusing on biosecurity, biosafety, ethics, and US national competitiveness. Dr. Gronvall is also the author of the book *Preparing for Bioterrorism: The Alfred P. Sloan Foundation's Leadership in Biosecurity*. By describing the major grants that represented Sloan's investments in civilian preparedness, public health law, law enforcement, air filtering in buildings, influenza preparedness, and business

preparedness, Dr. Gronvall constructed, for a nontechnical audience, a chronicle of early gains in US efforts to confront the threat of bioterrorism.

Dr. Gronvall is a member of the Threat Reduction Advisory Committee (TRAC), which provides the Secretary of Defense with independent advice and recommendations on reducing the risk to the United States, its military forces, and its allies and partners posed by nuclear, biological, chemical, and conventional threats. In 2014-15, she led a preparatory group that examined the US government response to the Ebola outbreak in West Africa as a case study for DoD's strategic role in health security and that made recommendations for future DoD actions in response to disease outbreaks.
She served as the science advisor for the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism from April 2009 until the commission ended in February 2010. She has testified before Congress about the safety and security of high-containment biological laboratories in the United States and served on several task forces related to laboratory and pathogen security, most recently the National Institutes of Health Blue Ribbon Panel to Review the 2014 Variola Virus Incident on the NIH Campus (2016) and the Committee for Comprehensive Review of DoD Laboratory Procedures, Processes, and Protocols Associated with Inactivating Bacillus anthracis Spores, formed in response to the Dugway anthrax shipments (2015). Dr. Gronvall has investigated and presented policy recommendations on the governance of science to the Biological Weapons Convention (BWC) in Geneva, Switzerland.

Dr. Gronvall is an alumna of the European Union Visitors Program, a competitive program designed to increase mutual understanding between professionals and future leaders from non-EU countries and their EU counterparts, and the Council on Foreign Relations Term Member Program.

Dr. Gronvall is an associate editor of the journal *Health Security*. She is a founding member of the Center, and, prior to joining the faculty, she worked at the Johns Hopkins University Center for Civilian Biodefense Strategies. She was a National Research Council Postdoctoral Associate at the US Army Medical Research Institute of Infectious Diseases (USAMRIID) in Fort Detrick, Maryland.

Dr. Gronvall received a BS in biology from Indiana University, Bloomington. She subsequently worked as a protein chemist at the Memorial Sloan-Kettering Cancer Center and received a PhD from Johns Hopkins University for work on T-cell receptor/MHC I interactions.

Randeep Guleria, MD

Randeep Guleria is director, All India Institute of Medical Sciences (AIIMS). Dr. Guleria received his MD from the Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh. He joined the All India Institute of Medical Sciences and rose in ranks to become a professor and the head of the department of pulmonology and sleep disorders and was named director in 2017.

Dan Hanfling, MD

Dan Hanfling is a consultant on emergency preparedness, response, and crisis management. He is a contributing scholar at the Johns Hopkins Center for Health Security, clinical professor of emergency medicine at George Washington University, and adjunct faculty at the George Mason University School of Public Policy. He currently serves as the co-chair of the Institute of Medicine (National Academies) Forum on Medical and Public Health Preparedness for Catastrophic Events and is a special advisor in the Office of the Assistant Secretary (HHS) for Preparedness and Response (ASPR), focused chiefly on the National Hospital Preparedness Program.

Dr. Hanfling spent 18 years as principal consultant to the Inova Health System (Falls Church, VA) on matters related to emergency preparedness and response. He continues to practice emergency medicine at Inova Fairfax Regional Trauma Center and is an operational medical director for a regional helicopter EMS service. He was instrumental in founding one of the nation's first healthcare coalitions, the Northern Virginia Hospital Alliance, created in October 2002.

His areas of expertise include biodefense and mass casualty management, catastrophic disaster response planning with particular emphasis on scarce resource allocation, and the nexus between healthcare system planning and emergency management. In addition to his hospital and EMS clinical responsibilities, he serves as a medical team manager for the Fairfax County–based FEMA and USAID-sanctioned international urban search and rescue team (VATF-1, USA-1) and has responded to catastrophic disaster events across the globe.

