India-US Strategic Dialogue on Biosecurity

The Johns Hopkins
Center for Health Security

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

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Executive Summary

In November 2017, the Johns Hopkins Center for Health Security ("the Center") hosted a Track II dialogue (i.e. a non-governmental engagement) on biosecurity between experts from the United States and the Republic of India. The dialogue, which was held in Washington, DC, was organized in collaboration with the Department of Biotechnology (part of the Ministry of Science and Technology, Government of India). This was the third meeting of the dialogue; the first was held in Washington, DC in September 2016, and the second in New Delhi, India, in February 2017.[1,2] The 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, the world's two largest democracies, are of strategic importance to international security. Both nations are regional and global collaborators in health, defense, and trade; both also share strong commitments to reducing the threats of infectious disease and terrorism, strengthening their respective militaries, and expanding their bilateral economic partnership. In fact, following a June 2017 meeting between President Donald J. Trump and Prime Minister Narendra Modi in Washington, DC, the two leaders released a joint statement affirming, "President Trump and Prime Minister Modi pledged to deepen defense and security cooperation, building on the United States' recognition of India as a Major Defense Partner. The United States and India look forward to working together on advanced defense equipment and technology at a level commensurate with that of the closest allies and partners of the United States…As global partners, the United States and India resolved to further strengthen their collaboration in health, space, oceans, and other areas of science and technology."[3]

Recognizing both the value of strengthening US-India ties and the inherent synergies between biosecurity, defense, and health, the Center convened senior leaders and experts from the US and India to examine the biosecurity threat landscapes of their respective countries at the November 2017 dialogue session. The participants are employed by both government agencies and organizations outside government, and included those with expertise in biosecurity, biosafety, the life sciences and biotechnology, medicine, public health, geopolitics, and regional security. As this is a Track II dialogue, the participants did not represent their governments, but provided insight based on their personal expertise.

Members of the Indian delegation included:

- **Harsh Vardhan Batra, PhD,** Retired Director, Defense Food Research Laboratory, Defense Research & Development Organization
- **Subodh Kumar, PhD,** Scientist "F," Division of Microbiology, Defense Research & Development Establishment
- **Indira Nath, MD,** Former Head and Senior Professor, Department of Biotechnology, AIMMS New Delhi; Former Raja Ramanna Fellow and Emeritus Professor, NIOP Delhi
- **Abhijit Poddar, PhD**, Biosafety Support Unit, Regional Centre for Biotechnology, Department of Biotechnology, Government of India
- **H. Krishna Prasad, PhD,** Emeritus Medical Scientist, Department of Biotechnology, AIIMS New Delhi
- **S.R. Rao, PhD,** Senior Advisor, Department of Biotechnology, Ministry of Science and Technology, Government of India
- **Balachandran Ravindran, PhD,** Professor Emeritus, Department of Biotechnology, Institute of Life Sciences, Bhubaneswar
- **Ambassador Rakesh Sood, PhD,** Distinguished Fellow, Observer Research Foundation

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
- **Ambassador Ronald F. Lehman II, PhD,** Counselor to the Director, Lawrence Livermore National Laboratory; Former Assistant Secretary for International Security Policy, Department of Defense
- **Maureen O'Leary, PhD, MBA, CBSP,** Director, Environmental Health & Safety; Assistant Adjunct Professor, Geisel School of Medicine; President, ABSA International 2017
- **David J. Rakestraw, PhD,** S Program Manager, Global Health Security Principal Directorate, Lawrence Livermore National Laboratory

Several observers also attended the dialogue: **Judee Allen-Close**, Senior Foreign Affairs Officer, US Department of State; **Sumit Goswami**, Counsellor (Defence Technology), Embassy of India, Washington, DC; **Andrew Hollands**, Acting Africa Region Coordinator/West Africa Lead, Cooperative Biological Engagement Program, Defense Threat Reduction Agency; **Emily Kelley**, Acting Senior Operations Manager, Defense Threat Reduction Agency; **Christopher Rand Lewis**, India International Project Manager, Cooperative Biological Program, Defense Threat Reduction Agency; and **Connor Miller**, Global Futures Office, Defense Threat Reduction Agency.

Additionally, several speakers met with the dialogue participants to discuss recent developments in biosecurity and biodefense in the US and India, including **Christopher Park** (Director, Office of the Biological Policy Staff, US Department of State) and **Dr. David Relman** (Thomas C. and Joan M. Merigan Professor in Medicine, Microbiology, and Immunology; Co-Director, Center for International Security and Cooperation, Stanford University). Center staff facilitating the meeting included Dr. Thomas V. Inglesby, Director; Dr. Gigi Gronvall, Senior Associate; Anita Cicero, Deputy Director; Sanjana Ravi, Senior Analyst; Andrea Lapp, Director of Events, and Nicholas Alexopulos, Director of Communications.

Following the dialogue sessions, the delegations visited the Pentagon, where they received a briefing from **Dr. David Christian Hassell** (Deputy Assistant Secretary of Defense for Chemical and Biological Defense) on opportunities to further strengthen US-India defense collaboration. The dialogue participants also visited the White House, where they met with several members of the National Security Council (NSC) and the Office of Science & Technology Policy (OSTP): **Dr. Hillary H. Carter** (Director for Countering Biological Threats, NSC), **Peter Mamacos** (Director for Global Health and International Development, NSC), **Dr. Gerald Epstein** (Assistant Director, Biosecurity and Emerging Technologies, OSTP), and **Dr. Luciana Borio** (Director, Global Health Security, NSC). There, the delegations were briefed on recent White House engagements with India on a range of biosecurity priorities, efforts to advance the Global Health Security Agenda (GHSA), and processes for formulating national biodefense policy in the US.

