US-INDIA STRATEGIC DIALOGUE ON BIOSECURITY

Report on the fourth dialogue session

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Executive Summary

In February 2018, the Johns Hopkins Center for Health Security ("the Center") hosted a Track II dialogue on biosecurity between experts from the United States and the Republic of India. The dialogue, which was held in New Delhi, India, was organized in collaboration with the DBT-UNESCO Regional Centre for Biotechnology, an autonomous institute of the Department of Biotechnology (part of the Ministry of Science and Technology, Government of India). This was the fourth meeting of the dialogue, following previous engagements in Washington, DC, in September 2016 and November 2017, as well as a meeting in New Delhi, India, in February 2017.[1,2,3] 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.

Bilateral ties between the US and India have advanced considerably in recent years, given both countries' interests in preserving stability, prosperity, and security in the Indo-Pacific region. As such, officials in both countries have repeatedly affirmed their commitment to strengthening the US-India relationship amid evolving threat landscapes. In his inaugural address as the newest American ambassador to India, for example, Kenneth I. Juster identified 5 pillars underpinning the strong partnership between the 2 countries: economic and commercial relations; energy and the environment; regional cooperation; defense and counterterrorism; and science, technology, and health.[4] Notably, the latter 3 pillars also comprise a foundation for strengthening bilateral collaboration on biosecurity.

Recognizing the strategic convergence between the national security priorities of each country, the Center convened senior thought leaders, scientists, public health practitioners, and medical experts from the US and India to examine each country's approaches to a broad range of known and emerging biological threats, consider biosecurity priorities of mutual concern, and identify challenges and opportunities warranting further bilateral collaboration. 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 Track II 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 included:

- **Manish Kakkar, MD, MPH,** Senior Public Health Specialist, Public Health Foundation of India
- **Indira Nath, MD,** former Head and Senior Professor, Department of Biotechnology, AIIMS Delhi; former Raja Ramanna Fellow and Emeritus Professor, NIOP, Delhi
- **Abhijit Poddar, PhD,** Biosafety Support Unit, Government of India
- **Habibar Rahman, PhD,** Regional Representative for South Asia, International Livestock Research Institute
- **V. Siva Reddy, PhD,** Chief Scientific Officer, Biosafety Support Unit, Government of India
- **Chitra Sarkar, PhD,** Dean, All India Institute of Medical Sciences
- **Pranjali Vishwakarma, PhD,** Scientist, Biosafety Support Unit, Government of India

- **Sudhanshu Vrati, PhD,** Executive Director, Regional Centre for Biotechnology, Government of India

Members of the American delegation included:

- **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
- **Ambassador Laura S. H. Holgate,** Senior Nonresident Fellow, Belfer Center for Science and International Affairs, Harvard University
- **Maureen O'Leary, PhD, MBA, CBSP,** Director, Environmental Health & Safety, Dartmouth College
- **David J. Rakestraw, PhD,** S Program Manager, Global Health Security Principal Directorate, Lawrence Livermore National Laboratory
- **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: **S.R. Rao, PhD,** Advisor, Department of Biotechnology, Ministry of Science and Technology, Government of India; **Saurabh Dalal, MD,** Consultant, National Disaster Management Authority, Government of India; **Paban Kumar Dash, PhD,** Division of Virology, Defence Research and Development Establishment; **Kayla Laserson, ScD,** Country Director, Division of Global Health Protection, Centers for Disease Control and Prevention; **Christopher Rand Lewis,** India International Project Manager, Defense Threat Reduction Agency; **Rajalakshmi Muralidharan, PhD,** Scientist "D," Department of Biotechnology, Ministry of Science & Technology, Government of India; **Kanica Rakhra, PhD,** Consultant, Disarmament and International Security Affairs Division, Ministry of External Affairs, Government of India; **Pankaj Sharma,** Joint Secretary of Disarmament and International Security Affairs, Ministry of External Affairs; and **Nidhi Tewari,** Undersecretary of Disarmament & International Security Affairs, Ministry of External Affairs. Additionally, **Dr. Deepak T. Nair** met with the participants at the Regional Centre for Biotechnology (RCB) in Faridabad, Haryana, and offered an overview of RCB's organization and operations, research priorities, and facilities.

Participants identified several key topics warranting continued discussion at the next meeting of the bilateral dialogue, which will continue through 2018:

- Identifying priority biosecurity issues to jointly pursue, including One Health, healthcare delivery and hospital preparedness, biotechnology, basic science research, biosecurity policy research and evaluation, biosafety training, and other forms of biosecurity capacity building;

- Establishing a formal partnership between RCB and the Center that facilitates continued bilateral collaboration around studying, preventing, and mitigating biological threats of mutual concern;

- Developing a plan to ensure the sustainability of a formal bilateral partnership on biosecurity issues;

- Leveraging shared capabilities in simulation, computing, modeling, data, and analytics to stimulate meaningful advances in the life sciences; and

- Examining the feasibility of elevating future biosecurity dialogues to the Track I (ie, government-to-government) level.

The next meeting of the dialogue is tentatively scheduled to be held in Washington, DC, in September 2018.

Indian and US participants in the dialogue

Introduction

In February 2018, the Johns Hopkins Center for Health Security hosted the fourth meeting of a Track II dialogue (ie, a nongovernmental engagement) on biosecurity between the United States and the Republic of India. The meeting was held in New Delhi, India, and featured subject matter experts in biosecurity, biosafety, the life sciences and biotechnology, medicine, public health, and regional security.

Previous dialogue meetings were held in Washington, DC, in September 2016 and November 2017, and in New Delhi in February 2017. These meetings, along with the February 2018 engagement, were sponsored by the Project on Advanced Systems and Concepts for Countering WMD (PASCC, sponsored by the Defense Threat Reduction Agency, DTRA) of the US Air Force Institute for National Security Studies. 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.