Dr. Hanfling received his undergraduate degree in political science from Duke University, including a general course at the London School of Economics, and completed his medical degree at Brown University. He completed his internship in internal medicine at Brown University and his emergency medicine training at the combined George Washington and Georgetown University residency program. He has been board certified in emergency medicine since 1997.

Tom Inglesby, MD

Tom Inglesby is the director of the Center for Health Security of the Johns Hopkins Bloomberg School of Public Health. The Center for Health Security is dedicated to protecting people's health from the consequences of epidemics and disasters. Dr. Inglesby is also professor in the Department of Environmental Health and Engineering in the Johns Hopkins Bloomberg School of Public Health with a joint appointment in the Johns Hopkins School of Medicine.

Dr. Inglesby's work is internationally recognized in the fields of public health preparedness, pandemic and emerging infectious disease, and prevention of and response to biological threats. He is chair of the Board of Scientific Counselors, Office of Public Health Preparedness and Response, US Centers for Disease Control and Prevention (CDC). He is also chair of the National Advisory Council of the Robert Wood Johnson Foundation's National Health Security Preparedness Index. He was a member of the CDC Director's External Laboratory Safety Workgroup that examined biosafety practices of the CDC, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA) following high-profile laboratory incidents in federal agencies. He was on the 2016 Working Group assessing US biosecurity on behalf of the President's Council of Advisors on Science and Technology (PCAST). He has served on committees of the Defense Science Board, the National Academies of Sciences, the Institute of Medicine, and in an advisory capacity to NIH, BARDA, DHS, and DARPA.

Dr. Inglesby has authored or co-authored more than 115 publications, including peer-reviewed research, reports, and commentaries on issues related to health security and preparedness for epidemics, biological threats, and disasters. He is editor-in-chief of the peer-reviewed journal *Health Security*, which he helped establish in 2003. He was a principal editor of the *JAMA book Bioterrorism: Guidelines for Medical and Public Health Management*. He has been invited to brief White House officials from the past 4 presidential administrations on national biosecurity challenges and priorities, and he has delivered congressional testimony on a number of issues related to public health preparedness and biosecurity. He is regularly consulted by major news outlets for his expertise. He is a member of the Board of Directors of PurThread, a company dedicated to developing antimicrobial textiles.

Dr. Inglesby completed his internal medicine and infectious diseases training at Johns Hopkins University School of Medicine, where he also served as assistant chief of service in 1996-97. Dr. Inglesby received his MD from Columbia University College of Physicians and Surgeons and his BA from Georgetown University. He sees patients in a weekly infectious disease clinic.

Susan J. Koch, PhD

Susan J. Koch is an independent consultant, specializing in policy issues regarding arms reduction and the proliferation of weapons of mass destruction. She is a distinguished research fellow at the National Defense University Center for the Study of Weapons of Mass Destruction, a senior scholar at the National Institute for Public Policy, an associate faculty member in the Department of Defense and Strategic Studies at Missouri State University, and a member of the Department of Defense Threat Reduction Advisory Committee.

From 1982 until 2007, Dr. Koch held a series of senior positions in the White House National Security Council staff, the Office of the Secretary of Defense, the Department of State, and the US Arms Control and Disarmament Agency, focused on nonproliferation and arms reduction policy. Dr. Koch began her government career in the Directorate of Intelligence of the Central Intelligence Agency, analyzing West European political issues.

Dr. Koch has received the Presidential Distinguished Executive Award, the Presidential Meritorious Executive Award, the Department of Defense Distinguished Civilian Service Medal 5 times, the Department of Defense Nunn-Lugar Trailblazer Award, the Arms Control and Disarmament Agency Distinguished Honor Award, and the Department of State Meritorious Honor Award. Before her government service, she taught international and comparative politics at Mount Holyoke College and the University of Connecticut. Dr. Koch received a BA from Mount Holyoke College and an MA and PhD in political science from Harvard University.

Ambassador Ronald F. Lehman II, PhD

Ronald F. Lehman II is the counselor to the director of Lawrence Livermore National Laboratory. He is also the chair of the US Department of Defense Threat Reduction Advisory Committee (TRAC) and recently co-chaired the National Academy of Sciences' study on the future of Cooperative Threat Reduction. Since 1996, Dr. Lehman has been the chairman of the governing board of the International Science and Technology Center, a 39-nation intergovernmental organization. He was director of the US Arms Control and Disarmament Agency from 1989 to 1993, when START I, START II, the Chemical Weapons Convention, Conventional Forces in Europe, Open Skies, and other historic agreements were concluded.