The next meeting of the dialogue is scheduled for February 2018. Participants identified several topics and opportunities for collaboration that merit further discussion between the delegations, including:

- The possibility of jointly executing a seminal project (for example, around zoonotic disease mitigation) to demonstrate the potential of US-India biosecurity collaboration to policymakers in both countries;
- Jointly developing strategies for improving medical countermeasure development and distribution;
- Identifying and leveraging synergies between civilian and military biodefense efforts in both countries;
- Developing strategies for experts in both countries to share best practices and lessons learned from responding to biological threats;

- Formalizing future collaborative efforts between the US and India on biosecurity priorities of mutual concern, perhaps through memoranda of understanding;
- And establishing a center in India dedicated to examining regional and global biosecurity contingencies.

Over the course of the two-day meeting, members of both delegations affirmed the value of the Track II format in facilitating open conversations about shared biosecurity priorities and challenges, and expressed great interest in identifying specific issues to elevate to the Track I level. Participants also expressed their continued commitment to raising the profile of the dialogue, as well as ensuring that biosecurity remains a shared priority for both India and the US.

Back row, left to right: Maureen O'Leary, Subodh Kumar, David Rakestraw, Balachandran Ravindran, William P. Hostyn, Abhijit Poddar, Harsh Vardhan Batra, Dan Hanfling, David R. Franz, H. Krishna Prasad, Andrew Hollands, David Relman, Judee Allen-Close, Sanjana Ravi, Connor Miller

Front row, left to right: Anita Cicero, Indira Nath, Ron Lehman II, S.R. Rao, Thomas V. Inglesby, Rakesh Sood, Gigi Kwik Gronvall, Sarah R. Carter.

Introduction

In November 2017, the Johns Hopkins Center for Health Security hosted the third meeting of a Track II dialogue (i.e. a non-governmental engagement) on biosecurity between the United States and the Republic of India. The meeting was held in Washington, DC, and featured subject matter experts in biosecurity, biosafety, the life sciences and biotechnology, medicine, public health, geopolitics, and regional security.

The first two meetings of this dialogue were held in Washington, DC and New Delhi, India in September 2016 and February 2017, respectively. These meetings, along with the November 2017 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 initiative, having expanded participation in the dialogue and assisted in developing content for meetings.

India and the US share a long-standing relationship marked by close collaboration on a broad range of economic, defense, health, and security issues. Building on the US-India Joint Strategic Vision for the Asia-Pacific and Indian Ocean Region articulated under the Obama Administration – which recognizes both countries as catalysts of regional and global prosperity and security – President Donald J. Trump and Prime Minister Narendra Modi recently reaffirmed their commitment to strengthening US-India ties, highlighting opportunities for bilateral cooperation on counterterrorism, military collaboration, health, science, and technology.[3,4] Secretary of State Rex Tillerson has also noted recently that "the world's center of gravity is shifting to the heart of the Indo-Pacific"; as such, the growing strategic convergence between the two countries offers opportunities for the US and India to act jointly as stabilizing forces in the region.[5] Additionally, both countries have affirmed their commitment to advancing bilateral collaboration on health, highlighting opportunities to strengthen global health security, promote research on high-priority diseases, and increase access to medicines.[6]

Given these developments and the inherent synergies between defense, health, and security, the purpose of the November 2017 biosecurity dialogue meeting was to further discussions examining the India and the US's respective biosecurity threat landscapes, exchange lessons learned from past crises, compare approaches to formulating national biosecurity policy, and identify actionable next steps for advancing bilateral collaboration between the two countries on critical biosecurity issues of mutual concern. The meeting itself consisted of five dialogue sessions, each preceded by brief opening remarks delivered by one or two participants from each country; these remarks set the stage for subsequent group dialogue. Topics of discussion included the changing geopolitical contexts of the Western hemisphere and South Asia; the evolving biosecurity threat landscapes in both the US and India; scientific challenges in biosecurity, including advances in synthetic biology and the future of pathogen management; and strategies for bridging science, surveillance, and public health action.

The five sessions were interspersed with policy briefings delivered by Christopher Park (Director, Office of the Biological Policy Staff, US Department of State), Dr. David Relman (Thomas C. and Joan M. Merigan Professor in Medicine, Microbiology, and Immunology; Co-Director, Center for International Security and Cooperation, Stanford University), Dr. David Christian Hassell (Deputy Assistant Secretary of Defense for Chemical and Biological Defense), Dr. Hillary H. Carter (Director for Countering Biological Threats, NSC), Mr. Peter Mamacos (Director for Global Health and International Development, NSC), Dr. Gerald Epstein (Assistant Director, Biosecurity and Emerging Technologies, OSTP), and Dr. Luciana Borio (Director, Global Health Security, NSC). In addition to the invited participants and the Johns Hopkins Center for Health Security staff, several observers also attended the dialogue: Judee Allen-Close, Senior Foreign Affairs Officer, US Department of State; Sumit Goswami, Counsellor (Defence Technology), Embassy of India, Washington, DC; Andrew Hollands, Acting Africa Region Coordinator/West Africa Lead, Cooperative Biological Engagement Program, Defense Threat Reduction Agency; Emily Kelley, Acting Senior Operations

Manager, Defense Threat Reduction Agency; Christopher Rand Lewis, India International Project Manager, Cooperative Biological Program, Defense Threat Reduction Agency; and Connor Miller, Global Futures Office, Defense Threat Reduction Agency.