India and the US are both committed to preventing and countering biosecurity threats, strengthening global health security, and building productive defense partnerships. For example, India's Department of Biotechnology has launched a major initiative in conjunction with the US National Institute of Allergy and Infectious Diseases to support vaccine research and development: the Indo-US Vaccine Action Program.[5] Additionally, the Trump Administration's National Security Strategy specifically names India as a "Major Defense Partner" of the United States and commends its emergence as a global player in commerce and defense.[6] In this vein, both countries also maintain a deep commitment to preserving stability in the Indo-Pacific region and countering threats of terrorism.

Given this mutual interest in deepening US-India bilateral engagement, the purpose of the February 2018 biosecurity dialogue meeting was to continue examining the US and India's respective approaches to biosecurity threats, pinpoint priorities of mutual concern, identify issues requiring greater government attention, and consider opportunities for joint research efforts. The meeting itself 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 national priorities and challenges in biosecurity, biosafety, and health security; public health and health system responses to epidemics; dual-use issues in the life sciences; national legislation and governance for key biosecurity issues; One Health; and future opportunities for biosecurity collaboration between the United States and India.

In addition to the invited participants and the Johns Hopkins Center for Health Security staff, several observers also attended the dialogue: **S. R. Rao, PhD,** Advisor, Department of Biotechnology, Ministry of Science and Technology, Government of India; **Saurabh Dalal, MD,** Consultant, National Disaster Management Authority, Government of India; **Paban Kumar Dash, PhD,** Division of Virology, Defence Research and Development Establishment; **Kayla Laserson, ScD,** Country Director, Division of Global Health Protection, Centers for Disease Control and Prevention; **Christopher Rand Lewis,** India International Project Manager, Defense Threat Reduction Agency; **Rajalakshmi Muralidharan, PhD,** Scientist "D," Department of Biotechnology, Ministry of Science & Technology, Government of India; **Kanica Rakhra, PhD,** Consultant, Disarmament and International Security Affairs Division, Ministry of External Affairs,

Government of India; **Pankaj Sharma,** Joint Secretary of Disarmament and International Security Affairs, Ministry of External Affairs; and **Nidhi Tewari,** Undersecretary of Disarmament & International Security Affairs, Ministry of External Affairs. Additionally, **Dr. Deepak T. Nair** met with the participants at the Regional Centre for Biotechnology (RCB) in Faridabad, Haryana, and offered an overview of RCB's organization and operations, research priorities, and facilities.

Dialogue participants underscored the value of the Track II format in encouraging open dialogue around complex biosecurity issues facing the United States and India, facilitating bilateral institutional collaboration, and building bridges between scientific communities of practice in both countries.

National Priorities and Challenges in Biosecurity, Biosafety, and Health Security

The first session of the dialogue examined the ways in which biosecurity interfaces with the life sciences, health care, the environment, and other security contingencies in the United States and India. Addressing the relationship between biosecurity and the life sciences, participants noted that emerging and evolving biological threats often function as an impetus for scientific innovation, citing recent efforts in both countries to develop a universal influenza vaccine. The Indian delegation also described how newly developed vaccines are integrated into India's universal vaccination programs. Conversely, some participants pointed out that scientific research and innovation may also carry inherent biosecurity risks. A group of Canadian scientists, for example, recently published details of an experiment involving synthetic reconstruction of horsepox virus—details of which could inform future efforts to synthesize other orthopox viruses *de novo*. Participants suggested that new, multidisciplinary approaches to scientific research and practice could lead to important advances in biological threat preparedness and response capabilities. One participant encouraged the delegations to consider the growing convergence of biology and chemistry, highlighting potential opportunities emerging at their nexus; in fact, research groups across India are already making headway in integrating biochemistry, cell and structural biology, and synthetic chemistry in studies of macromolecules.

In addition to the life sciences, the delegations also considered defense and economic contingencies shaping their respective national and regional biological threat landscapes. One participant remarked, "We should examine the current geopolitical climate and consider how it affects issues such as mass violence and nuclear preparedness. This [approach] should also factor into discussions around biological threats. Wherever we can find commonality or universality—particularly with respect to response capacities—the better off we'll be." In this vein, both countries have taken steps to assess their respective emergency response capacities in the context of threats emerging across the entire spectrum of naturally emerging, accidental, and deliberate biological risks. India, for example, has established a National Disaster Response Force capable of responding to chemical, biological, radiological, and nuclear threats in addition to natural disasters. Through its Integrated Disease Surveillance Program, India's National Centers for Disease Control and Prevention also plays important roles in detecting and coordinating public health responses to emergent threats. Cross-border threats also remain a major priority in India: One participant described ongoing challenges in monitoring zoonotic threats along India's shared borders with Myanmar, Pakistan, Bhutan, and Bangladesh, as well as between state lines. Another Indian participant noted that infectious threats increasingly traverse the urban-rural divide, recommending that ongoing One Health efforts in both countries should account for urbanization, trade, commerce, and rural development as potential catalysts of zoonotic outbreaks. Both groups also acknowledged the persistent threat of deliberate misuse of pathogens by terrorist groups.