Previously, he served in the US Department of Defense as assistant secretary for International Security Policy, in the State Department as ambassador and US chief negotiator on Strategic Offensive Arms (START I), and in the White House as deputy

assistant to the president for National Security Affairs. He has also served on the National Security Council staff as a senior director, in the Pentagon as deputy assistant secretary, on the senior professional staff of the US Senate Armed Services Committee, and in Vietnam, commissioned in the US Army.

In past years, he served on the Presidential Advisory Board on Proliferation Policy, on the State Department's International Security Advisory Board, as chair of the NATO High Level Group, on the governing board of the US Institute of Peace, and as a US representative to a number of United Nations disarmament and review conferences. Dr. Lehman formerly co-chaired the Policy Advisory Group on nonproliferation for the US Senate Foreign Relations Committee. He was on the Defense Science Board Task Forces on Globalization and Security, on Tritium, on Global Strike, and on Defense Against Biological Weapons. He is currently on the National Research Council Committee on US Air Force Strategic Deterrence Military Capabilities in the 21st Century and served on the National Research Council's Committee on Science, Technology, and Health Aspects of the Foreign Policy Agenda of the United States and on its Committee on Alternative Technologies to Replace Anti-Personnel Landmines.

Dr. Lehman was detailed to the administrator of the National Nuclear Security Administration as counterterrorism coordinator after the September 11, 2001, attacks. For the Department of Energy, he was the US-Snezhinsk Working Group co-chair for the Joint Russian-American Steering Committee on the Nuclear Cities Initiative. He served on the advisory panel for USSTRATCOM's Global Innovation and Strategy Center. He was on the Council on Foreign Relations Independent Task Force on the US Nuclear Posture. He was a public affairs fellow at the Hoover Institution on War, Revolution, and Peace at Stanford University and an adjunct professor at Georgetown University.

He received his PhD from Claremont Graduate University (1975) and his BA from Claremont McKenna College (1968). He is on the Board of Governors of the Keck Center for International and Strategic Studies at Claremont McKenna College, having served previously as its board chair. For many years, he was the director of the Center for Global Security Research at LLNL.

Diane Meyer, RN, MPH

Diane Meyer is a senior analyst at the Johns Hopkins Center for Health Security and a research associate at the Johns Hopkins Bloomberg School of Public Health. She is an associate editor of the peer-reviewed journal Health Security. Her primary research interests include emerging infectious diseases, improving outbreak preparedness and response, response to humanitarian crises, and hospital preparedness. At the Center,

Ms. Meyer contributes to a number of different projects that focus on public health, including improving health sector resilience to infectious diseases, improving public communication during public health emergencies, and improving outbreak response.

In 2016, Ms. Meyer earned an MPH degree from the Johns Hopkins Bloomberg School of Public Health (JHSPH), where she concentrated in infectious diseases. Her capstone focused on gastrointestinal anthrax from a global public health perspective. During her time at JHSPH, she worked as a research assistant for the Johns Hopkins Division of Infectious Diseases. While at JHSPH, she also earned a certificate in Public Health Preparedness.

Ms. Meyer has a BA in biology from Carroll College and a BSN from Georgetown University. Prior to attending graduate school, she worked as a burn and trauma intensive care nurse at a level 1 trauma center in Washington, DC.

Indira Nath, MD

Indira Nath is former senior professor and founder and head, Department of Biotechnology, All India Institute of Medical Sciences; former Raja Ramanna fellow and emeritus professor, National Institute of Pathology (ICMR), New Delhi, India; director of Lepra Research Centre, Hyderabad, India; and dean, Medical School, AIMST, Sungai Petani, Malaysia. She received an MBBS and MD (pathology) from the All India Institute of Medical Sciences (AIIMS), New Delhi, and later served on the faculty of AIIMS, making pioneering contributions to immunology research with her seminal work on cellular immune responses in human leprosy and a search for markers for viability of the leprosy bacillus, which is not cultivable. She has also mentored many MBiotech, MD, and PhD students and made contributions to education, medical and science policies, science integrity, and women scientists' issues at national and international levels. She continues to serve on committees of science and medical agencies/academies. She was co-chair for the InterAcademy Panel of Responsible Research Conduct and chair for the ICSU program on health and well-being in the changing environment.

