# India-US Strategic Dialogue on Biosecurity

## Johns Hopkins Center for Health Security


Report on the second dialogue session held between the United States & India

Report Release:
May 2017

## Johns Hopkins Project Team

**Sanjana J. Ravi, MPH**
Senior Analyst

**Thomas V. Inglesby, MD**
Chief Executive Officer and Director

**Gigi Kwik Gronvall, PhD**
Senior Associate
Principal Investigator

## Project Sponsor

**Project on Advanced Systems and Concepts for Countering Weapons of Mass Destruction (PASCC)**
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 of 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.

# Table of Contents

## Executive Summary

In February 2017, the Johns Hopkins Center for Health Security hosted a Track II (non-governmental) dialogue on biosecurity between experts in India and the US in New Delhi, India. The meeting was held in collaboration with the Department of Biotechnology within the Indian Ministry of Science and Technology. This was the second meeting of the biosecurity dialogue; the first was held in Washington, DC in September, 2016.* The effort is supported 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.

There are multiple goals for the dialogue: to expand knowledge and understanding between India and the US about biological threats; increase awareness and probability of exchanges for early warning and detection of unusual biological events; deepen relationships between participants to serve as technical resources to each other going forward; and to identify issues that may warrant official government-to-government priority. Importantly, bilateral ties between the United States and India, the world's two largest democracies, are of great consequence to global security, defense, and health. In an era of rapid globalization, major geopolitical transitions, and evolving national security landscapes, partnership between the two nations on critical issues in biosecurity and biodefense remains especially important. Developing shared bilateral understandings of and approaches to tackling hard problems in biosecurity promises to strengthen trust and cooperation between the US and India, enhance health and security in both nations, and facilitate productive collaborative efforts between Indian and American policymakers, national security experts, life scientists, public health professionals, and healthcare practitioners.

Participants agreed that strengthening bilateral engagement would advance biosecurity in both India and the US. Participants also discussed and shared views about a range of biosecurity topics, such as the need for risk assessments to identify biosecurity threats and outcomes of concern, the technologies and modeling approaches required to characterize and counter biological threats, and the challenges of regulating pathogens. Several participants called out the need for additional professional disciplines to be brought into the biosecurity discussion, such as agriculture and climatology. A high priority was placed on strengthening communication between technical experts and policymakers, building a culture of trust in biological laboratories, and creating additional opportunities for US and Indian biosecurity experts to exchange knowledge and share best practices.

* The report from the first meeting can be found here: http://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2016/India%20US%20Biosecurity%20Dialogue_FINAL_Oct%2018.pdf

Dialogue participants represented academia, government, and industry in the US and India, and included experts in biosecurity, biosafety, biodefense, the life sciences, regulatory policy, global health security, and regional security.

Members of the Indian delegation included:

- **Rakesh Bhatnagar, PhD**, Professor, JC Bose National Fellow, Jawaharlal Nehru University
- **Jaishree Garhyan, PhD**, Jawaharlal Nehru University
- **Ravi Khetarpal, PhD**, Regional Advisor, Strategic Science Partnerships, Centre for Agriculture and Biosciences International, South Asia
- **Subodh Kumar, PhD**, Scientist "F", Defence Research & Development Establishment, Defence Research & Development Organization, Ministry of Defence, Government of India
- **Jayati Mullick, PhD**, Scientist "E"; Group Leader, Avian Influenza; In-charge, High Containment Laboratory, National Institute of Virology
- **Indira Nath, MD**, Former Head & Senior Professor, Department of Biotechnology, AIIMS Delhi, Former Raja Ramanna Fellow & Emeritus Professor, NIOP Delhi
- **S.R. Rao, PhD**, Advisor, Ministry of Science & Technology, Government of India
- **Balachandran Ravindran, PhD**, Professor Emeritus, Department of Biotechnology, Institute of Life Sciences
- **Siva Reddy, PhD**, Chief Scientific Officer, Biosafety Support Unit, NPC Building
- **Ambassador Rakesh Sood, PhD**, Observer Research Foundation
- **Sudhanshu Vrati, PhD, FASc, FNASc**, Executive Director, Regional Centre for Biotechnology, NCR Biotech Science Cluster

Members of the US delegation included:

- **Sarah R. Carter, PhD,** Principal, Science Policy Consulting LLC
- **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
- **Maureen O'Leary, PhD, MBA**, Director, Environmental Health & Safety, Dartmouth College, and president-elect of the American Biological Safety Association (ABSA)
- **David Rakestraw, PhD**, S Program Manager, Global Health Security Principal Directorate, Lawrence Livermore National Laboratory

**Dr. Krishnaswamy VijayRaghavan** (Secretary, Department of Biotechnology, Ministry of Science & Technology, Government of India), gave a keynote presentation about countering biological threats without stifling scientific and technological progress, underscoring the importance of supplementing big data and mathematical modeling approaches with a deep understanding of the social contexts of disease transmission. He pointed to the importance of the Department of

Biotechnology in India, established over thirty years ago when India recognized how transformative biotechnology would be for its future.

Several observers also attended the dialogue: **Anand Kamavisdar**, Director, Americas Division, Ministry of External Affairs, Government of India; **Daniel L. Garcia**, Senior Lab Advisor, Centers for Disease Control & Prevention (CDC); **Shaun Hayeslip**, International Security and Nonproliferation/Regional Affairs, Department of State; **Kayla Laserson**, Country Director, Division of Global Health Protection, CDC; **Evelyn F. Ostrom**, Chief, Regional Cooperative Engagement Office, Pacific-Southeast Asia, Defense Threat Reduction Agency, US Embassy; **Amit Parikh**, Department of Biotechnology, Ministry of Science & Technology, Government of India; **Abhijeet Poddar**, Scientist, Biosafety Support Unit, Regional Center for Biotechnology, Department of Biotechnology, Ministry of Science & Technology, Government of India; and **Namrata Singh**, Centre for Agriculture and Biosciences International (CABI).

