US-India Strategic Dialogue on Biosecurity

Report from the First Dialogue Session
Washington, DC, 20-21 September 2016

UPMC Center for Health Security
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Executive Summary

India is an important strategic partner to the United States in health, defense, commerce, and global security. Both nations have established bilateral agreements in science and technology, and share common goals in diminishing epidemic disease and supporting the Global Health Security Agenda. Both are also global leaders in biotechnology, engage in joint military exercises, and play key roles in nonproliferation activities around biological and chemical weapons. Furthermore, as the world's most populous democracies, the US and India are uniquely poised to benefit from strengthening bilateral ties and increasing collaborative efforts around shared national security priorities, which include a constantly evolving biological threat landscape. In fact, following a June 2016 meeting, President Barack Obama and Prime Minister Narendra Modi affirmed that "the United States and India will work together to combat the threat of terrorists accessing and using chemical, biological, nuclear and radiological materials."[1]

For these reasons, in September 2016, the UPMC Center for Health Security hosted a Track II dialogue between India and the US that focused on biosecurity. The meeting took place in Washington, DC, and was sponsored by the Project on Advanced Systems and Concepts for Countering WMD (PASCC; sponsored by the Defense Threat Reduction Agency) of the United States Naval Postgraduate School (the program has since been moved to the US Air Force Institute for National Security Studies).

The purpose of this meeting was to explore biosecurity perspectives of India and the US, examine policy frameworks for mitigating biological threats, share lessons learned and best practices for enhancing biosecurity, and foster partnership and engagement between the two nations. The meeting was attended by participants representing academia, government, and industry in the US and India.

Dialogue participants included experts in biosecurity, biosafety, biodefense, the life sciences, regulatory policy, global health security, and regional security.

The participants from India included the following**:**

- **Rakesh Bhatnagar, PhD,** *Professor, JC Bose National Fellow, Jawaharlal Nehru University*
- **Pawan K. Dhar, PhD,** *Professor & Head, Synthetic Biology, Jawaharlal Nehru University, who sent a statement after visa delays prohibited him from attending in person.*
- **Jaishree Garhyan, PhD**, from *Jawaharlal Nehru University*
- **Indira Nath, MD,** *Former Head & Senior Professor, AIIMS Delhi, Former Raja Ramanna Fellow & Emeritus Professor, NIOP Delhi*
- **S.R. Rao, PhD,** *Advisor, Ministry of Science & Technology, Government of India*

The participants from the US included the following:

- **Parney C. Albright, PhD,** *President & CEO, HRL Laboratories*
- **David R. Franz DVM, PhD,** *Former Commander, US Army Medical Research Institute for Infectious Diseases*

- **Margaret A. Hamburg, MD,** *Foreign Secretary, Academy of Medicine; Former Commissioner, Food & Drug Administration*
- **Amb. 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,** *Director, Environmental Health & Safety, Dartmouth College, and president-elect of the American Biological Safety Association (ABSA)*