Dr. Nath was a member of the Scientific Advisory Committee to Cabinet, Foreign Secretary INSA (1995-1997), council member (1992-1994 and 1998-2006), and vice president (2001-2003) of the Indian Academy of Sciences, Bangalore, and chairperson, Women Scientists Programme, DST (2003). She was conferred civil awards, notably: Padmashri, India (1999); Chevalier Ordre National du Merite, France (2003); and Silver Banner, Tuscany, Italy (2003).

Scientific recognition brought her both national and international awards, some notable ones being Raja Ramanna Fellowship (2010-14), SS Bhatnagar Medal of INSA 2013, SN Bose Professorship of the Indian National Science Academy (1998-2002), L'Oreal UNESCO Award for Women in Science (Asia Pacific) (2002), SS Bhatnagar Award (1983), and the Basanti Devi Amir Chand Award by ICMR (1994). She was elected a fellow of the Indian National Science Academy, Delhi; the National Academy of Sciences (India), Allahabad (1988); the Indian Academy of Sciences, Bangalore (1990); the National Academy of Medical Sciences (India) (1992); the Royal College of Pathology (1992); and the Academy of Sciences for the Developing World (TWAS) (1995). She was conferred a DSc (hc) in 2002 by the Pierre and Marie Curie University, Paris, France.

Maureen O'Leary, PhD, MBA, CBSP

Maureen O'Leary is the director of environmental health and safety at Dartmouth College. She received her undergraduate degree from Worcester Polytechnic Institute and obtained her MBA and PhD from the University of Massachusetts, Amherst. Before Dartmouth, she was a senior science advisor at MRIGlobal and served as the director of science integration in Almaty, Kazakhstan, for 15 months. While in Kazakhstan, she collaborated with US government and Kazakhstan ministry officials to provide advice on biosafety and biosecurity issues, policy, and laboratory design/training for the development of the Central Reference Laboratory there. Prior to working at MRIGlobal, she was the assistant director of academic safety and environmental health at the University of Massachusetts, Amherst.

Dr. O'Leary has been an active member of ABSA since 2004, was the president of the New England Biosafety Association (NEBSA) from 2010 to 2014, served on the board of the International Federation of Biosafety Associations (IFBA) from 2014 to2017, and was president of ABSA International in 2017.

S. R. Rao, PhD

S. R. Rao is advisor, Department of Biotechnology, Ministry of Science and Technology, Government of India. He has served in various positions in the department since 1989 and was associated with implementation of several national-level programs on R&D, technology development, and commercialization of biotechnology. Currently, his main responsibility is regulation of genetically engineered products including biosafety and biosecurity as a scientific member secretary of statutory body, namely Review Committee on Genetic Manipulation, mandated with scientific risk assessment and management under rules 1989 of Environmental Protection Act, 1986, of India.

Dr. Rao also serves as chairman of the Scientific Panel on GM Foods of the Food Safety Standards Authority of India (FSSAI), dealing with risk assessment of GM foods, and is also responsible for establishment of the Biotechnology Regulatory Authority of India through enactment of legislation that replaces the existing regulatory framework.

Dr. Rao specializes in core and cross-sectoral policy issues of biotechnology policy, development, regulation, safety, public private partnership, international relations, biotech R&D innovation and development, and public concerns and consensus building. He has published more than 40 scientific papers and is chief editor of the Journal of Biosafety Research, launched in 2016.

V. Siva Reddy, PhD

V. Siva Reddy is chief scientific officer, Biosafety Support Unit.

David A. Relman, MD

David A. Relman is the Thomas C. and Joan M. Merigan professor in Medicine, and Microbiology & Immunology at Stanford University, and chief of Infectious Diseases at the Veterans Affairs Palo Alto Health Care System. He is also senior fellow and director of a new biosecurity initiative at the Freeman Spogli Institute for International Studies at Stanford.