The dialogue was marked by enthusiastic engagement from both the US and Indian delegations. Participants underscored the value of the Track II format in facilitating frank conversations around hard problems in biosecurity, promoting multidisciplinary collaboration within and between both countries, encouraging open exchanges of ideas and best practices, and building peer-to-peer rapport between subject matter experts. Participants also identified several topics that warrant further discussion at the next dialogue meeting, which is scheduled to be held in New Delhi, India in February 2018. These topics include, but are not limited to: jointly executing a seminal project (for example, around zoonotic disease mitigation) to demonstrate the potential of US-India biosecurity collaboration to lawmakers in both countries; jointly developing strategies for improving medical countermeasure development and distribution; identifying and leveraging synergies between civilian and military biodefense efforts in both countries; developing strategies for experts in both countries to share best practices and lessons learned from responding to biological threats; formalizing future collaborative efforts between the US and India on biosecurity priorities of mutual concern, perhaps through memoranda of understanding; and establishing a center in India dedicated to examining regional and global biosecurity contingencies.

Changing Geopolitical Context

During the first session of the meeting, dialogue participants discussed how technological innovation often catalyzes shifts in geopolitical power, which in turn transform regional and global threat landscapes. The launch of *Sputnik 1*, for example, raised concern among western nations over the perceived technological superiority of the Soviet Union. The subsequent technological revolution triggered by the Sputnik crisis intensified the US-Soviet arms race and escalated Cold War tensions between the two countries. From the crucible of this arms race, however, emerged global arms control regulations, major technological advances that proved consequential for both the defense and civilian sectors, and a global transition from command to market economies. Perhaps most importantly, the post-Sputnik technological revolution gave rise to modern-day multidisciplinary approaches to scientific practice and inspired innovators to develop new technologies in an open-society context.

Ambassadors Ron Lehman and Rakesh Sood

Dialogue participants observed that an analogous technological revolution appears to be underway in the life sciences. One speaker, for example, highlighted the role of robotics in the success of the Human Genome Project, describing how newly developed laser cell sorters provided the equivalent of millions of human technicians processing genetic samples simultaneously. Notably, the life sciences revolution has not been restricted to such large-scale scientific endeavors; the do-it-yourself biology (DIY-bio) movement, for instance, illustrates the extent to which biotechnology has been democratized among ordinary consumers. Other emerging biotechnologies have become similarly ubiquitous in the private and consumer sectors, far outstripping the ability of most governments to regulate their use. Concurrently, there is little to no global consensus on how to mitigate the potential threats these technologies pose, which has complicated efforts to develop needed regulatory or policy frameworks. The speakers agreed that as new biotechnologies continue to emerge, mature, and proliferate, international norm-setting and multi-stakeholder governance approaches will become increasingly important in mitigating their associated risks. The speakers also observed that many recent advances in biotechnology have originated from non-government laboratories and are subsidized by non-governmental funding streams, which could present governance and oversight challenges.

The biotech revolution is unfolding at a critical juncture in the US-India bilateral relationship. The US's military and diplomatic pivot to Asia – a shift initiated by the Obama administration that has continued under the Trump administration – and its growing focus on the Indo-Pacific region have culminated in several joint efforts with India centering around defense and technology. Participants underscored the importance of the 2015 Framework for the US-India Defense Relationship, which formally extends the countries' bilateral defense collaboration to 2025; the Joint Strategic Vision for the Asia-Pacific and Indian Ocean Region, which articulates a vision for ensuring peace and stability in the region; and the Defense Technology and Trade Initiative, which facilitates US-India dialogue around cooperative research and development efforts for defense technologies.[7]

Dialogue participants also acknowledged that amid constantly fluctuating geopolitical and technological landscapes, peer-to-peer exchanges between scientists in different countries will become increasingly valuable, as will bridge-building between DIY-bio communities and nascent biotech companies. One speaker observed that of all the available global mechanisms for regulating technology – export controls, bans, and treaties, for

example – science diplomacy remains an option with considerable untapped potential, particularly in the context of biotechnology development and regulation. Recalling the Obama administration's support for India's entry into the Australia Group,[*] and given India's recent admission as the Wassenaar Arrangement's[8†] 42nd member, another speaker also suggested that US-India participation in multilateral arrangements such as these could further facilitate scientific exchanges between the two countries.

[*] **The Australia Group** is an informal coalition of countries that assists member states in identifying exports requiring control, so as not to contribute to the proliferation of biological and chemical weapons.

[†] **The Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Use Goods and Technologies** is a multilateral export control regime promoting transparency in transfers of conventional arms and dual-use goods and technologies. Participating states implement national policies to ensure that transfers of such technologies do not enable recipients to develop destabilizing military capabilities. The Arrangement admitted India as its 42nd member state in December 2017.

Evolving Biosecurity Threat Landscapes

After considering broad geopolitical trends and technological risks, dialogue participants next examined the unique biosecurity landscapes of the US and India. Participants generally felt that national approaches to mitigating infectious disease threats have not appreciably changed since the 2014 West Africa Ebola epidemic. However, some encouraging progress has been made at the international level. India, for example, is among the nations leading the Coalition for Epidemic Preparedness Innovations (CEPI), which aims to accelerate vaccine development for infections with epidemic potential, and for which viable commercial markets may not exist.