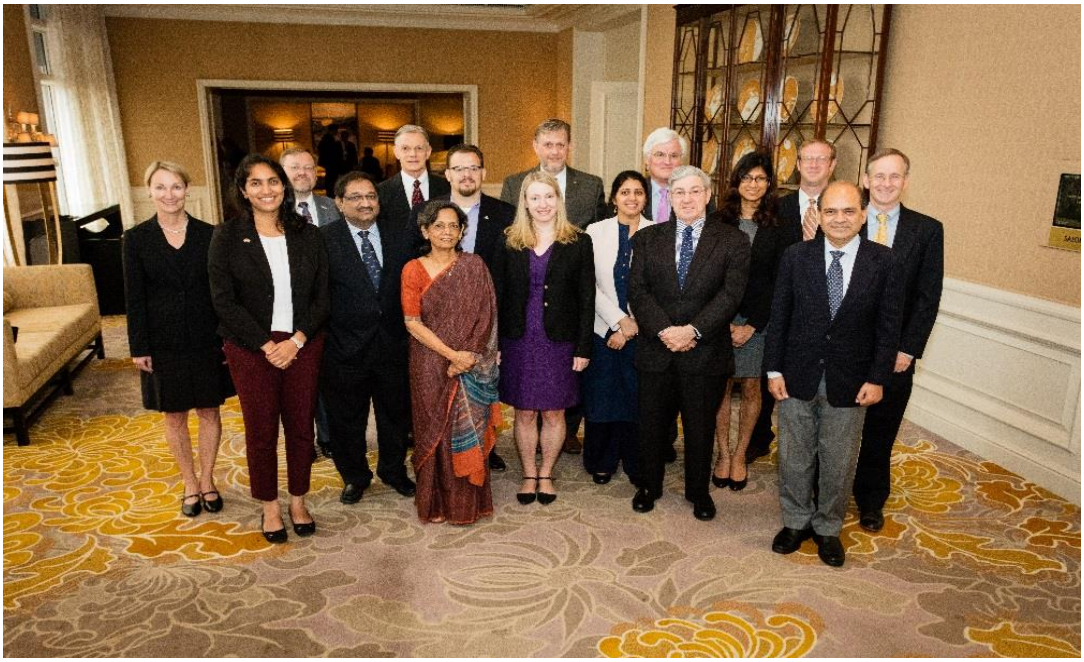
In addition to the participants and UPMC Center for Health Security staff, there were several observers of the dialogue, including the following: Dave Hall, International Project Manager, Cooperative Biological Engagement Program, Defense Threat Reduction Agency; Shaun Hayeslip, Deputy Team Chief, South Asia, Department of State; and Heema Sharma, Technical Intramural Research Training Fellow, National Institutes of Health.

The meeting consisted of six plenary sessions, each preceded by opening remarks delivered by select participants. These remarks, in turn, set the stage for subsequent group dialogue. Broadly, topics of discussion included each nation's biosecurity and biosafety priorities; challenges in the life sciences, basic research, medical countermeasure development, emerging biotechnology regulation, and risk assessment; approaches to strengthening national and international responses to naturally occurring biological threats; strategies for countering deliberate biological threats; and potential opportunities for future regional partnerships.

In addition to the plenary sessions, there were policy briefings and presentations. Rear Admiral Kenneth Bernard (United States Public Health Service, ret.; Member, Threat Reduction Advisory Committee, Department of Defense; former Special Assistant to the President for Security and Health on the National Security Council Staff, White House), discussed the approach that the US has taken towards biosecurity since 2001. Dr. Meg Flanagan (Microbiologist, Biological Policy Staff, Department of State) discussed the US perspectives and goals for the 8th Review Conference of the Biological Weapons Convention, which will be held in Geneva, Switzerland in November, 2016. Dr. Ronald K. Hann, Jr. (Director, Chemical and Biological Technologies Department, Defense Threat Reduction Agency) discussed programmatic efforts within the Defense Threat Reduction Agency (DTRA) to address biodefense challenges in the US military. Additionally, meeting participants also traveled to the White House to have a discussion with Dr. Beth Cameron (Senior Director for Global Health Security & Biodefense, National Security Council, the White House) and Ms. Eleanor Celeste (Policy Analyst for Medical and Forensic Sciences, Office of Science and Technology Policy, the White House).

A second meeting of the India-US biosecurity dialogue is tentatively scheduled to be held in New Delhi, India, in February 2017. Potential subjects of discussion for this meeting include: developing planning scenarios around biological threats of mutual concern; best practices around dual-use science risk mitigation; comparative risk assessments for biological threats; strategies for early outbreak detection; identifying incentives for advanced development of medical countermeasures; criteria for building BSL-3 and BSL-4 laboratories; and applications of microbial forensics in outbreak investigations. Other suggestions included further exploration of the Joint External Evaluation (JEE) process, envisioning the future of biosafety practice at high-containment facilities, and engaging with strategic partners in government (e.g. budgetary

authorities and national security policymakers) to further raise the profile of the dialogue and ensure that biosecurity remains a priority for both nations.