Dr. Relman was an early pioneer in the modern study of the human indigenous microbiota (microbiome). Most recently, his work has focused on human microbial community assembly and community stability and resilience. He was a founding member of the National Science Advisory Board on Biosecurity, a member of the Working Group on Biodefense for the President's Council of Advisors on Science and Technology at the White House, and served as president of the Infectious Diseases Society of America. He is a member of the National Academy of Medicine and currently serves on the Intelligence Community Studies Board at the National Academies of Science.

Ambassador Rakesh Sood, PhD

Rakesh Sood is a Distinguished Fellow at ORF. He has over 38 years of experience in the field of foreign affairs, economic diplomacy, and international security issues. He has a postgraduate degree in physics and in economics and defence studies.

Ambassador Sood has served in the Indian missions in Brussels, Dakar, Geneva, and Islamabad in different capacities and as deputy chief of mission in Washington, DC. He set up the Disarmament and International Security Affairs Division in the foreign ministry, which he led for 8 years until the end of 2000. During this period, Ambassador Sood was in charge of multilateral disarmament negotiations, bilateral dialogues with Pakistan, and strategic dialogues with other countries, including the US, the UK, France, and Israel.

Ambassador Sood then served as India's first Ambassador–Permanent Representative to the Conference on Disarmament at the United Nations in Geneva. He also chaired a number of international working groups, including those relating to negotiations on landmines and cluster munitions, and was a member of the UN Secretary General's Disarmament Advisory Board from 2002 to 2003. Ambassador Sood has served as special envoy of the Prime Minister for Disarmament and Non-proliferation Issues, Indian Ambassador to France, Indian Ambassador to Nepal, and Indian Ambassador to Afghanistan.

Since his retirement, he has been writing and commenting regularly in both print and audiovisual media on India's foreign policy, its economic dimensions, and regional and international security issues. He is a frequent speaker and contributor at various policy planning groups and think tanks in India and overseas.

Sudhanshu Vrati, PhD

Sudhanshu Vrati is executive director, Regional Centre for Biotechnology. Dr. Vrati received his PhD in biochemistry from the Australian National University and his MSc in microbiology from G. B. Pant University of Agriculture and Technology, Pantnagar.

APPENDIX C: SPEAKERS' BIOGRAPHIES

COL Matthew Hepburn, MD

Matthew Hepburn, MC, USA, joined DARPA as a program manager in 2013. His work aims to address the dynamic threats of emerging infectious diseases with potential impact on national security.

Prior to joining DARPA, Col. Hepburn served as the director of medical preparedness on the White House national security staff. Additional previous assignments include: chief medical officer at a level II medical facility in Iraq; clinical research director at the US Army Medical Research Institute for Infectious Diseases; exchange officer to the United Kingdom; and internal medicine chief of residents at Brooke Army Medical Center at Fort Sam Houston, Texas.

Col. Hepburn completed internal medicine residency and infectious diseases fellowship programs at Brooke Army Medical Center. He holds doctor of medicine and bachelor of science in biomedical engineering degrees from Duke University.

Hamid Jafari, MBBS

Hamid Jafari currently serves as the principal deputy director, Center for Global Health, at the Centers for Disease Control and Prevention (CDC).

Until February 2016, Dr. Jafari was the director of Global Polio Eradication at World Health Organization headquarters, Geneva, and the overall leader of the Global Polio Eradication Initiative. Before this appointment, Dr. Jafari served as the project manager of WHO's National Polio Surveillance Project in India (2007-2012), where he was the main technical advisor to the government of India on the implementation of the nation's large-scale polio eradication, measles control, and routine immunization activities and directed WHO's extensive network of more than 2,000 field staff.

Previously, Dr. Jafari served as director of the Global Immunization Division at the CDC, Atlanta. He has also served as the medical officer for polio eradication in the regional office of WHO for the Eastern Mediterranean in Egypt on assignment from CDC.

Dr. Jafari is a graduate of CDC's Epidemic Intelligence Service (EIS) program, class of 1992. He obtained his MBBS degree from Sind Medical College, Karachi University. He completed his residency training in pediatrics at Dartmouth Medical School and his pediatric infectious disease fellowship training at the University of Texas Southwestern

Medical Center, Dallas. Dr. Jafari completed a research fellowship at Harvard Medical School. He has been certified by the American Board of Pediatrics in the subspecialty of pediatric infectious diseases. Dr. Jafari has published more than 70 scientific papers and book chapters on pathogenesis of infectious diseases, polio eradication, and other vaccine-preventable diseases.