Participants noted that while the US was still learning the lessons of Ebola and Zika, some forthcoming developments may help chart a path forward. For example, as mandated by the National Defense Authorization Act for Fiscal Year 2017, the National Security Council plans to release a National Biodefense Strategy that articulates federal policy for countering the full spectrum of naturally occurring, accidental, and deliberate biological threats to human, plant, and animal health. The strategy is also required to address naturally occurring biological threats from emerging infectious diseases and influenza, as well as biological threats posed by biological weapons and laboratory accidents.[9]

The Indian dialogue participants raised some concerns about emerging technological capabilities such as advanced methods of gene editing and gene drives, acknowledging the ethical and environmental implications associated with modifying genomes and intervening with evolutionary processes. The Indian delegation also reported that the Ministry of Science and Technology's Department of Biotechnology and the Indian Council of Medical Research have collaborated to incorporate dual-use research considerations into ethical guidelines for clinical trials and stem cell research. Biosafety also remains a high priority in India; the Indian delegation shared that a national biosafety bill, the Biotechnology Regulatory Authority of India Bill 2013, is currently under review in Parliament.

The participants also addressed the implications of several biosecurity challenges of mutual concern. For example, both countries have encountered difficulties integrating biosecurity-strengthening efforts across their human, veterinary, defense, and agricultural sectors. Both countries also struggle to ensure that biosecurity remains a top priority for policymakers amid a range of other national security threats. A number of US participants observed that science policy did not appear to be high priorities for the current administration, citing the absence of a science advisor at the White House and wavering support for ongoing research efforts at the National Institutes of Health and the National Science Foundation. The Indian delegation echoed the challenges posed by the absence of scientific and technical expertise among lawmakers, and noted that even input from thought leaders outside of government seldom informs India's national biosecurity policymaking process. In both countries, the absence of technical expertise among lawmakers complicates efforts to assign appropriate levels of risk to biological threats of varying origin.

Despite these barriers, both delegations acknowledged the importance of growing convergence between scientists and diplomats across national borders. Several participants noted that continued international engagement is critical to sustaining momentum in life sciences research and strengthening regional and global biosecurity. Growing rapport between the American and Indian governments has also facilitated further information and intelligence-sharing between the two countries. One speaker applauded this development, observing that the knowledge required to address challenges in biosecurity and the life sciences in both countries remains highly distributed; open exchanges of information could help resolve this shared challenge. Additionally, both delegations agreed that elevating these shared challenges to the Track I level could accelerate progress toward more robust national approaches to biosecurity.

Remarks by Christopher Park, Director of Biological Policy, US Department of State

The delegations received a briefing from Christopher Park (Director of Biological Policy, US Department of State) on the role of the Biological Weapons Convention (BWC) in addressing emerging biosecurity threats. Mr. Park acknowledged the limitations of the BWC forum, noting that the formal dialogue process is often hindered by competing political interests and has become an increasingly weak vehicle for examining technical issues. Still, he echoed the dialogue participants' support for increased peer-to-peer scientific engagement, recommending that countries committed to strengthening biosecurity organize their own bilateral or multilateral engagements and report their findings at the next BWC meeting. Mr. Park also underscored the importance of liaising with the World Health Organization and NGOs to ensure that BWC mechanisms for countering deliberate threats can also extend to naturally emerging and accidental threats. Mr. Park concluded with a discussion of options for strengthening various BWC programs centered around international cooperation, science and technology, national implementation, and preparedness and response.

Christopher Park & Gigi Kwik Gronvall

Remarks by Dr. David Christian Hassell, Deputy Assistant Secretary of Defense for Chemical and Biological Defense

The delegations visited the Pentagon, where they received a briefing from Dr. David Christian Hassell (Deputy Assistant Secretary of Defense for Chemical and Biological Defense). Dr. Hassell offered an overview of ongoing collaborations between the US Department of Defense (DoD) and India's Ministry of Defense, highlighting progress made under the India-US Defense Technology and Trade Initiative, and expressing interest in deepening the defense partnership between the two countries. Dr. Hassell also described the priorities of DoD's Chemical & Biological Defense (CBD) program for 2017-2018, which include understanding the risks and opportunities posed by synthetic biology, accelerating efforts against high-priority non-traditional agents, revamping DoD medical countermeasure programs, and evaluating the application of CBD programs to nonproliferation and counter-proliferation efforts. Both delegations identified potential synergies between the US and Indian defense enterprises with respect to improving threat detection capabilities and increasing engagement between their respective defense, private, academic, and civilian sectors.

Scientific Challenges to Biosecurity: Advances in Synthetic Biology and the Future of Pathogen Management

The delegations next examined potential solutions to long-standing challenges at the nexus of biosecurity and scientific practice. Speakers discussed a recent effort by Canadian scientists to synthesize horsepox virus using commercially available genetic material. Though not a technical breakthrough – experts have previously concluded that orthopox viruses could indeed be synthesized – the experiment has revived discussions about the ethical and security risks associated with carrying out research demonstrating the feasibility of orthopox construction. In this vein, several speakers highlighted the importance of implementing robust oversight mechanisms to mitigate biosecurity risks in the context of life sciences research. Others, however, countered that existing regulatory regimes already pose considerable burdens to scientists – particularly those conducting low-risk research – and could, in fact, disincentivize scientific innovation. Risk assessment may play an important role in alleviating such burdens.