Additionally, **Dr. Dinakar M. Salunke** (Director, International Center for Genetic Engineering and Biotechnology, ICGEB) met with the delegations to discuss ICGEB's collaborative efforts with international partners in biomedicine, agriculture, environmental protection, and biopharmaceuticals, and **Drs. Rakesh Bhatnagar** and **Jaishree Garhyan** offered participants a tour of Jawaharlal Nehru University's (JNU) BSL-3 laboratory facilities.

The next meeting of the dialogue is tentatively scheduled for September, 2017. Participants identified a range of topics warranting further discussion, including the following issues:

- Increased understanding of military and defense programs in biosecurity in India and the US;
- Developing a technological strategy for capabilities to address unknown biological threats;
- Applications of microbial forensics to aid in differentiating between naturally occurring, accidental, and deliberate threats.
- Developing interdisciplinary approaches to problems in biosecurity and disaster preparedness by encouraging public health practitioners, scientists, and defense experts to engage with sociologists, communication specialists, and economists;
- Integrating "One Health" approaches into existing biosecurity-strengthening efforts;
- Modeling approaches to biological threat characterization, including the future of regulating a specific list of pathogens; and
- Strategies for information-sharing on biosafety, as well as for continuing education for biosafety officers, trainers, and students in the life sciences;

There may be an opportunity to further national discussions on biological threats at a Summit on Countering Weapons of Mass Destruction Terrorism, which Prime Minister Shri Narendra Modi has proposed to host in 2018.

**Back row:** Shaun Hayeslip, Dan Hanfling, Jaishree Garhyan, William P. Hostyn, Ravi Khetrapal, Abhijeet Poddar, Gigi Kwik Gronvall, David R. Franz, Evelyn F. Ostrom, Sanjana Ravi, Namrata Singh, Balachandran Ravindran, Amit Parikh

**Front row:** Siva Reddy, Daniel L. Garcia, David Rakestraw, Sarah Carter, Indira Nath, Thomas Inglesby, S.R. Rao, Rakesh Sood, Maureen O'Leary, Subodh Kumar

## Introduction

In February 2017, in New Delhi, India, the Johns Hopkins Center for Health Security hosted a Track II dialogue (i.e. not an official government-government meeting) on biosecurity between experts in India and the US. The first meeting of this dialogue was held in Washington, DC in September, 2016.† Both meetings were supported 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. For the New Delhi meeting, the Department of Biotechnology of the Government of India's Ministry of Science and Technology was a collaborative partner, providing its strong support for the meeting, working with the Johns Hopkins Center for Health Security to develop the agenda and content for the dialogue, as well as inviting a range of senior level speakers and organizing laboratory site visits.

Bilateral ties between the United States and India, the world's two largest democracies, are of great consequence to global security, defense, and health. The US and India have forged a number of defense collaborations, such as the Defense Trade and Technology Initiative (2012), in which both nations will work to develop joint military capabilities; the India-US Declaration on Defense Cooperation (2014), which solidifies both nations' commitment to bilateral partnership; and the 2015 Framework for the US-India Defense Relationship, which will guide the nations' joint military efforts through 2025. Additionally, the US and India collaborate on numerous research efforts in the health and life sciences, including the Indo-US Vaccine Action program, the US-India Health Initiative, polio eradication activities, and global biosurveillance efforts. Both nations are also part of multilateral efforts related to health security; India and the US are signatories to the Biological Weapons Convention, the International Health Regulations, and participate in the Global Health Security Agenda. However, as the security importance of the biological sciences continues to grow, it is important to provide multiple opportunities of bilateral engagement and expert exchange, and to establish opportunities to jointly examine biosecurity threats of common interest.

The purposes of the meeting were to expand knowledge and understanding between India and the US regarding high consequence issues related to biological threats; increase awareness and probability of exchanges for early warning and detection of unusual biological events; deepen relationships between dialogue participants so they can serve as resources to each other going forward; and, identify issues that may warrant official government priority. The meeting was attended by participants representing academia, government, and industry in India and the US. Participants included experts in biosecurity, biosafety, biodefense, the life sciences, regulatory policy, global health security, and regional security. In addition to elevating the transparency and visibility of

† The report from the first meeting can be found here: http://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2016/India%20US%20Biosecurity%20Dialogue_FINAL_Oct%2018.pdf

national biosecurity efforts in each country, the Track II forum also offered participants the opportunity to focus on biological threats as an entry point for deeper discussions of other shared national security priorities, including terrorism, weapons of mass destruction, national defense capabilities, and regional security contingencies.

The meeting consisted of six plenary sessions, each preceded by opening remarks delivered by the participants. These remarks, in turn, set the stage for subsequent group dialogue. Broadly, topics of discussion included national perspectives on biosecurity, the misuse of legitimate biological research for harm, biosecurity and biosafety in laboratories, preparedness for and scientific responses to emerging infectious diseases; risk assessment and reduction of future biological threats for the modern age, and strategies for productive international engagement and collaboration around biosecurity.

The plenary sessions were interspersed with policy briefings and presentations delivered by select speakers. Dr. Krishnaswamy VijayRaghavan (Secretary, Department of Biotechnology, Ministry of Science & Technology, Government of India) described how rapidly evolving biotechnologies not only strengthen biological threat prevention, detection, and mitigation capabilities, but could also enable manipulation of pathogens, ecosystems, and evolutionary processes. Dr. VijayRaghavan's remarks also addressed the broader implications of technological advances for health and national security in both India and the US, as well as for relations between the two nations.