Eric Toner, MD

Eric Toner is a senior scholar with the Johns Hopkins Center for Health Security and a senior scientist in the Johns Hopkins Bloomberg School of Public Health, Department of Environmental Health and Engineering. He is an internist and emergency physician. His primary areas of interest are healthcare preparedness for catastrophic events, pandemic influenza, and medical response to bioterrorism. He is managing editor of the online newsletter Clinicians' Biosecurity News and is an associate editor of the journal *Health Security*, the leading peer-reviewed journal in this field.

Dr. Toner has authored scores of scholarly papers and government reports on healthcare and pandemic preparedness, and he has organized numerous meetings of national leaders on the topics of hospital preparedness, pandemic influenza, emerging infectious diseases, mass casualty disasters, biosecurity, biosurveillance, and nuclear preparedness. He has spoken at many national and international conferences on a range of biosecurity topics and appeared on a number of high-profile national television and news features on pandemic flu and bioterrorism preparedness. He has been the principal investigator of several US government–funded projects to assess and advance healthcare preparedness. Dr. Toner has served on a number of national working groups and committees, including the Institute of Medicine's Forum on Medical and Public Health Preparedness for Catastrophic Events.

Dr. Toner has been involved in hospital disaster planning since the mid-1980s. Prior to joining the Center, he was medical director of disaster preparedness at St. Joseph Medical Center in Towson, Maryland, where he practiced emergency medicine for 23 years. In 2003, he spearheaded the creation of a coalition of disaster preparedness personnel from the 5 Baltimore County hospitals, the health department, and the Office of Emergency Management. During this time, he also headed a large emergency medicine group practice and co-founded and managed a large primary care group practice and an independent urgent care center.

Dr. Toner received his BA and MD degrees from the University of Virginia. He trained in internal medicine at the Medical College of Virginia.

Kevin Yeskey, MD

Kevin Yeskey currently serves as the principal deputy assistant secretary to the Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health and Human Services (HHS). The office leads the nation in preventing, responding to, and recovering from the adverse health effects of man-made and naturally occurring disaster and public health emergencies.

Dr. Yeskey spent more than 24 years as a physician in the US Public Health Service (USPHS) and retired as a captain. In his PHS career, he served in various agencies in HHS, including the Indian Health Service, the Health Services and Resources Administration, and the Centers for Disease Control and Prevention. From 2007 to 2012, he was the deputy Assistant Secretary for Preparedness and Response and the director of the Office of Preparedness and Emergency Operations.
From 1986 to 1999, Dr. Yeskey was a member of the HHS Disaster Medical Assistance Team of the National Disaster Medical System (NDMS), serving as the team commander from 1993 to 1999. He was the chief medical officer for the NDMS program from 1998 to 1999. Dr. Yeskey also served as medical policy advisor to FEMA operations prior to retiring from the USPHS.

Dr. Yeskey received his bachelor's degree from Brown University and his medical degree from the Uniformed Services University of the Health Sciences. He has been board certified in emergency medicine for over 30 years.

APPENDIX D: MEETING AGENDA

The Johns Hopkins Center for Health Security
in collaboration with
DBT-UNESO Regional Centre for Biotechnology
Department of Biotechnology, Ministry of Science & Technology,
Government of India

September 6-7, 2018
James Monroe Room
St. Regis Hotel
923 16th Street, NW, Washington, DC

India-United States Biosecurity Dialogue
AGENDA

DAY 1: SEPTEMBER 6

08:30-09:00 **Breakfast in the Benjamin Franklin Room**

09:00-09:30 **Welcome, Introductions, Goals for Meeting**

Tom Inglesby, Director, Johns Hopkins Center for Health Security
S. R. Rao, Advisor, Department of Biotechnology, Ministry of Science & Technology, Government of India

09:30-10:30 **Dialogue Session 1: Shared Priorities and the Evolving Geopolitical Climate**

Opening Remarks: Ambassador Rakesh Sood and Ambassador Ronald F. Lehman II

Biosecurity concerns and challenges are continually evolving in the context of the geopolitical climate. In this opening session, we will discuss each country's biosecurity concerns, including natural, accidental, and deliberate biological threats. What are the most important shared national security and diplomatic priorities for the 2 countries? How will these priorities change, given the evolving geopolitical climate? Have these priorities changed since the last dialogue meeting in February? What collaborative opportunities between the US and India exist to address biosecurity concerns? Introductory speakers will provide opening remarks (5-7

minutes) on this topic, followed by a discussion by all participants.