Back row: Maureen O'Leary, Ronald K. Hann, Jr., David R. Franz, William P. Hostyn, Parney Albright, Shaun Hayeslip
Second row: Sanjana Ravi, S.R. Rao, David Hall, Jaishree Garhyan, Heema Sharma, Tom Inglesby
Front row: Indira Nath, Gigi Kwik Gronvall, Ronald F. Lehman, Rakesh Bhatnagar

Introduction

As an emerging global leader and a key regional player in South Asia, India's efforts in the life sciences, health, defense, and biological threat mitigation are of increasing consequence to both regional and global biosecurity. India boasts a robust bioeconomy, with a biotechnology industry valued at $11 billion (as of 2016), a vaccine market valued at $602 million (as of 2012), and several pharmaceutical plants approved by the US Food & Drug Administration.[2,3,4] The nation also maintains numerous BSL-3 laboratories, along with the only BSL-4 facility in South Asia.[5] However, India remains vulnerable to naturally occurring threats, including emerging zoonotic and vectorborne diseases, antibiotic-resistant bacteria, and lower respiratory tract infections. Historical tensions with neighboring countries, terrorist activity across South Asia, and state and non-state interests in biological and nuclear weapons pose national security threats to both India and the US. Additionally, a high volume of regional commerce and travel – along with India's shared borders with Pakistan, Myanmar, Sri Lanka, China, Bhutan, Bangladesh, and Nepal – underscore the potential risk of transnational disease spread.

In September 2016, the UPMC Center for Health Security hosted a Track II biosecurity dialogue between the United States and India. The meeting took place in Washington, DC, and was sponsored by the Project on Advanced Systems and Concepts for Countering WMD (PASCC) of the Naval Postgraduate School (the program has since been moved to the US Air Force Institute for National Security Studies).

The purpose of this meeting was to explore the biosecurity perspectives of the US and India, examine policy frameworks for mitigating biological threats, share lessons learned and best practices for enhancing biosecurity, and foster continued partnership and engagement between the two nations to strengthen resilience in an evolving threat landscape. The meeting was attended by participants representing academia, government, and industry in the US and India. Speakers included experts in biosecurity, biosafety, biodefense, the life sciences, regulatory policy, global health security, and regional security.

The meeting consisted of six plenary sessions, each preceded by opening remarks delivered by select participants. These remarks, in turn, set the stage for subsequent group dialogue. Broadly, topics of discussion included each nation's biosecurity and biosafety priorities; challenges in the life sciences, basic research, medical countermeasure development, emerging biotechnology regulation, and risk assessment; approaches to strengthening national and international responses to naturally occurring biological threats; strategies for countering deliberate biological threats; and potential opportunities for future regional partnerships.

The six sessions were interspersed with policy briefings by Rear Admiral Kenneth Bernard (United States Public Health Service, ret.; Member, Threat Reduction Advisory Committee, Department of Defense; former Special Assistant to the President for Security and Health on the National Security Council Staff, White House), Dr. Beth Cameron (Senior Director for Global Health Security & Biodefense, National Security Council), Ms. Eleanor Celeste (Policy Analyst for Medical and Forensic Sciences, Office of Science and Technology Policy), Dr. Meg Flanagan (Department of State), and Dr. Ronald K. Hann, Jr. (Chemical and Biological Technologies Department, Defense Threat Reduction Agency). In addition to the participants and UPMC

Center for Health Security staff, there were several observers of the dialogue, including: Dave Hall (International Project Manager, Cooperative Biological Engagement Program, Defense Threat Reduction Agency), Shaun Hayeslip (Deputy Team Chief, South Asia, Department of State), and Heema Sharma (Technical Intramural Research Training Fellow, National Institutes of Health).