In addition to the invited participants and the Johns Hopkins Center for Health Security team, there were several observers of the dialogue: Anand Kamavisdar, Director, Americas Division, Ministry of External Affairs, Government of India; Daniel L. Garcia, Senior Lab Advisor, Centers for Disease Control & Prevention (CDC); Shaun Hayeslip, International Security and Nonproliferation/Regional Affairs, US Department of State; Kayla Laserson, Country Director, Division of Global Health Protection, US CDC; Evelyn F. Ostrom, Chief, Regional Cooperative Engagement Office, Pacific-Southeast Asia, US Defense Threat Reduction Agency, US Embassy in Singapore; Amit Parikh, Department of Biotechnology, Ministry of Science & Technology, Government of India; Abhijeet Poddar, Department of Biotechnology, Ministry of Science & Technology, Government of India; and Namrata Singh, Centre for Agriculture and Biosciences International (CABI).

Additionally, Dr. Dinakar M. Salunke (Director, International Center for Genetic Engineering and Biotechnology, ICGEB) met with the delegations to discuss ICGEB's collaborative efforts with international partners in biomedicine, agriculture, environmental protection, and biopharmaceuticals. Finally, Drs. Rakesh Bhatnagar and Jaishree Garhyan, two members of the Indian delegation, offered participants a tour of Jawaharlal Nehru University's (JNU) laboratory facilities and described JNU's ongoing efforts in life science research.

The dialogue was marked by engagement and extensive contributions from participants from both countries. Participants and observers expressed great satisfaction with the openness of the discussion, and the potential for future biosecurity engagement between the US and India. Speakers from both nations affirmed the value of the Track II format in creating an open forum for frank discussions of complex problems in biosecurity and their associated national security implications.

A third meeting is tentatively scheduled to be held in Washington, DC in September, 2017. Participants identified numerous topics for examination, such as how to reduce the potential for laboratory accidents (such as information sharing mechanisms to learn about "near-misses" that do not become accidents), as well continuing education for biosafety officers, trainers, and students in the life sciences regarding the potential for biotechnology to create new serious biosecurity threats. Participants from both nations also underscored the need to increase mutual understanding of defense-related programs in biosecurity, deepening understandings of risk assessment, and develop novel interdisciplinary approaches to hard problems in biosecurity and disaster management. Finally, participants agreed upon the importance of addressing biological threats at the Summit on Countering Weapons of Mass Destruction Terrorism, which India's Prime Minister, Narendra Modi, has offered to host in 2018. Such efforts promise to continue raising the profile of biological threats in the national security planning efforts of both nations.

## Meeting Overview

### The Evolving Biological Threat: Remarks by Dr. Krishnaswamy VijayRaghavan

Inaugural remarks were delivered by Dr. Krishnaswamy VijayRaghavan, Secretary of the Department of Biotechnology, Ministry of Science & Technology, Government of India. Dr. VijayRaghavan offered participants a broad overview of the challenges associated with a perpetually shifting biological threat landscape. Biological crises are as old as humanity, and have compelled human populations to devise strategies for detecting, averting, countering, and strengthening immunity to many such threats. However, given immense variability in the virulence and transmissibility of both known and emerging pathogens, the vulnerability of naïve populations, and persistent challenges in health service delivery, dangerous pathogens continue posing considerable threats to population health and global security. Rapid globalization, the growing ubiquity of biotechnology, and enhanced abilities to manipulate biological systems have converged to a critical singularity: one at which biological and technological evolutionary processes that typically unfold over centuries manifest in mere decades, thereby accelerating scientific innovation while also catalyzing the emergence of novel and increasingly complex threats.

Dr. Krishnaswamy VijayRaghavan, Secretary, Department of Biotechnology, Ministry of Science & Technology, Government of India
Image courtesy of BioSpectrum

Dr. VijayRaghavan proposed strategies for countering such threats without stifling scientific and technological progress, underscoring the importance of supplementing big data and mathematical modeling approaches with a deep understanding of the social contexts of disease transmission. Novel collaborative approaches rooted in network theory could also function as blueprints for international biosecurity engagement. Dr. VijayRaghavan emphasized the need for India, the US, and other nations to become critical nodes in the global scientific community, pointing out that the presence of several such nodes – i.e., countries leading high-intensity R&D activities in the realms of biodefense and pandemic preparedness – in fact secures the entire world from both known and unknown biological threats. Without encouraging open exchanges of data, bi- and multilateral protocol-sharing, and frequent engagement between academia, government, and private sector stakeholders in biosecurity, the global community will lack the collective capacities required to rapidly detect and counter nascent biological threats. He pointed to the importance of the Department of Biotechnology in India, which was established over thirty years ago when India recognized how transformative biotechnology would be for its future. He also noted that Prime Minister Modi has been very supportive of science, and that India, an enthusiastic supporter of the Coalition for Epidemic Preparedness Innovations (CEPI), has agreed to host its next Board meeting.

## National Perspectives on Biosecurity

During the first plenary session of the dialogue, participants considered each nation's approach to the threats of biological weapons versus other catastrophic, destabilizing threats such as nuclear weapons. It should be noted that the terms biosecurity and biosafety have different connotations in different professional fields. For the purposes of this dialogue, discussions were focused on the prevention of infectious disease outbreaks and from deliberately introduced disease through bioterrorism and biowarfare.

Both delegations agreed that discussion of bioweapons in an open, interdisciplinary forum could serve as a valuable entry point for potentially more complex discussions around nuclear, chemical, and cyber threats. It was noted that nuclear and space technologies were the last two classes of technology whose development were spearheaded by national governments, which has facilitated their proliferation and regulation. Conversely, biotechnology development has historically been decentralized across both the public and private sectors, thereby complicating efforts to establish multilateral and international norms governing its use.

The public-private, multi-stakeholder dynamic of the US and India's respective biosecurity landscapes has also generated challenges in communicating with policymakers about biological risks. Participants from both nations noted that reactive government responses to biosecurity crises and the infrequency of catastrophic biological events has resulted in many policymakers seeing biological threats as a lower priority than nuclear and chemical threats. Several speakers expressed concern, pointing out that the technical and cost barriers towards misuse of biological sciences and biological information are much lower than they are for nuclear technologies. Both delegations also agreed that the potential for transnational spread associated with naturally occurring, accidental, and intentionally caused biological threats sets them apart from chemical, nuclear, radiological, and cyber threats. Managing and sharing information regarding biological threats, implementing and enforcing biosecurity protocols, and proactive policy formulation remain critical to strengthening national capabilities for containing biological threats at their source.