Left to right: David Rakestraw, Indira Nath, and David Relman

Both the United States and India continue to support ongoing international efforts to counter biological threats. Following its entry into the Wassenaar Arrangement last year, India joined the Australia Group in January 2018, a multilateral export control regime that aims to assist member states (including the United States) in identifying exports that could potentially contribute to biological and chemical weapon development.[7] Additionally, Amandeep Singh Gill, India's ambassador at the Indian Mission to the Conference on Disarmament in Geneva, co-chaired the most recent meeting of the Biological Weapons Convention, where a delegation from India hosted a successful side event describing the country's approach to biosecurity. The United States has continued to support efforts to strengthen global health security across the world, including in India, which is focusing on 3 Global Health Security Agenda (GHSA) action packages.[*] Regarding continued international collaboration, an American participant remarked, "These are times when risks from emerging scientific and biological capabilities are much more palpable, real, and obvious. Risks have increased, but in today's political climate, it's much harder to talk about these risks because of the potential politicization of risk and polarization of dialogue." As such, participants highlighted the importance of proactive approaches to risk management in biosecurity: anticipating potential risks, improving science education, and encouraging more interaction between science and policy communities.

The first session of the meeting concluded with a discussion of strategies for achieving greater integration between biosecurity policy and science. Both delegations agreed that health should be considered a national security priority and offered examples of how their respective governments formulate national security policies addressing biological threats. In 2009, for example, the Obama Administration released Presidential Policy Directive-2, a strategy that outlines national approaches to countering both naturally emerging and deliberate threats.[8] Additionally, the United States is currently developing a national biodefense strategy and has enlisted both the National Academy of Sciences and the White House's Office of Science and Technology Policy to consider the policy implications of emerging biological threats. In India, meanwhile, RCB serves as an important link between scientists and the government.

Participants described several challenges in information sharing between policymakers and researchers, such as those associated with classified information. While some participants pointed out that declassifying all sensitive information could pose a threat in and of itself, others noted that limited transparency around intelligence on deliberate biological threats nevertheless creates information asymmetries that complicate threat characterization and perception among policymakers. Echoing previous dialogue meetings, several participants also called for greater collaboration between different communities of practice, noting that working in silos precludes a more comprehensive, holistic approach to countering biosecurity threats.

[*] India is contributing to the GHSA Action Packages on Antimicrobial Resistance and Immunization and is currently in the process of being confirmed as a contributor to the Biosafety & Biosecurity Action Package.

Public Health and Health System Responses to Epidemics

The delegations next considered public health and healthcare responses to epidemics, identifying health system elements critical for countering complex health threats. Many participants advocated for a systems-based approach to healthcare response, while also advocating for greater consideration of legal and ethical concerns in outbreak management strategies. One participant articulated 4 foundational components for implementing effective health system responses during an outbreak: building a broad foundation for medical readiness by encouraging collaboration among public health, EMS, emergency management, and hospitals; ensuring healthcare and medical response coordination, given separation between public health and healthcare delivery architectures; ensuring continuity of healthcare services; and building healthcare surge capacities.

With respect to enhancing healthcare capacities, participants identified 3 key aims: scaling population health strategies, reducing the costs of delivering care, and improving patient care experiences. A US speaker noted that the latter 2 aims do not always align with the first, underscoring the challenge of incentivizing private healthcare institutions to enhance medical readiness for large-scale events. Another speaker concurred, noting that many government hospitals in India cater largely to low- and middle-income populations, while private-sector hospitals generally retain a more affluent clientele; as such, emergency response and surge capacities at private-sector hospitals are not well-characterized. Still, India's healthcare response capabilities have matured considerably in recent years, with steps taken toward universal health coverage, improving patient registration, strengthening decision support systems and reporting mechanisms, and building regional networks of healthcare facilities. A member of the American delegation pointed out that while regionalization is important, both countries should continue to invest in efforts to build local healthcare response capacities that can support national needs during major crises.

Maureen O'Leary & Christopher Rand Lewis

In addition to building operational healthcare capacities, improving communication capabilities remains an important priority for both countries. India, for example—which recognizes 22 official languages—encounters major challenges in identifying and deploying critical messages to at-risk populations in the appropriate language. Several states, including Andhra Pradesh and Tamil Nadu, have developed communication systems, but these have yet to be tested. Both delegations agreed that both countries should work to strengthen such systems, as well as invest in additional risk communication efforts, such as training scientists and other technical experts to communicate with the public on biosecurity and health issues. One speaker also noted that communication between technical experts (eg, publishing best practices in the scholarly literature) might also prove beneficial to healthcare practitioners in both countries.

Both delegations agreed that data collection, sharing, and management capabilities comprise an important cornerstone of effective healthcare responses. Still, while there was broad agreement that

decision making during crises should be science-based and data-driven, existing data collection and management capacities in both countries remain limited. In the United States, for example, biosurveillance systems still do not allow plant, animal, and human health sectors to readily share data. Data management in India is becoming increasingly important, as evidenced by recent trends toward medical record digitization; data management also features prominently in national planning and preparedness efforts. A US participant also suggested—given the capabilities of India's information technology sector—that both countries examine the potential for integrating human language processing into their respective emergency response communication systems. Another speaker, however, stressed that new approaches to data collection and management should generate actionable information, and recommended that both countries assess whether existing systems can process data to inform decision making during a crisis in a timely fashion.

Dual-Use Issues in the Life Sciences

Dialogue participants examined emergent concerns at the nexus of life sciences research and biosecurity. Speakers from both countries highlighted the enormous potential for findings of cutting-edge research to spur advances in energy, health, and technology, while underscoring the need to mitigate risks stemming from their potential misuse. A participant from India, for example, described the potential role of gene drives in eliminating vectors of infectious diseases, but also noted that they could theoretically catalyze irreversible ecosystem changes. Another speaker from the United States pointed out that while there are many ways in which biology could do harm, biotechnology itself remains a critical tool in countering such risks.