William P. Hostyn, Sarah Carter, Maureen O'Leary, and Balachandran Ravindran

The dialogue participants examined national policies and governance frameworks for addressing these scientific challenges, noting the similarities and differences between relevant regulations in India and the US. The Indian delegation reported that as early as 1989, India enacted "Rules for the Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989" to regulate genetic engineering and genome editing efforts.[10] Similarly, the US National Institutes of Health released the Guidelines for Recombinant DNA Research in 1976, along with the 1986 Coordinated Framework for Regulation of Biotechnology (updated in 2017).[11,12] More recently, the US Department of Health and Human Services also released voluntary screening guidelines to identify potential misuses of synthetic DNA obtained through commercial providers.[13] Under the Obama administration, the White House also formulated the Potential Pandemic Pathogen Care and Oversight (P3CO) policy to ensure consistent oversight of federally funded research efforts "anticipated to create, transfer, or use enhanced pathogens with pandemic potential."[14] Additionally, the National Academies of Sciences, Engineering, and Medicine has developed a framework for assessing both the potential risks posed by synthetic biological technologies and national biodefense capabilities for mitigating those risks.[15]

Both delegations underscored the need to design regulatory frameworks that encompass both emerging technologies (e.g. organisms created using synthetic biological techniques) in addition to well-characterized threats. A speaker from India highlighted the role of international mechanisms in addressing the risks associated with life sciences research. India, for example, is a signatory to The Cartagena Protocol on Biosafety to the Convention on Biological Diversity, an international agreement that aims to ensure safe handling, transport, and use of genetically modified organisms.[16] The Cartagena Protocol compels state parties to "cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety," and articulates risk assessment, risk management, and reporting responsibilities.[17] The Cartagena Protocol's focus on the transboundary movement of genetically modified organisms (e.g. crops) is of particular importance to India, which borders eight neighboring countries.

There was broad agreement among participants from both countries that ethics, education, outreach, and strong risk communication underlie effective implementation of any policy or regulatory framework for minimizing risk in the life sciences. One speaker from the US underscored the importance of operationalizing bioethics, maintaining that the ethical implications of high-risk research should be considered before the

experiments are conducted, rather than as an afterthought. Others agreed, and recommended that biosecurity experts in both countries engage with commercial biotechnology providers to address biosafety concerns. Several speakers also commented on the importance of incorporating biosafety and bioethics considerations into life sciences curricula for students. India, in fact, has already reported some success in this area: its BLiSS Program, administered by the Department of Biotechnology, offers biosafety training to educators in northeast India.[18]

Opportunities for Science & Defense Collaboration Between the US and India

The dialogue participants examined potential opportunities for advancing science and defense collaboration between the two countries. One speaker highlighted challenges in identifying biosecurity priorities of mutual concern between the US and India, pointing out that India's threat landscape is characterized primarily by concerns regarding naturally emerging zoonoses and outbreaks, whereas technological and deliberate threats are more prominent concerns in the US, alongside natural infectious disease threats. Each country also allocates different levels of funding and resources toward countering biosecurity threats. It was noted that US-India collaboration remains critical to mitigating infectious disease threats globally; each country's efforts in research, clinical management, and manufacturing, for example, has revolutionized the way the world manages HIV/AIDS. The US delegation also noted the positive trajectory of the US-India bilateral relationship, and suggested that ongoing collaborations between the two countries' militaries (i.e. conducting joint exercises) might serve as a basis for future biosecurity cooperation.

Both delegations acknowledged the difficulty of determining which pathogens or technologies will likely pose the most serious societal threats. One speaker suggested that focusing research efforts on microbial strains that are most likely to jump to human populations could pave the way for earlier detection and characterization of such threats. Another participant concurred, but noted that this approach requires labs to screen samples on large scales; as such, supplying labs with affordable research equipment could lower the cost barriers for pathogen discovery and early detection efforts. Both delegations agreed that identifying actionable, shared biosecurity and life sciences research priorities will require India and the US to continue building trust between their respective governments in addition to promoting peer-to-peer exchanges. A speaker from India observed that while trust and engagement between individual practitioners in the US and India appears to be robust, institutional collaboration often fluctuates with the political climate.

Despite the differences between each country's respective threat assessments, both delegations agreed that there remains enormous potential for scientific and technological collaboration between the US and India across their respective defense and civilian sectors, particularly in the realm of vaccine and diagnostics research, discovery, and development. Other potentially fruitful areas of collaboration noted in discussions include development of detection technologies and new modes of physical protection (e.g. hazmat suits), advancing synthetic biology, and examining defense applications of biomaterials. The dialogue participants also identified several technological capabilities which – if pursued jointly between the two countries – could elicit solutions to long-standing challenges in biosecurity. Both delegations, for example, expressed great interest in applying artificial intelligence, advanced computing, modeling, simulation, and big data to forecast the emergence and trajectories of novel biological threats. Citing the "Innovation S-Curve,"[19] one speaker also observed that the initial optimism inspired by newly emerging technologies often wanes before those technologies fully mature. However, certain technological capabilities (e.g. computer-aided drug discovery and development) have reached a point where new collaborative efforts could lead to important advances in biological threat reduction. A speaker from the US agreed, describing a