L-R: Drs. Tom Inglesby, Dan Hanfling, Jaishree Garhyan, and David Franz

## Misuse of Legitimate Biological Sciences Research

As development of new biotechnologies accelerates and existing technologies continue to mature, national authorities must consider strategies for countering the concomitant security risks associated with both state and non-state actors. In this vein, characterizing the risks and potential outcomes of

misuse of legitimate biological research (so-called "dual-use" research) stands as an important priority for both the US and India. Speakers from both nations acknowledged the difficulty of designing regulatory approaches for dual-use research that mitigate risk without curbing scientific innovation. However, given that many biotechnologies – e.g., CRISPR-Cas9, gene drives, and do-it-yourself biology kits – concurrently serve beneficial purposes and carry potential risks for nefarious use, participants also agreed that regulators should avoid classifying novel biotechnologies as "good" or "bad." In fact, a few speakers noted that the skill sets required to weaponize pathogens reside largely in the agricultural and pharmaceutical industries, further underscoring the difficulty of divorcing commercial biotechnologies from potential nefarious applications. It was also noted that in-depth, publicly available assessments of how commercial biotechnological capabilities could potentially contribute to unsanctioned weaponization efforts do not exist.

Participants also agreed that the rise of increasingly sophisticated techniques for synthesizing DNA from scratch underscore the value of information management and bioinformatics in addressing the security risks surrounding dual-use research; supplementing existing biosafety practices with these could further reduce the risks associated with life sciences research. Given the rapid rate of technological evolution, an argument was made for a shift in regulatory paradigms: focusing on outcomes of concern instead of formulating reactive policies in response to biological threats as they manifest. Additionally, conducting regular risk assessments and sharing findings openly could help accelerate development of countermeasures for a broad range of biological threats. Participants from both nations agreed that robust global science engagement is a powerful means of strengthening trust between nations as well as early warning capabilities for transnational threats.

## Biosecurity & Biosafety in Laboratories

Drs. Siva Reddy & Maureen O'Leary

Participants affirmed the value of biological risk assessments and regulation, but acknowledged that advances in technology and the life sciences are outstripping nations' abilities to characterize associated risks and regulate them effectively. At the same time, it was recognized that reactive or excessive regulation and punitive approaches to biosafety oversight could, in fact, discourage reporting of laboratory accidents, impede open discussions of best practices in biosafety, and hamper scientific progress. Regular (and openly shared) assessments of the conditions under which accidents most frequently occur could help both regulators and researchers more effectively mitigate threats with pandemic potential in high-containment facilities.

Both delegations underscored the importance of establishing strong cultures of trust in laboratories conducting research in the life sciences. These cultures – supported by an appropriate balance between innovation and oversight, global norms for biosafety and biosecurity, and robust international scientific collaboration – remain imperative to countering the threat of biological accidents, as well as insider threats. Several speakers pointed out that cultures of trust often function as effective deterrents to nefarious actors. Additionally, participants noted that compliance with national biosafety regulations and international norms could complement global nonproliferation efforts. In fact, the American Biological Safety Association (now, officially ABSA International) and the Society for Biosafety-India (SBS) have already established a collaborative effort to exchange information and best practices in biosafety, as well as to offer feedback on issues surrounding regulated pathogens. Speakers from both nations also agreed that the WHO Laboratory Biosafety Manual could offer a solid foundation for establishing and harmonizing global biosafety norms.

## Emerging Infectious Diseases, Preparedness, and the Scientific Response

Participants next turned to the threat of emerging and re-emerging infectious diseases, highlighting healthcare and medical surge capacity needs, vulnerabilities in national biosurveillance systems, and strategies for evidence-based decision-making during outbreaks. Since 1970, roughly 40 new infectious diseases have emerged among human populations, of which nearly 70% are zoonoses. These diseases typically emerge at the intersection of numerous forces: drug resistance, porous borders, migration and travel, urbanization, changing climates and ecosystems, and social unrest. Speakers from both nations added that rapid rates of globalization mean that infectious disease threats in one country in fact pose a threat to all. Participants underscored the need for enhanced efforts to conduct continuous surveillance at national, regional and global scales. However, existing international biosurveillance mechanisms such as the Global Outbreak Alert & Response Network (GOARN) remain understaffed and underfunded, and may be insufficient for rapidly detecting transnational pathogen spread.[‡]

Participants proposed that a systems-based approach to epidemic response – one grounded in the rule of law and complemented by ethical governance of scarce resources – is critical to minimizing loss of life while preserving social order and public trust in institutions. Incident management, biosurveillance reporting capabilities, and access to medical and non-medical countermeasures were all identified as necessary factors for swift responses to infectious disease threats.

---

‡ Persaud N, Smith F, and Lewinski J. No More Epidemics: A Call to Action. Published 2016. Accessed March 26, 2017. Available at: http://nomoreepidemics.org/wp-content/uploads/2016/12/A-Call-to-Action.pdf

Both delegations agreed that effective communication before, during, and after crises remains an important component of mitigating biological threats. Speakers identified information-sharing systems as important tools for course-correcting epidemic response efforts during an event, noting that effective early warning systems for biothreats are usually bolstered by an underlying communications strategy. Communication policies should aim to protect proprietary institutional information while also allowing stakeholders and policymakers to share actionable information required to implement biosecurity countermeasures.

L-R: Ms. Evelyn Ostrom, Mr. Bill Hostyn, and Dr. David Franz

Participants stressed the need to convince political leaders that efforts to strengthen biosecurity and global health security concomitantly strengthen national security – a challenge shared by both nations. Several speakers observed that the dearth of political will around biological threat mitigation could be remedied, in part, by increased political engagement by technical experts, but that dedicated communications specialists could also help connect the policy and practice communities addressing biosecurity threats.