10:30-10:45 **Coffee Break**

10:45-11:30 R**emarks by Kevin Yeskey**, Principal Deputy Assistant Secretary for Preparedness and Response, Office of the Assistant Secretary for Preparedness and Response, US Department of Health and Human Services

US Healthcare System Response to Infectious Disease Emergencies

11:30-11:45 **Group Photo**

11:45-12:45 **Lunch in the Benjamin Franklin Room**

12:45-13:45 **Dialogue Session 2: Medical Care Delivery During an Infectious Disease Outbreak**

Opening Remarks: Randeep Guleria and Dan Hanfling

How prepared are our health systems to respond to a large infectious disease outbreak? What partnerships, programs, and/or strategies exist to improve response during outbreaks? What lessons have been learned from previous responses? A representative from each country will provide opening remarks (5-7 minutes) on this topic, followed by a discussion by all participants.

13:45-14:30 **Remarks by Hamid Jafari**, Principal Deputy Director, Center for Global Health, US Centers for Disease Control and Prevention

Global Health Security Priorities—A US Perspective

14:30-14:45 **Coffee Break**

14:45-16:15 **Biosafety Case Studies and Group Discussion**

Opening Remarks: V. Siva Reddy, Maureen O'Leary, and Gigi Kwik Gronvall

During opening remarks, representatives will discuss biosafety incidents that have occurred in each of their countries (7-10 minutes). The presentations will be followed by a discussion on

biosafety. Topics addressed will include: How does your country approach these types of events? What has changed in the way your country would respond to similar events in the future? How would an investigation be conducted if a similar event did occur? What biosafety practices are necessary to prevent future incidents?

17:45 **Depart for Dinner**

18:00 **Dinner**
Woodward Table, 1426 H Street, NW, Washington, DC

DAY 2: SEPTEMBER 7

08:00-08:30 **Breakfast in the Benjamin Franklin Room**

08:30-09:30 **Dialogue Session 3: Future Concerns in Emerging Biotechnology**

Opening Remarks: Indira Nath and David A. Relman

How does your country address the potential misuse of emerging biotechnologies? Is there biotechnology research going on outside of your country that concerns you? What biotechnologies of the future are most concerning to you? How can the global community work to mitigate the potential misuse of these technologies? A representative from each country will provide opening remarks (5-7 minutes) on this topic, followed by a discussion by all participants.

09:30-09:45 **Coffee Break**

09:45-10:45 **Dialogue Session 4: New Technologies**

Opening Remarks: Sudhanshu Vrati and Susan Koch

What kinds of technologies are needed to ensure biosecurity in the ever-changing threat landscape? How can we create those technologies? What kinds of partnerships are needed? How can the expertise of private industry be harnessed to improve biosecurity? Introductory speakers will provide opening remarks (5-7 minutes) on this topic, followed by a discussion by all participants.

10:45-11:15 **Identifying Next Steps and Possibilities for US-India Collaboration**

Opening Remarks: S. R. Rao and Dave Franz

Are there issues that should be elevated to Track I consideration between India and the US? How can the US and India collaborate? What issues should be developed more deeply at the next meeting of the dialogue in February? Introductory speakers will provide opening remarks (5-7 minutes) on this topic, followed by a discussion by all participants.

11:15-12:15 **Lunch in the Benjamin Franklin Room**

12:15-14:15 **Modified Clade-X Tabletop Exercise**

Moderator: Tom Inglesby
During this modified tabletop exercise, participants will be presented with a fictional infectious disease outbreak that threatens national and global public health and economic and political security. Participants will advise US leadership on a number of important issues and challenges that may emerge during a novel pandemic.

14:15-14:30 **Coffee Break**

14:30-15:00 **Col. Matthew Hepburn**, Program Manager, Biological Technologies Office, Defense Advanced Research Projects Agency (DARPA)

DARPA's Investments in Biotechnology for National Security

15:00 **Walk to the White House**

16:00 **White House Meeting**

17:30 **Meeting Adjourns**

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