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newly formed public-private partnership between the Lawrence Livermore National Laboratory, GlaxoSmithKline, the University of California San Francisco, and the National Cancer Institute, which will aim to transform cancer drug delivery; similar partnerships between US and Indian civilian and defense institutions could accelerate efforts to strengthen biosecurity in both countries.[20]

Realizing the dividends of bilateral scientific collaboration will require the US and India to tackle a few critical barriers. There was broad agreement among both delegations that the two countries should formalize their science and defense partnerships through formal commitments of money, resources, and political will. Echoing earlier discussions, participants also underscored the need to facilitate increased scientific engagement between practitioners in each country, citing the US-India 21st Century Knowledge Initiative as an exemplar mechanism of productive peer-to-peer scientific exchange.[21] Finally, there remains a need for both countries to address lingering challenges in facilitating technology transfers and addressing the intellectual property considerations associated with regulating products that emerge from bilateral collaborative efforts.

Remarks by Dr. David Relman, Thomas C. and Joan M. Merigan Professor in Medicine, Microbiology, and Immunology; Co-Director, Center for International Security & Cooperation, Stanford University

The delegations engaged in an interactive discussion with Dr. David Relman regarding potential risks associated with life sciences research and strategies for improving peer-to-peer engagement. Dr. Relman's remarks centered around three hard problems in pursuing life sciences research: tangibly characterizing the impacts of rapidly evolving scientific capabilities on the threat landscape, fostering productive conversations about risk in the life sciences, and building more effective governance mechanisms for life sciences research. Dr. Relman noted that forecasting every possible outcome and application of high-risk research is immensely difficult, given the unpredictability of the "human variable" (i.e. human agency) in developing and promulgating new technologies. Considering the trend toward more affordable, easily accessible biotechnologies, dialogue participants affirmed the value of promoting increased peer-to-peer scientific exchanges governed by codes of conduct, cultures of trust and accountability between collaborators, and willingness to engage with the inherent security concerns associated with high-risk research. Dr. Relman agreed, but highlighted the misalignment between such engagements and existing incentive structures in the life sciences world, suggesting that this misalignment discourages scientists from actively promoting cultures of trust and ethics. Given financial and technical disparities between different parts of the world, and recognizing that all communities share in the consequences of high-risk research, Dr. Relman and both delegations also concurred that scientists share a moral imperative to build partnerships with resource-poor practitioners and institutions.

Bridging Science, Surveillance, and Public Health Action

The delegations next examined the challenges associated with operationalizing scientific discoveries and technological advances into meaningful public health and healthcare responses during a biosecurity emergency. One speaker observed that consequence management is the final pathway for responding to any kind of threat – yet, planning for consequential threats remains chronically under-funded by many national governments, often resulting in mismatches between healthcare needs and available resources during a crisis.

Given this perennial shortcoming in emergency response, both delegations agreed that the US and India share a moral imperative to plan for all plausible threats, and should assess such threats in a global context. Speakers also identified several key gaps in emergency response that both countries could address jointly: workforce training, healthcare provider-community engagement, building medical surge capacities, and enhancing medical countermeasure development and distribution. One speaker also noted that certain emerging technologies could help bridge these so-called "last mile challenges"; drones, for example, could improve medical countermeasure distribution in resource-poor settings.

Noting the enormous benefits to be reaped from leveraging each country's considerable science and technological capabilities, both delegations agreed that the US and India should examine opportunities for meaningful collaboration on medical countermeasure development, production, and delivery. A speaker from India observed that India is already the world's largest producer of childhood vaccines, has played a major role in transforming efforts to prevent and manage hepatitis B and HIV/AIDS worldwide. Given the lower costs of producing vaccines, biosimilars, and other pharmaceuticals in India, both delegations agreed that the country could also be instrumental in manufacturing next-generation therapeutics (e.g. monoclonal antibodies) on large scales during infectious disease crises. Participants also reiterated the importance of strengthening each country's architecture for facilitating peer-to-peer dialogue, noting that such relationships not only foster scientific innovation, but also encourage exchanges of best practices and lessons learned from responding to emergencies.

S.R. Rao

Discussions with Dr. Hillary H. Carter, Peter Mamacos, Dr. Luciana Borio (National Security Council, the White House), and Dr. Gerald Epstein (Office of Science and Technology Policy, the White House)

The dialogue participants visited the White House and met with several members of the National Security Council, which advises the President on national security, coordinates national security policy across government, and engages with the US government interagency on critical biosecurity and global health issues. In this capacity, the NSC also oversees implementation of the US's legacy global health programs, such as the President's Malaria Initiative and the President's Emergency Plan for AIDS Relief, as well as the Global Health Security Agenda (GHSA). Acknowledging the comprehensive approach to biosecurity adopted by both countries, the NSC staff affirmed that the US views India as an important partner in addressing the threats of antimicrobial resistance and tuberculosis, increasing access to medicines, accelerating medical countermeasure production, and developing new biotechnologies. The Indian delegation also expressed great interest in reviewing the forthcoming National Biodefense Strategy, noting commonalities between both countries' processes for formulating national biosecurity policy.