## Risk Assessment and Reduction of Prospective Biological Threats

Both delegations expressed great interest in jointly examining and developing risk assessment strategies for characterizing plant, animal, and human biosecurity threats. Participants from both nations acknowledged several challenges in quantifying risk and using risk assessments to effectively allocate resources toward threat mitigation activities and formulate policy. Additionally, risk assessment often remains a fragmented effort conducted by experts in different siloes (e.g. plant health, animal health, and human health; emerging diseases, laboratory accidents, new technologies, and deliberate threats). Findings from these efforts are not necessarily integrated across the entire spectrum of known biorisks. Participants noted that varying perceptions of risk further complicate efforts among biosecurity stakeholders to develop a collective understanding of biological threats. Risk perception related to biotechnology can be tied to a narrow subset of outcomes though the different stages of biotechnology development and use carry varying degrees of risk. Furthermore, risk communication efforts often proceed in a reactive fashion, typically after a crisis manifests. Finally, both delegations described transparency, knowledge, and information management as crucial components of biorisk management, maintaining that these are also critical to the success of any national biosecurity enterprise.

## Bilateral Engagement & Collaboration

Biosecurity is a "grand challenge" in national security – one requiring continuous investment and strategic national action; participants agreed that strengthening bilateral engagement would advance biosecurity in both India and the US. Considering the delegations' willingness to contribute openly to discussions of bioweapons, biosafety, and epidemics, participants sought to identify strategies for furthering productive bilateral engagement in biosecurity.

Drs. Kayla Laserson & S.R. Rao

Participants suggested additional mechanisms for sustaining biosecurity engagement, including a formal partnership (i.e. establishing a memorandum of understanding) between the Johns Hopkins Center for Health Security and the Department of Biotechnology. It was also conveyed that India plans to establish a new center of excellence that could catalyze further collaboration on these issues. Other ideas for strengthening bilateral biosecurity engagement include increased collaboration on grants from the National Institutes of Health, reducing constraints on sample-sharing between countries, expanding bilateral collaboration on risk assessment, and partnering with the World Health Organization to streamline operating protocols for pandemic response. Additionally, others suggested identifying potential linkages between the Global Health Security Agenda, the US State Department's Cooperative Biological Engagement Program, and deepening understanding and exchange between the US and India's defense priorities in biosecurity.

## Future Priorities

Both delegations agreed that numerous issues warrant continued dialogue and examination at the next dialogue meeting, which is tentatively scheduled to be held in September 2017. Potential topics may include development of strategies to increase biosafety in laboratories, including learning from accidents and "near-misses"; continuing education for biosafety officers, trainers, and students in the life sciences in the realm of dual use research; and the potential for biotechnology to unintentionally create new biological threats. Several speakers from both nations expressed interest in a deeper examination of how to prepare for surprise biological threats, the "unknown unknown"; this is a serious challenge for surveillance and response. Participants thought that more attention should be paid towards how nations regulate pathogens and pathogen access, including how new or emerging threats are added to the regulations, based on their potential to cause outcomes of concern. Both delegations also identified national risk assessments, potential applications of computational

modeling in epidemic response, and military biosecurity programs as key priorities for future discussions.

Participants from both sides stressed the need for deeper thinking around biosecurity engagement with respect to plant and animal health, and changing climates. Several speakers expressed interest in developing case studies in biosafety and One Health to illustrate the full scope of the risks and consequences associated with biological threats. Others, citing the interdisciplinary nature of biological threat mitigation, suggested inviting sociologists, communication experts, and economists to the next dialogue meeting to help develop more comprehensive approaches to hard problems in biosecurity. Such approaches could facilitate integration of systems thinking into biothreat preparedness and mitigation strategies.

Finally, as a means of further raising the international profile of biological threats, both delegations agreed that the US and India should identify biosecurity priorities to discuss at the Summit on Countering Weapons of Mass Destruction Terrorism in 2018, which India's Prime Minister, Shri Narendra Modi, has offered to host.

Participants identified a broad range of topics warranting further dialogue and collaboration in forthcoming dialogues, including the following:

- Developing strategies for information-sharing on biosafety, as well as for continuing education for biosafety officers, trainers, and students in the life sciences.
- Increasing understanding of military and defense programs in biosecurity between India and the US;
- Integrating One Health approaches into existing biosecurity-strengthening efforts;
- Developing interdisciplinary approaches to hard problems in biosecurity and disaster preparedness by encouraging public health practitioners, scientists, and defense experts to engage with sociologists, communication specialists, and economists;
- Developing a technological strategy for capabilities to address unknown biological threats;
- Modeling approaches to biological threat characterization, including the future of the select agent list; and
- Applications of microbial forensics to aid in differentiating between naturally occurring, accidental, and deliberate threats.

There may be an opportunity to further discussions on biological threats at a Summit on Countering Weapons of Mass Destruction Terrorism, which Prime Minister Shri Narendra Modi has proposed to host in 2018. In addition, the India-US dialogue has tentatively planned to hold another session in September, 2017, in Washington, DC. Such efforts promise to continue raising the profile of biological threats in national security planning efforts in both nations.

Bilateral ties between the United States and India, the world's two largest democracies, are of great consequence to global security, defense, and health. In an era of rapid globalization, major

geopolitical transitions, and evolving national security landscapes, partnership between the two nations on critical issues in biosecurity and biodefense remains especially important. Developing shared bilateral understandings of and approaches to tackling hard problems in biosecurity promises to strengthen trust and cooperation between the US and India, enhance health and security in both nations, and facilitate productive collaborative efforts between Indian and American policymakers, national security experts, life scientists, public health professionals, and healthcare practitioners.