Left to right: Deepak T. Nair, Paban Kumar Dash, Dan Hanfling, Gigi Kwik Gronvall, Siva Reddy, and Indira Nath

Given the level of technical expertise required to misuse biotechnology, participants emphasized the value of bottom-up approaches to biosafety and biosecurity, beginning at the institutional level. Several speakers from the United States stressed the importance of building institutional cultures of trust and responsible innovation, and strong leadership in laboratories. Another US participant applauded the idea, but identified potential barriers in operationalizing such an approach: "The issue is intention—how do you read the intention of a person who is doing an experiment? A lot of people will focus on the sequences that scientists work with, and we are not good at reading sequences and extrapolating to function. How do we create norms so that everyone is expected to think about these trade-offs between risk and scientific effectiveness?"

The delegations also considered whether there are any "red lines" that life scientists should never cross; here, several speakers from India underscored the value of institutional biosafety committees (IBCs) as safeguards against unethical or unsafe experiments. Others countered that while IBCs serve an important role, they focus predominantly on the physical risks associated with a given experiment—often to the exclusion of informational risks—and that new tools for addressing the informational risks associated with publishing the results of dual-use research are needed. One participant also advocated for gaining a broader perspective of risk perceptions, noting that "harm and spread" (ie, virulence and transmissibility) are the most frequently cited criteria for assessing risk among laypersons and researchers outside the life sciences.

The delegations also examined national policies for minimizing biosecurity risks in the life sciences. The US policy for addressing risks associated with dual-use research of concern (DURC), for example, applies to research supported by federal dollars, and identifies 7 types of experiments requiring oversight, as well as a compendium of tools for mitigating emergent risks.[9] Though both countries possess robust tools for identifying risks in the life sciences, one participant noted that national approaches to regulating novel technologies remain asynchronous. A US participant observed that private-sector funding drives the bulk of life sciences research in the United States. Accordingly, intellectual property considerations play a major role in dictating whether certain

experiments are performed, given the potential for commercializing resultant products. Still, some private-sector groups in the United States have developed their own codes of conduct for responsible research, supplemented by federal institutional guidance.

One speaker cited export controls as important examples of legal mechanisms for minimizing scientific risks. In the United States, for example, scientists are required to consider whether their research teams include foreign nationals; additionally, some dual-use technologies require their developers to obtain export control licenses.[10] Still, the participant cautioned that export controls are very blunt tools and that basic biology research is not considered to be subject to export rules or to "deemed export" considerations (ie, a release of controlled technologies to foreign persons in the United States). As such, promoting cultures of responsibility remains key in mitigating biosecurity risks in the life sciences. Participation in the GHSA, intersessional work at the Biological Weapons Convention, and continued bilateral engagement between countries leading efforts in the life sciences could help identify emergent risks and solutions by promoting peer-to-peer engagement between scientific communities of practice across the world.

National Legislation and Governance for Key Biosecurity Issues

The delegations examined the role of national legislation in strengthening biosecurity governance in each country. Participants identified several features of India's biological threat landscape shaping the country's approach to formulating legislation, including high population density, unmatched biodiversity, major trade and commercial interests, and a high potential for transboundary pathogen movement. The Indian delegation also noted the recent growth of the country's bioscience research enterprise across both the public and private sectors, highlighting the potential for risks to emerge from its still-nascent do-it-yourself biology (DIY Bio) community. Finally, one Indian participant noted that the country's decentralized public health model—in which health issues are handled predominantly at the state and district levels—could limit the scope of national legislation in biosecurity governance.

The participants' discussion of legislative approaches in the United States centered largely around the Federal Select Agent program. One speaker noted that the criteria for assessing the public health implications of select agents include the pathogenicity of the agent, its contagiousness, the availability of prophylactic or therapeutic countermeasures, anticipated impacts on vulnerable populations, and the likelihood of inciting mass panic in the event of an outbreak. Additionally, recent mishaps in the United States involving select agents—accidental shipments of live anthrax to facilities in 9 states and a military base in South Korea, failure to inactivate anthrax samples at a CDC BSL-3 laboratory, the discovery of smallpox vials at the National Institutes of Health, and the inadvertent transfer of *Burkholderia pseudomallei* into a breeding colony at Tulane University—underscore the importance of national guidelines and mechanisms for biosecurity and biosafety oversight. The most recent annual report of the Federal Select Agent program also highlighted the need to improve transparency and enhance communication efforts with both the public and the regulated community about the program itself, recent mishaps, and ongoing research efforts.[11]

Left to right: Maureen O'Leary, Christopher Rand Lewis, Deepak T. Nair, and S. R. Rao

Both countries have enacted national measures to govern the implementation of biosecurity and biosafety efforts. Key measures in the United States include the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which establishes federal protocols for responding to bioterrorism and other public health emergencies; the 2009 executive order, Strengthening Laboratory Biosecurity in the United States; and the 2010 executive order, Optimizing the Security of Biological Select Agents and Toxins in the United States.[12,13,14] More recently, in December 2017, the US government ended a moratorium on federally funded, gain-of-function research involving pathogens of pandemic potential, such as influenza viruses.[15]

India has taken similar steps to strengthen national oversight of potential biological risks, having enacted laws such as the Environmental Protection Act (1986), the Epidemic Diseases Act (1987), the Biological Diversity Act (2002), the Food Safety and Standards Act (2006), the Disaster Management Act (2005), and the Weapons of Mass Destruction and their Delivery Systems

(Prohibition of Unlawful Activities) Act (2005). Notable among these are the Environmental Protection Act, which outlines safety measures for the handling of environmental substances (including microorganisms). The Act also explicates regulatory procedures for products of genetic engineering; in this vein, India's biosafety legislation encompasses modern biotechnological advances (such as genome editing) and is jointly implemented by the Ministries of Home Affairs, Health & Family Welfare, Defense, External Affairs, Science & Technology, and Agriculture. In 2017, India also updated its Regulations and Guidelines for Recombinant DNA Research and Biocontainment, which clarifies practices for handling hazardous biological materials and offers biosafety recommendations for laboratories performing biological research.[16] The Ministry of Environment's Risk Analysis Framework (2016) offers further guidance on assessing risks relating to human and environmental health, particularly those stemming from genetically modified organisms.[17]