The NSC staff and Indian dialogue participants also discussed shared biosecurity priorities, which include biosafety, select agents, global health security, building rapid emergency response capabilities. Both expressed support for the GHSA – which, under the recently issued Kampala Declaration, has been extended to 2024.[22] The Indian delegation reiterated that the current political climate offers unique opportunities for collaboration between the US and India on shared challenges in biosecurity, global health security, and defense medicine. The NSC staff also expressed interest in jointly strengthening empirical knowledge bases for risk assessment and basic science. The briefing concluded with agreement that there is value in continued bilateral cooperation between both countries on biosecurity, perhaps by leveraging India's unique medical countermeasure development capabilities.

Future Priorities

Both delegations expressed great interest in continuing discussions of shared biosecurity priorities at the next meeting of the dialogue, which is scheduled to be held in New Delhi, India in February 2018. Participants identified a set of potential issues to examine at this meeting, along with action items to pursue in the interim. These include, but are not limited to:

- Developing a memorandum of understanding to formalize collaborative efforts in biosecurity between the US and India;
- Identifying and jointly implementing a milestone project tackling a subset of shared biological threats;
- Conceptualizing a program for facilitating increased peer-to-peer exchange between US and Indian life scientists on biosecurity priorities;
- Examining opportunities for building public-private partnerships to tackle challenges in biological threat detection and rapid response;
- Identifying actionable ways of strengthening the medical countermeasure enterprises of each country;
- Considering options for establishing a regional biosecurity center headquartered in India;
- Continuing to examine recent developments in global health security;

Additionally, in December 2017, members of both the Center for Health Security and the Indian delegation hosted a side event at the Biological Weapons Convention Meeting of States Parties (chaired by Ambassador Amandeep Singh Gill, Joint Secretary for Disarmament & International Security, Ministry of External Affairs, Government of India). The side event will discuss findings from the India-US biosecurity dialogue as well as India's biosecurity priorities, including biotechnology, biosafety, and biocontainment.

Appendix A: Dialogue Participants

India-US Strategic Dialogue on Biosecurity
November 6-7, 2017

Professional Biographies

Harsh Vardhan BATRA, PhD

Harsh Vardhan Batra is the retired director of Defense Food Research Laboratory, Defense Research Development Organization, India. He is currently chairman of the Department of Biotechnology Taskforce of Veterinary Vaccine and Diagnostics and Canine Health, an expert member of the task force on tuberculosis, and an executive council member of Translational Research Platform Veterinary Biologicals, Chennai.

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.

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 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'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*, 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 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.

William P. HOSTYN, MS

William (Bill) Hostyn is the chief, Global Futures, 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. In Global Futures, he is further involved in developing the agency strategic plan, with his staff leveraging stakeholder interviews, scenario-based planning, SWOT analysis, policy analysis, and crowdsourcing. 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 strategy 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 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 a 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.

Subodh KUMAR, PhD
Subodh Kumar is a scientist in the Division of Microbiology, Defence R&D Establishment, Government of India. He received his PhD in microbiology and immunology at the Postgraduate Institute of Medical Education and Research and his MSc in microbiology from the Central Research Institute, Kasuali.

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

Previously, he served in the US Department of Defense as assistant secretary for International Security Policy, in the State Department as ambassador and US chief negotiator on Strategic Offensive Arms (START I), and in the White House as deputy assistant to the President for National Security Affairs. He has also served on the National Security Council staff as a senior director, in the Pentagon as deputy assistant secretary, on the senior professional staff of the US Senate Armed Services Committee, and in Vietnam, commissioned in the United States Army.

Indira NATH, MD, FRCPath, DSc
Indira Nath is formerly senior professor and founder and head, Department of Biotechnology, All India Institute of Medical Sciences. After retirement she held several positions, including SN Bose Professor of the Indian National Science Academy, Raja Ramanna fellow and emeritus professor, National Institute of Pathology (ICMR), New Delhi, India; director of Lepra Research Centre, Hyderabad; and dean of the Medical School, AIMST, Malaysia. Her research interests are in immunology of infectious diseases, with her seminal work on cellular immune responses in human leprosy. She is involved in medical education, medical and science policies, science integrity, biosafety/biosecurity, and women scientists' issues at national and international levels.

She is a fellow of 3 Science and Medical Academies of India and the Academy of Sciences for Developing World (TWAS). She has received prestigious national awards for her research as well as the L'Oreal UNESCO Women in Science Award for Asia Pacific, and civil awards, notably, Padmashri, India; Chevalier Ordre National du Merité, France; and Silver Banner, Tuscany, Italy. She was conferred a DSc (hc) 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, and is a current board member on the International Federation of Biosafety Associations (IFBA) and the president of ABSA International.

Abhijit PODDAR, PhD

Abhijit Poddar is working as scientist (microbiology) at Biosafety Support Unit (BSU) established under 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.

H. Krishna PRASAD, PhD

H. Krishna Prasad is emeritus medical scientist, Department of Biotechnology, All India Institute of Medical Sciences. Prior to this he was professor, Department of Biotechnology, All India Institute of Medical Sciences. Dr. Prasad received his MS and PhD from All India Institute of Medical Sciences.

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 senior 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 recombinant products and biocontainment 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 responsible for establishment of the Biotechnology Regulatory Authority of India that replaces the existing regulatory framework. Dr. Rao has 25 years of experience 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, and founder of *Asian Biotechnology Development Review,* a publication reflecting cross-cutting issues in Asian biotechnology.

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 is professor emeritus at the Institute of Life Sciences, Bhubaneswar, an autonomous research institution under the 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 the 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. 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.

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 defense 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.