## Appendix A: Dialogue Participants

# India-US Strategic Dialogue on Biosecurity

8-9 February 2017
Shangri-La Hotel, New Delhi, India

### *Rakesh BHATNAGAR, PhD*

Rakesh Bhatnagar completed his PhD from the National Sugar Institute, Kanpur. Dr. Bhatnagar's research group has been actively working on the molecular biology and immunology of a number of infectious diseases—namely, anthrax, rabies, tuberculosis, and brucellosis, culminating in many international publications and patents. The mandate of his laboratory is understanding the mechanisms of host-pathogen interactions, identifying potential vaccine and drug targets, and developing improved and safe vaccines and therapeutics for these infections diseases. His research group aims to cover a wide breadth of both fundamental and applied sciences. Fundamental research includes exploration of phenomena like programmed cell death and 2 component signal transaction in *Bacillus anthracis*, and deciphering novel virulence determinants in *Mycobacterium tuberculosis*. His vision is to investigate these processes for design of novel antibacterial strategies.

Dr. Bhatnagar's applied research includes development of vaccines and therapeutics. He has to his credit the development of a genetically engineered protective antigen (PA)–based vaccine against anthrax, which confers significant protection against virulent spore challenge in mice, guinea pigs, New Zealand white rabbits, and rhesus macaques. The vaccine has successfully undergone preclinical toxicity studies and phase I and II human clinical trials. Therapeutics development includes developing a bi-specific monoclonal antibody against the 2 anthrax toxins, and his group is currently working to develop a cognate single chain antibody that will also target the 2 toxins simultaneously, as well as humanizing it. In Brucella infection biology, his group is working to develop a recombinant vaccine and identify new vaccine candidates against the disease. Novel vaccine delivery methods such as liposomes and nanoparticles are also being tested for antigen delivery.

Dr. Bhatnagar is the recipient of several awards and honors, including J. C. Bose fellowships; he is a Fellow at the National Academy of Sciences, a Fellow at the Indian Academy of Sciences, and a Fellow at the Indian National Sciences Academy. His laboratory has been ranked 7th among the top 10 eminent researchers publishing commendable research papers on anthrax. Dr. Bhatnagar is the recipient of the President of India award for innovation.

### *Sarah R. CARTER, PhD*

Sarah Carter is the principal at Science Policy Consulting LLC, where she focuses on societal and policy implications of emerging biotechnologies, including issues of biosafety, biosecurity, and environmental risk assessment and mitigation.

Previously, she worked in the Policy Center of the J. Craig Venter Institute, where she led influential projects on the accelerating pace of synthetic biology and the challenges it creates for policymakers. In October 2015, she concluded a project on the biosecurity implications of DNA synthesis with the release of "DNA Synthesis and Biosecurity: Lessons Learned and Options for the Future." Earlier, Dr. Carter led a project on the US biotechnology regulatory system and the ways that synthetic biology and its applications will lead to new regulatory challenges, which resulted in the 2014 report "Synthetic Biology and the U.S. Biotechnology Regulatory System: Challenges and Options."

In 2009-10, Dr. Carter was a policy analyst at the White House Office of Science and Technology Policy (OSTP), where she focused on issues relating to climate change and sustainability. She is also a former AAAS Science and Technology Policy Fellow and a former Mirzayan Fellow of the National Academies. She earned her PhD in neuroscience from the University of California-San Francisco and her bachelor's degree in biology from Duke University.

### *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.

### *Jaishree GARHYAN, PhD*

Jaishree Garhyan has a broad background in the field of infectious diseases, with specific training and expertise in *Mycobacterium tuberculosis* (Mtb). She has worked extensively with *H. pylori* and the bioterror weapon *Bacillus anthracis*. Her research work includes the mechanism of latent tuberculosis with a special emphasis on bone marrow stem cell niche and interaction of Mtb with other pathogens. Over the years, she has acquired extensive experience in providing training in BSL-3 laboratories in India and has worked in BSL-3s in the United States as well. Dr. Garhyan has played a crucial role in enhancing awareness of biosecurity and biosafety in the university setting in India. She has led the training for biosafety in independent symposiums and workshops in association with the American Society for Microbiology. She is a member of a nonprofit science organization and contributes to boosting science in the challenging regions of India.

Dr. Garhyan has a growing interest in global biosecurity, biosafety, and global health and emergency preparedness. She has played a crucial role in Indo-US biosecurity and biosafety workshops since 2014, conducted in INSA, New Delhi, and Seychelles. Dr. Garhyan is an active member of the biosafety association of India and has actively participated in and presented at Asia-Pacific biosafety association meetings in the past.

### *Gigi GRONVALL, PhD*

Gigi Gronvall is a senior associate at the Johns Hopkins Center for Health Security and visiting faculty at the Johns Hopkins Bloomberg School of Public Health. She is an immunologist by training.

Dr. Gronvall is the author of the book *Synthetic Biology: Safety, Security, and Promise*, published in fall 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 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 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.

### *William P. HOSTYN, MS*

William Hostyn is the director, Advisory Committees and Programs Office, Defense Threat Reduction Agency (DTRA). In this capacity, he is the senior Department of Defense (DoD) Designated Federal Officer responsible for the Threat Reduction Advisory Committee (TRAC), a federal advisory committee to the DoD. TRAC 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. Additionally, Mr. Hostyn is the DoD program manager for the Project on Advanced Systems and Concepts for Countering Weapons of Mass Destruction (PASCC).

Mr. Hostyn maintains international and interagency interface on programs, policy, and doctrinal issues and continues to be a principal liaison with think-tanks in the Washington, DC, area; the National Defense University, Center for the Study of WMD; the United States Air Force Academy, Institute for National Security Studies; and the Naval Post Graduate School, Center on Contemporary Conflict (PASCC program).

Prior to his current assignment, Mr. Hostyn was the chief, Systems and Engineering Division, in DTRA's Advanced Systems and Concepts Office (ASCO). While assigned to ASCO, he oversaw the development and execution of technical projects and strategic international dialogues that cut across federal agencies for weapons of mass destruction (WMD) threat reduction in nuclear, chemical, biological, and emerging requirements.