The delegations next identified critical gaps in existing national guidelines for biosafety and biosecurity. Several speakers underscored the potential value of harmonizing regulated pathogen or "select agent" criteria between countries, pointing out that synchronized standards could facilitate bilateral scientific collaboration. Others highlighted the importance of supporting risk-based approaches to biosafety, but cautioned that regulations should not hinder responsible research, nor be overly prescriptive. Speakers from both countries agreed that the United States and India should focus on strengthening leadership infrastructure and increasing transparency as a means of promoting cultures of trust and responsibility at institutions conducting high-consequence life sciences research. Finally, both delegations agreed that their respective national governments should issue guidance addressing oversight strategies for emerging biotechnologies.

One Health Security

Dialogue participants considered challenges and opportunities in One Health, a public health paradigm that recognizes the interconnectedness of human, animal, and environmental health. Participants described One Health as an important component of both human and national security and agreed that ongoing efforts in the life sciences and biosecurity could concurrently spur advances in One Health. Both countries currently face considerable challenges at the nexus of human and animal health. India, for example, has one of the largest livestock populations in the world, with nearly as many poultry as people. The country is also a hotspot for many emerging zoonoses, and several such diseases—including brucellosis, foot-and-mouth disease, and Kyasanur Forest disease—have become endemic, creating considerable economic losses. Though India's zoonotic threat landscape differs from that of the United States, both delegations identified the shared challenges posed by the increasingly frequent movement of animals, plants, and humans across international borders and the associated health risks.

Participants also identified several barriers associated with preparing for and responding to zoonotic threats. One participant from India noted that despite robust surveillance efforts—India has completed forecasting analyses for 13 diseases well in advance of their emergence—predicting the arrival of new zoonoses and characterizing their impacts on human health remains challenging, given that zoonoses typically emerge slowly. Vaccine development presents additional regulatory challenges; one participant noted, for example, that despite a large burden of brucellosis in India, vaccine candidates cannot be tested in-country due to prohibitions on cattle experimentation. Several Indian participants also highlighted challenges in delivering vaccines, such as cold chain preservation in high-risk, resource-poor settings. Participants from both countries underscored the difficulties of securing programmatic and financial support for tackling such "last mile" challenges, recommending that One Health research efforts align more closely with demonstrated challenges in public health policy implementation and practice. However, an American participant pointed out that research incentives might differ in the United States, where the agriculture sector is built on a large business model.

Participants next considered strategies for operationalizing One Health in India. Both delegations highlighted the importance of incorporating animal health considerations into public health and medical curricula to promote multidisciplinary collaboration among early-career practitioners. Additionally, groups across the country have already formed partnerships aimed at coordinating One Health efforts, including the National Centre for Disease Control, the Ministry of Health and Family Welfare, the Indian Council on Medical Research, and the Public Health Foundation of India. Health authorities in India have also taken steps to collaborate with their counterparts in SAARC (South Asian Association for Regional Cooperation) countries on One Health issues.

Participants also underscored the ways in which continued bilateral engagement in GHSA activities could complement and enhance ongoing One Health efforts. In 2015, for example the United States awarded $15 million to institutions across India working to mitigate a range of infectious disease threats, including the National Institute of Veterinary Epidemiology and Disease Informatics (NIVEDI) and Manipal University.[18] NIVEDI currently leads a project aiming to expand anthrax detection and response capacities in Karnataka and Assam, while Manipal University is coordinating a surveillance study on acute febrile illness associated with Kyasanur Forest disease, anthrax, brucellosis, and Zika virus disease, among others.[19] Finally, both the United States and India jointly support the GHSA's antimicrobial resistance action package. India also supports the immunization action package, while the United States is among the leaders for action packages addressing zoonotic diseases, national laboratory systems, and medical countermeasures and personnel deployment.

Future Priorities

Both delegations expressed strong support for continued bilateral engagement on biosecurity issues. As such, the fifth meeting of the dialogue is tentatively scheduled to be held in Washington, DC, in the fall of 2018. The dialogue participants have already identified several topics meriting continued discussion. These include, but are not limited to:

- Identifying priority aims to jointly pursue, such as One Health, healthcare delivery and hospital preparedness, biotechnology, basic science research, biosecurity policy research and evaluation, biosafety training, and other forms of biosecurity capacity building;

- Establishing a formal partnership between RCB and the Center that facilitates continued bilateral collaboration around studying, preventing, and mitigating biological threats of mutual concern;

- Developing a plan to ensure the sustainability of a formal bilateral partnership on biosecurity issues;

- Leveraging shared capabilities in simulation, computing, modeling, data, and analytics to stimulate meaningful advances in the life sciences; and

- Examining the feasibility of elevating future biosecurity dialogues to the Track I (ie, government-to-government) level.

The dialogue participants also identified several action items to be pursued in the interim period before the next meeting. The Indian delegation outlined steps to formalize RCB, including establishing an executive body comprised of ministerial partners from across government and creating a scientific advisory committee to oversee programmatic work. Both delegations also considered options to formalize a partnership between RCB and the Center, identify research priorities, and develop a corresponding work plan.

Appendix A: Dialogue Participants

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* (formerly *Biosecurity and Bioterrorism*), 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* (formerly *Biosecurity and Bioterrorism*). 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.

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.