Appendix B: Meeting Agenda

The Johns Hopkins Center for Health Security
in collaboration with
the Department of Biotechnology, Ministry of Science & Technology,
Government of India

November 6-7, 2017
Concorde Room
Sofitel Washington, DC
806 15th Street NW

AGENDA

DAY 1: NOVEMBER 6

08:30-09:00	**Breakfast in the Montmartre Room**
09:00-09:30	**Welcome, Goals for Meeting, Introductions** Tom Inglesby, Director, Johns Hopkins Center for Health Security S.R. Rao, Advisor, Department of Biotechnology, Ministry of Science & Technology, Government of India
09:30-10:30	**Dialogue Session One: Changing Geopolitical Context** ***Opening Remarks:*** Ambassador Rakesh Sood & Ambassador Ron Lehman Bilateral collaboration on shared priorities in science, technology, defense, and health are a cornerstone of the United States' and India's relationship. How will rapidly evolving geopolitical dynamics and regional contingencies shape the national security landscapes in both countries? What are the most important shared national security and diplomatic priorities for the two countries? How might the US and India leverage formal and less-formal opportunities to collaboratively strengthen biosecurity both regionally and globally?
10:30-10:45	**Coffee Break**
10:45-11:45	**Dialogue Session Two: Evolving Biosecurity Threat Landscapes** ***Opening Remarks:*** Indira Nath & David Franz In what ways have Indian and US approaches to biological threats evolved in the last year? What do India and the US see as the greatest biological threats to their respective countries? How are national programs organized to address these threats? Within each country, what is the balance of concern related to naturally occurring, accidental, and deliberate biosecurity threats?

11:45-12:00	**Remarks by Christopher Park,** Director of Biological Policy, US Department of State *Next Steps for the Biological Weapons Convention in 2017*
12:00-12:45	**Lunch in the Montmartre Room**
12:45	**Group Departs for the Pentagon by Shuttle**
14:00-14:45	**Tour of the Pentagon**
15:00-17:00	**Remarks by David Christian Hassell,** Deputy Assistant Secretary of Defense for Chemical and Biological Defense
	Q&A and Discussion
17:00	**Depart Pentagon for Dinner**
18:00	**Dinner at Equinox Restaurant** *818 Connecticut Ave NW, Washington, DC 20006*

DAY 2: NOVEMBER 7

08:00-08:30	**Breakfast in Montmartre Room**
08:30-10:00	**Dialogue Session Three: Scientific Challenges to Biosecurity, including Advances in Synthetic Biology and the Future of Pathogen Management** ***Opening Remarks:*** Sarah Carter, Maureen O'Leary, H. Krishna Prasad, and Balachandran Ravindran How do India and the US see the future of biotechnology changing the potential risks of biological accidents and deliberate misuse? How might regulatory control of pathogens affect national biosecurity? To what extent do India and the US screen the laboratorians working on high consequence pathogens in their laboratories? What lessons should be drawn from instances of dual-use research of concern, and the increased accessibility of powerful biotechnologies? How do India and the US address the issue of research intended to create novel "Potential Pandemic Pathogens"?
10:00-10:15	**Coffee Break**
10:15-11:15	**Dialogue Session Four: Opportunities for Science & Defense Collaboration Between India and the US** ***Opening Remarks:*** David Rakestraw, Subodh Kumar, and Harsh Vardhan Batra In this session, we will discuss how the US and India could diminish biosecurity risks through scientific engagement, as well as through regional and global collaboration between the scientific, public health, and security communities. What areas of life science collaboration would be compelling to defense programs in both the India and the US? How might India and the US collaborate more effectively on biosecurity related research programs? Are there barriers to cooperation now which can be identified? What biosecurity research programs outside of defense would be emerging opportunities for collaboration?
11:15-11:45	**Preparation for White House Briefing** In this session, dialogue participants will prepare for meeting with **Hillary H. Carter** (Director for Countering Biological Threats, National Security Council) and her NSC colleagues at the White House. At the afternoon White House session, India's dialogue members will have a chance to convey Indian priorities and to ask questions. We will also hear from NSC staff on their programs and priorities.
11:45-12:05	**Group Photo**
12:05-13:00	**Lunch in Montmartre Room *Remarks:* David Relman,** The Thomas C. and Joan M. Merigan Professor in Medicine, and Microbiology & Immunology, and Co-Director of the Center for International Security and Cooperation at Stanford University.

13:00-14:15	**Dialogue Session Five: Bridging Science, Surveillance, and Public Health Action: Achieving Results by Tackling Scientific and Operational Problems in Biosecurity** ***Opening Remarks:*** Dan Hanfling, Abhijit Poddar, and S.R. Rao How might India and the US learn from each other regarding how our respective countries address scientific and operational challenges in biosecurity? What is the research and development approach for acquiring medical countermeasure deemed of national importance? What are the plans for distributing medical countermeasures in emergencies? What are our respective approaches to responding to major biological emergencies? What are our national plans to care for large surges of acutely ill people in the hospital system?
14:15-14:45	**Identifying Next Steps & Priorities for Future Dialogues** Are there issues that should be elevated to Track 1 consideration between India and the US? What issues should be developed more deeply at the next meeting of the Dialogue in February?
14:45	**Depart for White House by Shuttle**
16:00	**White House Meeting**
17:30	**Meeting Adjourns; Group Returns to Hotel by Shuttle**

Appendix C: References

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