Mr. Hostyn retired from the United States Air Force in 2003 after more than 20 years of distinguished service. Having served on 3 major command staffs (Headquarters Tactical Air Command, Pacific Air Forces, and Air Force Space Command), he was primarily engaged in manpower and personnel force structure planning and execution of programs stemming from the Base Realignment and Closure Commission for installation-wide and unit-level activation, inactivation, and conversions in missile, satellite, and fixed and rotary wing weapon systems. A graduate of the Air University Contingency Warfare Planning Course, he further worked with Joint Chief of Staff (JCS) contingency warfare planning while serving on the Air Component Staff, Headquarters Seventh Air Force, Osan Air Base, Republic of Korea.

Mr. Hostyn has a BS in organizational management from Colorado Christian University, an MS in public administration from Troy State University, and an MS in national resources atrategy with a minor as a national security professional from the National Defense University, Industrial College of the Armed Forces.

### *Tom INGLESBY, MD*

Tom Inglesby is the director of the Johns Hopkins Center for Health Security in the Johns Hopkins Bloomberg School of Public Health. The Center is dedicated to protecting people's health from the

consequences of epidemics and disasters and to making communities more resilient to those challenges.

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 External Laboratory Safety Workgroup appointed by the CDC Director that examined biosafety practices of the CDC, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA). 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, and the Institute of Medicine and in an advisory capacity to NIH, BARDA, DHS, and DARPA.

During the past 18 years, Dr. Inglesby has authored or co-authored more than 100 publications, including peer-reviewed research, original 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 3 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 continues to see patients in a weekly infectious disease clinic.

### *Ravi KHETRAPAL, PhD*

Ravi Khetrapal is regional director, CABI South Asia. Dr. Khetrapal joined CABI in March 2010 and is engaged in enhancing CABI's profile in India. He is involved in the ongoing project of Plantwise Initiative among other projects.

Prior to joining CABI, he served the National Agricultural Research System in India for 3 decades, including as head, Plant Quarantine Division, National Bureau of Plant Genetics Resources, ICAR, New Delhi. Dr. Khetrapal led a number of research projects in seed-transmitted viruses, plant quarantine detection, and disinfestation procedures and GMO detection. He has contributed to

technical and policy issues and capacity-building in areas of phytosanitation, biosecurity, biosafety, and seed certification for viruses. He has a PhD in plant pathology and plant virology.

### *Subodh KUMAR, PhD*

Subodh Kumar is a scientist at the Defence Research & Development Establishment (DRDE), Defence Research & Development Organisation, Ministry of Defence, Government of India. He has a PhD in microbiology and immunology.

### *Jayati MULLICK, PhD*

Jayati Mullick is a scientist E, Group Leader, Avian Influenza Group, in charge of biosafety level 3 (BSL-3) labs, National Institute of Virology, Microbial Containment Complex, Pashan, Pune. Dr. Mullick received her BSc in biology and her MSc in biochemistry from the University of Nagpur, Nagpur, India. She received her PhD in biochemistry from Vallabhbhai Patel Chest Institute, University of Delhi, Delhi, India.

### *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/acadmies. She was co-chair for the InterAcademyPanel of Responsible research conduct and chair for the ICSU programme on health and wellbeing 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 WPI 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, and is a current board member on the International Federation of Biosafety Associations (IFBA) and the president of ABSA International.

### *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 & 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.

Ms. Ravi's work has also addressed the health security implications of emerging technologies. She has led research on the roles of mobile technology in emergency healthcare delivery, as well as potential applications of telemedicine in pandemic response. Additionally, she helped lead an evaluation of the Alfred P. Sloan Foundation's efforts to address the societal impacts of synthetic biology practice. Ms. Ravi is a Fellow in the 2015 class of the Synthetic Biology Leadership Excellence Accelerator Program.

Ms. Ravi has also contributed to a number of the Center's globally focused efforts. 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.

### *Balachandran RAVINDRAN, PhD*

Balachandran Ravindran is a microbiologist trained in JIPMER Pondicherry and Delhi University and later in Liverpool School of Tropical Medicine, UK, and the University of Connecticut Health Centre, USA. He has worked as a scientist with the Indian Council of Medical Research for more than 2 decades and since 2006 has been heading the Institute of Life Sciences, Bhubaneswar, an autonomous research institution under Department of Biotechnology, Ministry of Science and Technology, Government of India. His scientific interests include the immunobiology of infectious diseases such as malaria, filariasis, and sepsis; regulation of inflammation; macrophage biology; and evolution of immune system in mammals. His laboratory uses in vitro cell culture and experimental animals as well as humans exposed to pathogens as model systems.

Dr. Ravindran has been an active member of a large global consortium of investigators from universities and research institutions in the UK, the US, Germany, France, the Netherlands, Malaysia, and Indonesia for nearly a decade, working on immunobiology of metazoan pathogens. He has been a visiting scientist at University of Edinburgh, the University of Bonn, and the Pasteur Institute at Lille during the past 10 years. His group has published about 95 scientific papers in

international journals. Over the past 3 decades, 19 PhD and 16 MD students have worked in his laboratory, completed their degrees, and have been placed in major universities and research institutions in India and abroad. Currently, the strength of his laboratory is 3 PhD students, 3 postdoctoral fellows, and 1 scientist. In recent years, he has spent much of his time serving as a member of the board of governors and in scientific advisory committees of research institutions and universities. He has also spent time mentoring young investigators and functioning as a peer reviewer for several scientific journals and funding agencies in India and abroad.

### *Siva REDDY, PhD*

Siva Reddy is chief scientific officer, Biosafety Support Unit.

### *Ambassador Rakesh SOOD, PhD*

Ambassador 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.

### *Krishnaswamy VIJAYRAGHAVAN, PhD*

Krishnaswamy VijayRaghavan is secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India, and is distinguished professor and former director of the National Centre for Biological Sciences. Dr. VijayRaghavan has a PhD in molecular biology from the Tata Institute of Fundamental Research. During his postdoctoral work, he was a senior research fellow at the California Institute of Technology.