Ambassador Laura S. H. HOLGATE, MS

Laura S. H. Holgate is currently a consultant to the Third Way's project on advanced nuclear reactors and national security and to the Pacific Northwest National Laboratory. Ambassador Holgate served as US Representative to the Vienna Office of the United Nations and the International Atomic Energy Agency from July 11, 2016, to January 20, 2017. The United States

Mission to International Organizations in Vienna works with 7 major organizations of the United Nations system based in Vienna: the International Atomic Energy Agency; the UN Office on Drugs and Crime; the Preparatory Commission of the Comprehensive Test Ban Treaty Organization; the UN Office of Outer Space Affairs; the Wassenaar Arrangement; the UN Commission on International Trade Law; and the UN Industrial Development Organization. In this role, Ambassador Holgate advanced President Barack Obama's commitment to design and implement global approaches to reduce global threats and seize global opportunities in the areas of nuclear nonproliferation, nuclear security, verification of the Iran deal, nuclear testing, counterterrorism, anti-corruption, drug policy, export control, and the Nuclear Suppliers Group. She also promoted gender balance in the staff and programming of the Vienna-based international organizations.

Ambassador Holgate was previously the special assistant to the president and senior director for Weapons of Mass Destruction Terrorism and Threat Reduction on the National Security Council. In this role, she oversaw and coordinated the development of national policies and programs to reduce global threats from nuclear, biological, and chemical weapons; detect, identify, secure, and eliminate nuclear materials; prevent malicious use of biotechnology; and secure the civilian nuclear fuel cycle. She was also the US Sherpa to the Nuclear Security Summits and co-led the effort to advance the President's Global Health Security Agenda.

From 2001 to 2009, Ambassador Holgate was the vice president for Russia/New Independent States Programs at the Nuclear Threat Initiative. Prior to that, she directed the US Department of Energy's Office of Fissile Materials Disposition from 1998 to 2001, and was special coordinator for Cooperative Threat Reduction at the Department for Defense from 1995 through 1998, where she provided policy oversight of the "Nunn-Lugar" Cooperative Threat Reduction program.

Ambassador Holgate received a bachelor of arts degree in politics from Princeton University and a master of science degree in political science from the Massachusetts Institute of Technology; she spent 2 years on the research staff at Harvard University's Center for Science and International Affairs at the Kennedy School of Government. Ambassador Holgate is a member of the Strategic Advisory Group to Oak Ridge National Laboratory. She serves on the Steering Group of the Fissile Material Working Group and on the Szilard Advisory Board of the Center for Arms Control and Nonproliferation. She is a Distinguished Visitor at the Institute for International Science and Technology Policy at the Elliott School of Public Policy at the George Washington University. She is a past president of Women in International Security and a member of the Council on Foreign Relations.

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.

Manish KAKKAR, MD, MPH

Manish Kakkar is senior public health specialist, Public Health Foundation of India (PHFI). Dr. Kakkar joined PHFI in June 2006, coordinating functions of the communicable disease unit and providing technical support for research and training to national and state governments on priority communicable disease issues.

He has done niche work in incorporating surveillance, training, and research, aimed at crystallizing and integrating a strong public health approach to emerging and zoonotic infections. Launching the Roadmap to Zoonoses Initiative (RCZI) in India in 2008 as a national initiative on research, capacity building, and health promotion for prevention and control of zoonotic infections in India, he has been mobilizing support and consensus around creating a multidimensional, multisectoral, and integrated system-wide approach to the human-animal interface.

As member of the international expert group on WHO's Strategy for Management of Zoonotic Public Health Risks at Human-Animal Interface, he provided input on the global strategy, and, by virtue of being part of CDC/WHO/OIE/FAO's international expert group on operationalizing the One Health approach, he is expanding his understanding of infectious diseases and zoonotic infections, especially in the developing country context.

As a member of the One Health Alliance of South Asia (OHASA) and as team leader for a multi-country Ecohealth project of IDRC on Japanese Encephalitis in South Asia, he hopes to bring a more refined and sharper focus to the kind of interventions that can be planned and implemented for zoonoses control in India.

His other work at PHFI involves developing curricular content and learning modules for infectious disease–related components of MPH and DPH programs. He is working on Bihar Evaluation of Social Franchising and Telemedicine and has been guest editor for the *Asia Europe Journal*'s issue on migration (currently in press). He is also member of the National Task force set up to assess, review, and suggest measures on antimicrobial resistance.

Dr. Kakkar started his career as a senior resident doctor in the Department of Microbiology in MAMC and later moved to WHO's India Country Office, first as national consultant (Laboratory Surveillance) and then as national professional officer (Laboratory Surveillance).

Dr. Kakkar received his MBBS from the University College of Medical Sciences, Delhi, his MD from Maulana Azad Medical College (MAMC) in New Delhi, and his master's in public health from Harvard University, Boston.

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.

Abhijit PODDAR, PhD

Abhijit Poddar is working as scientist (microbiology) at the Biosafety Support Unit (BSU) established under the Regional Centre for Biotechnology, Department of Biotechnology, Government of India. In this position, Dr. Poddar performs regulatory risk assessment and risk analysis and examines proper risk management strategies for application on GE organisms and products thereof for the purpose of its import, export, exchange, and release. He has prepared several reports on risk assessment and risk management to facilitate decision making by the competent regulatory authorities in India. In addition, Dr. Poddar is engaged in the development of several guidelines and protocols for generating biosafety data to address the challenges raised by the emerging areas of biotechnology.

Dr. Poddar received his PhD (Sc) from Jadavpur University in 2013 for his work on one hyperthermostable microbial enzyme. Before joining BSU, he was actively involved in research on microbial systematic and bio-prospecting of extremophiles at the Institute of Life Sciences, India. Dr. Poddar has authored many national and international publications and successfully described 7 novel bacterial species, including 1 genus amendment.

Habibar RAHMAN, PhD

Habibar Rahman is deputy director general (Animal Science Division) at the Indian Council of Agricultural Research (ICAR) New Delhi. He has a BVSc & AH from Assam Agricultural University, an MVSc from Punjab Agricultural University, and a PhD in microbiology and public health from GB Pant University of Agriculture and Technology. He pursued his postdoctoral training at the Robert Koch Institute, Germany, and University of Utah, Salt Lake City, USA.

Dr. Rahman's career includes senior roles in the ICAR-National Institute of Veterinary Epidemiology & Disease Informatics (NIVEDI), the ICAR Research Complex of NEH Region, Gangtok and Shillong, and he was head of the division, Veterinary Public Health, Indian Veterinary Research Institute, Bareilly. Dr. Rahman has over 30 years of global research experience covering many aspects of veterinary science, especially the role of animal health for improved productivity. He has a substantial publication record, has supervised many students, and received a number of national awards.

David J. RAKESTRAW, PhD

David Rakestraw is currently the S Program manager at Lawrence Livermore National Laboratory (LLNL) in the Global Security Principal Directorate with responsibilities for chemical, biological, and explosive countermeasures programs. He received a BS degree in chemistry from Ohio Northern University (1983) and a PhD in chemistry from Stanford University (1988).

From 1988 to 2000, Dr. Rakestraw worked at Sandia National Laboratories, where he was engaged in a wide range of research and development activities. Early research activities included developing nonlinear spectroscopic methods for trace species detection. During the 1998-99 academic year, Dr. Rakestraw took a sabbatical from Sandia to become a consulting associate professor of chemistry at Stanford University.

In 2000, Dr. Rakestraw left his position as a distinguished member of the technical staff at Sandia to co-found Eksigent Technologies. At Eksigent Technologies, Dr. Rakestraw developed microscale chemical HPLC systems, which are now sold worldwide for application in drug discovery and development. Dr. Rakestraw joined LLNL in July 2006 as the chief technologist in the Chemistry, Materials, Earth and Life Sciences Directorate before transitioning to his current role in 2008. Dr. Rakestraw holds 18 US patents and has authored more than 65 peer-reviewed scientific publications.

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.

Sanjana RAVI, MPH

Sanjana Ravi is a senior analyst at the Johns Hopkins Center for Health Security and visiting faculty at the Johns Hopkins Bloomberg School of Public Health. She is an associate editor of the peer-reviewed journal *Health Security* (formerly *Biosecurity and Bioterrorism*) and editor of *Preparedness Pulsepoints,* a weekly news brief covering federal action in health security. Her primary research interests include global health systems, infectious disease emergencies, responses to humanitarian crises, and the intersections between health, security, and human rights.

Ms. Ravi's work focuses on understanding and improving public health and healthcare responses to a range of threats. She is involved with Center projects examining state and local preparedness, including an effort studying the roles of healthcare coalitions in enhancing emergency preparedness and another exploring risk communication challenges around emergency medical countermeasure distribution. Ms. Ravi has also written on public health preparedness in nuclear emergency planning zones in the United States, legal mechanisms for compensating victims of nuclear disasters, and the response and recovery challenges associated with catastrophes resulting in mass population displacement. Between 2014 and 2016, she helped plan the first ever strategic dialogues on biosecurity policy between the United States and partners in Singapore, Malaysia, Indonesia, and India. In addition, she has conducted independent research on the sociocultural dimensions of the 2014 Ebola outbreak in Liberia, connections between health threats and development challenges, and the impacts of conflict and violence on global healthcare delivery.

In 2013, Ms. Ravi received a master of public health degree in infectious disease management, intervention, and community practice from the University of Pittsburgh, where her thesis explored the dynamics of blood product management during public health emergencies. She also contributed to research on nosocomial infections and public health education initiatives in Pittsburgh and served as a Global Impact Fellow with Unite for Sight in Tegucigalpa, Honduras, delivering basic eye care to underserved regions. Ms. Ravi earned a BA in biology from Saint Louis University in 2011.

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.

Chitra SARKAR, PhD

Chitra Sarkar is dean, All India Institute of Medical Sciences.

Pranjali VISHWAKARMA, PhD

Pranjali Vishwakarma is a scientist, Biosafety Support Unit, National Productivity Council.

Sudhanshu VRATI, PhD

Sudhanshu Vrati trained as a virologist at the Australian National University, Canberra, as a doctoral student and subsequently at the CSIRO, Sydney, as a postdoctoral research scientist. He worked at the National Institute of Immunology, New Delhi, from 1987 to 2013, where his group primarily

focused on the biology of Japanese encephalitis virus (JEV) with research aimed at understanding virus replication, and designing antivirals and vaccine candidates. Dr. Vrati has been the first dean of the Translational Health Science and Technology Institute (2010-2016), where he headed the Vaccine and Infectious Disease Research Center. Since October 2016, Dr. Vrati has been working at the Regional Centre for Biotechnology (RCB) as its executive director. Dr. Vrati's research has focused on understanding RNA virus replication and designing antivirals and vaccine candidates against Japanese encephalitis (JE) and rotaviral diarrhea.