### *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

In collaboration with Department of Biotechnology, Government of India

8-9 February 2017, Meeting Room 1, Shangri-La Hotel, New Delhi, India

**8 February 2017**

**09:30 – 09:45 Welcome, Goals for Meeting, and Introductions**

Dr. S. R. Rao, Advisor, Department of Biotechnology, Ministry of Science & Technology, Government of India

Dr. Tom Inglesby, Director, Johns Hopkins Center for Health Security

**09:45 – 10:15 Inaugural Remarks:** Dr. Krishnaswamy VijyaRaghavan, Secretary, Department of Biotechnology, Ministry of Science & Technology, Government of India

**10:15 – 11:15 Dialogue Session One: National Outlook on Biosecurity and Security**

Biosecurity concerns and challenges change over time, and are addressed within the context of other political priorities. In this opening session, we will discuss how each country views concerns related to biosecurity threats and challenges – natural and deliberate. Is preparedness for biological threats considered of importance to each country's own national security? What are considered the most important elements of preventing and preparing for major biological threats? How was the outcome of the Biological Weapons Convention perceived? What geopolitical issues are affecting those priorities? To what extent are biological risks perceived to come from states vs. groups (or individuals)? What do you think of the efforts of the UN Security Council to fight international WMD terrorism, including bio? This session will also explore historical contexts underlying biosecurity practices in both countries. A representative from each country will provide opening remarks (5-7 minutes) on this topic, followed by a discussion by all participants.

***Opening Remarks:*** Ambassador Rakesh Sood; Dr. David Franz

11:15 - 11:30 Coffee Break

**11:30 – 12:30 Dialogue Session Two: Dual-use Issues in the Life Sciences**

Emerging biotechnologies are profoundly important to India and the US for medicine, health, and for 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. There are also concerns about misuse. How do the US and India see the future of biotechnology changing the potential risks of misuse? How does each country now manage these new risks? What new approaches might be needed in the future? In light of these trends, how should each country go about making strategic investments in biosecurity? A representative from each country will provide opening remarks (5-7 minutes) on this topic, followed by a discussion by all participants.

***Opening Remarks:*** Dr. Subodh Kumar, Dr. Sarah Carter

12:30 – 13:30 Lunch in TAMRA Restaurant, Shangri-La Hotel

**13:30 – 14:30 Dialogue Session Three: Biosecurity & Biosafety in Laboratories**

This session will focus on the future of biosafety in India and the US. What are the most pressing biosafety issues in India and in the US, and how does each view biosafety problems on the horizon? How much political attention is paid to biosafety? How can collaborations between the US and India better serve the future incorporation of biosafety principles into scientific work and scientific training? How is biosecurity prioritized relative to biosafety? What scientific practices or training is concerning to you from a biosafety perspective, taking place anywhere in the world? A representative from each country will provide opening remarks (5-7 minutes) on this topic, followed by a discussion by all participants.

***Opening Remarks:*** Dr. Siva Reddy, Dr. Jayati Mullick, Dr. Maureen O'Leary

14:30 – 15:00 Group Photo, and board bus

**15:00 – 18:00 Visit to the International Centre for Genetic Engineering and Biotechnology (ICGEB) and Jawaharlal Nehru University (JNU)**

18:00 Meeting Adjourns

18:00 Dinner Caraway Restaurant, The Grand New Delhi

---

**9 February, 2017**

**09:30 – 10:45 Dialogue Session Four: Emerging Infectious Diseases, Preparedness and the Scientific Response**

This discussion will explore approaches for early detection and surveillance in response to new outbreaks, opportunities to improve international collaboration on these issues, and the scientific response to emerging infectious diseases. What has been learned in the response to SARS, MERS, novel flu, Ebola, and/or Zika? What disease containment lessons emerge from these outbreaks? What are priority areas in terms of building national response capacity, and building the technical capacity to mount an effective response? What is the perception of progress made and future action needed to adhere to the International Health Regulations and the Global Health Security Agenda? A representative from each country will provide opening remarks (5-10 minutes) on this topic, followed by a discussion by all participants.

***Opening Remarks:*** Dr. Sudhanshu Vrati, Dr. Dan Hanfling

10:45 – 11:00 Coffee Break

**11:00 - 12:45 Dialogue Session Five: Risk Assessment and Reduction of Future Biological Threats for the Modern Age**

In this session, we will discuss how the US and India can diminish biosecurity risks through scientific engagement (for example, as it has been envisaged through US biological threat reduction and engagement programs). How does each country undertake risk assessment for biological risks, and is that risk assessment connected to policy and to resource allocation? How are opportunities to *prevent* biosecurity risks perceived as policy options, and are there policies that are intended to reduce future risks? This discussion will consider the role of collaborative relationships between scientists, public health practitioners, and the security community intended to reduce or prevent biosecurity risks.

***Opening Remarks:*** Dr. S.R. Rao, Dr. Ravi Khetrapal, Dr. David Franz

12:45 – 14:00 Lunch in TAMRA Restaurant, Shangri-La Hotel

**14:00 – 15:15 Dialogue Session Six: Productive Engagement and Collaboration**

This discussion will explore how India and the US can productively collaborate and foster engagement on biosecurity issues. Collaborations could include formal and less-formal opportunities to collectively and collaboratively reduce the threat of emerging infectious diseases such as MERS and new influenza viruses, deliberate and accidental misuse of biological research, risk assessment, and/or opportunities to increase the likelihood of early intervention, attribution, and resolution of an outbreak. What challenges or opportunities should receive Track 1 attention by India and the US but are not as yet? A representative from each country will provide opening remarks (5 minutes) on this topic, followed by a discussion by all participants.

***Opening Remarks:*** Dr. Indira Nath, Dr. David Rakestraw

**15:15 – 16:00 Proposals for Future Biosecurity Dialogue Topics**

Group Discussion about topics for discussion for the next meeting.

**16:00 Meeting Adjourns**