Appendix B: Meeting Agenda

India-US Strategic Dialogue on Biosecurity

The Johns Hopkins Center for Health Security
in collaboration with
DBT-UNESCO Regional Centre for Biotechnology

8-9 February 2018
Imperial Hotel, New Delhi, India

8 February 2018
Emily Eden & Hodges Room

9:00-9:30 **Welcome, Goals for the Meeting, and Introductions**

Prof. Sudhanshu Vrati, Executive Director, DBT-UNESCO Regional Centre for Biotechnology
Dr. Tom Inglesby, Director, Johns Hopkins Center for Health Security

9:30-11:00 **Session One: National Priorities and Challenges in Biosecurity, Biosafety, and Health Security**
Health security concerns and challenges continue to evolve over time. In this opening session, we will discuss how each country currently views biosecurity threats —natural, accidental, and deliberate—and opportunities for strengthening national efforts to respond. Have there been changes or new developments over the past year of dialogue? What are the main elements of our respective national programs to prevent and respond to major biological threats? How was the outcome of the Biological Weapons Convention perceived, and what lies ahead for the intersessional process? What geopolitical issues affect these priorities? To what extent are biological risks perceived to come from states vs. groups or individuals? This is also an opportunity for new participants in the dialogue to share high-level perspectives on these issues. A representative from each country will provide opening remarks (5-7 minutes) on this topic, followed by a discussion among all participants.

Opening Remarks: V. Siva Reddy and Tom Inglesby

11:00-11:15 Coffee Break

11:15-12:45 **Session Two: Public Health and Health System Response to Epidemics**
In this session, participants will focus on how the Indian and US medical and public health systems detect and respond to new outbreaks of infectious disease. From the earliest cases, when the cause of an epidemic (natural, deliberate, or accidental) may be unclear, through the transition into a concerted public health system response, the differences and commonalities of approaches in India and the US will be discussed.

Topics of discussion include the responsibilities of national vs. local government agencies and the roles of hospitals and the public health system. What are the key Indian and US systems for disease surveillance? What is the process for communicating with the public during epidemics? A representative from each country will provide opening remarks (5-7 minutes) on this topic, followed by a discussion among all participants.

Opening remarks: Chitra Sarkar and Dan Hanfling

12:45-13:45 Lunch in meeting room

13:45-15:00 **Session Three: Dual-Use Issues in the Life Sciences**
Emerging biotechnologies are profoundly important to India and the United States for medicine, health, and economic development. These developments are accompanied by the opportunity to develop more effective medical countermeasures and public health measures (such as using gene drives to reduce mosquito populations), but also increased risks for the potential for new weapons and for consequential accidents. How do the United States and India see the future of biotechnology changing the potential risks of misuse? How does each country manage these new risks? What current Indian and US policies address dual-use research in the life sciences? Are these approaches sufficient for dual-use issues that may emerge in the future? A representative from each country will provide opening remarks (5-7 minutes) on this topic, followed by a discussion among all participants.

Opening Remarks: Pranjali Vishwakarma and Laura Holgate

15:00-15:45 Group photo and coffee break

15:45-17:15 **Session Four: National Legislation and Governance for Key Biosecurity Issues**
This session will illuminate the approaches that the United States and India have taken with respect to biosafety and biosecurity governance, focusing on the passage and implementation of national legislation. This will encompass a discussion of relevant laws in both countries, including those addressing pathogen control (eg, the US Select Agent Regulations), emergency preparedness for bio-events (eg, the US's Pandemic and All Hazards Preparedness Act), biosafety, and other issues. Participants will also discuss future plans for biosecurity and biosafety governance and legislation.
15-minute presentation by Maureen O'Leary on US legislation
15-minute presentation by Abhijit Poddar on Indian legislation
Group discussion

17:30-18:30 Cocktail Hour at 1911 Bar, Imperial Hotel

18:30 Dinner at Spice Route Restaurant, Imperial Hotel

9 February 2018
Daniells Tavern

9:00-9:45	**"Do-It-Yourself" (DIY) Biology: Challenges and Potential Benefits to Health Security** Presentation by Gigi Gronvall, followed by group discussion
9:45-10:30	**Gene Drives and Emerging Risks** Presentation by David Relman, followed by group discussion
10:30-10:45	Coffee Break
10:45-12:00	**Session Five: One Health Security** A comprehensive approach to health security requires the principles of "One Health" to address natural and deliberate threats against humans, animals, and the environment. While the importance of One Health has been acknowledged for a long time, it has proven challenging to integrate such concerns across government departments, funding sources, and expertise. This session will focus on the key commonalities between human and animal emerging disease prevention and response. It will focus on the extent to which One Health approaches are being pursued in the United States and India. What would stronger One Health look like in practice? Are other countries building One Health programs in ways that are worth emulating? A representative from each country will provide opening remarks (5-7 minutes) on this topic, followed by a discussion among all participants. **Opening Remarks**: Dave Franz and Habibar Rahman
12:00-13:00	Lunch in meeting room
13:00-14:15	Transit by bus to visit and meetings at DBT-UNESCO Regional Centre for Biotechnology, Faridabad, Haryana
14:15-15:00	Introduction to RCB activities and presentation on proposed scientific and technical inter-institutional (RCB-JHCHS) partnership.
15:00-16:00	**Session Six: Ideas for Substantial Biosecurity Science or Program Collaboration Between India and the United States** Participants have previously agreed that meaningful, bilateral science collaboration should be explored, either via the India-US dialogue itself or through other mechanisms of US-India collaboration, using the dialogue as a catalyst. In this session, participants will identify shared biosecurity priorities that might benefit from bilateral collaboration, examine elements of previously successful collaborative efforts in this realm, and consider opportunities for future cooperation on biosecurity issues. What capacities and priorities do the United States and India each bring to the table, and how might they complement one another? A representative from each country

	will provide opening remarks (5-7 minutes) on this topic, followed by a discussion among all participants.
	Opening Remarks: Indira Nath and Dave Rakestraw
16:00-16:30	**Future Priorities.** Participants will propose new issues and topics of discussion for future dialogue meetings.
16:30	Meeting Adjourns
16:30-17:30	Return by bus to Imperial Hotel

Appendix C: References

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