Both delegations fully engaged in the dialogue. Participants and meeting observers conveyed that they were impressed with the content and quality of the discussion in each session. Dialogue participants saw great value in convening influential, experienced multidisciplinary stakeholders to examine strategies for tackling critical biosecurity threats of consequence to both nations. Participants also expressed high interest in continuing to examine these issues in a Track II forum to further promote dialogue and collaboration between the US and India. A second meeting is tentatively scheduled to be held in New Delhi, India in February 2017. Participants suggested many discussion topics that could help in continuing to deepen the understanding of biosecurity in the two countries as well as to identify potential areas of collaboration between the US and India. These include, but are not limited to: developing planning scenarios around biological threats of mutual concern; best practices around dual-use science risk mitigation; comparative risk assessments for biological threats; strategies for early outbreak detection; identifying incentives for advanced development of drugs, vaccines, and therapeutics, criteria for building and maintaining BSL-3 and BSL-4 laboratories; and applications of microbial forensics in outbreak investigations.

Meeting Overview

The following sections describe key themes and findings from the meeting discussions.

Priorities, Strengths, and Challenges in National Biosecurity

The dialogue commenced with an overview of perspectives about biological threats in the US and India, including strengths, priorities, and remaining gaps. Given recent experiences with naturally occurring outbreaks of emerging infectious diseases – such as SARS, H1N1 and H5N1 influenza, Ebola, Zika, chikungunya, and dengue – both India and the US have designated preparedness and response to biological threats as an important governmental priority. Other events have further raised the profile of biosecurity threats in the US, including the 2001 Amerithrax attacks, accidental shipments of anthrax from the US Department of Defense, and gain-of-function experiments with H5N1 influenza. Similarly, several outbreaks of unknown origin have illustrated the risks associated with biological threats in India, including a scrub typhus outbreak in northeastern India during the Indo-Pakistan War in 1965; 1994 outbreaks of pneumonic plague and bubonic plague in Surat and Beed, respectively; and a 1996 outbreak of dengue in New Delhi.[6] Both the US and India report varying levels of multidisciplinary collaboration with respect to biosecurity threat mitigation.

Participants discussed the extent to which a national focus on preparing for emerging infectious diseases also prepared countries for accidental and deliberate threats. For example, while it is clear that many of the anticipated responses to such events would be similar (epidemic response, vaccine development, care for the sick, etc.), it is also true that deliberate events would follow different patterns, could be of larger scale, and would involve different components of government. Ensuring that these problems are visible in a place in government which can provide strategic guidance and sufficient resources was a priority in both delegations. Both delegations affirmed the importance of having biosecurity policy frameworks that account for novel threats and prevent ad-hoc national responses to infectious disease crises. In this vein, India's National Disaster Management Authority (NDMA) is in the process of updating its guidelines for managing biological disasters. The movement of pathogens across national borders remains a threat, particularly due to regional and global travel, commercial activity, and shared borders with neighboring countries. Finally, participants discussed the importance of strengthening multi-sector collaboration, such as within the Global Health Security Agenda (GHSA).

Strengthening National and International Responses to Natural Threats

The global epidemics of Zika and Ebola have highlighted the need for robust national capabilities for countering emerging infectious diseases. Both India and the US have invested considerable resources in their respective MCM research, development, and manufacturing enterprises. India and the US are also regional leaders in responding to public health emergencies of all kinds, including both natural disasters and biosecurity threats. In this vein, participants discussed national and international response mechanisms designed to detect and respond to naturally occurring infectious disease outbreaks. India's NDMA, for example (a civilian body with paramilitary components), consists of twelve battalions of soldiers that are highly adept at responding to natural disasters. More recently, NDMA has also provided assistance (e.g. patient transport) during infectious disease epidemics. The US participants noted analogous functions

between NDMA and several US-led entities, including the Federal Emergency Management Agency (FEMA) and the National Disaster Medical System (NDMS). Participants from both nations discussed how dedicated biosecurity training for these entities may help enhance national response capacities.

Speakers discussed the value of adopting a risk-based approach to sizing response systems to biological threats; that is, setting specific threat benchmarks (e.g. the number of sick patients, specific emergency conditions, etc.) that countries should prepare for, and then designing programs and infrastructure to address those needs. Participants from both nations highlighted the need to invest in dedicated capabilities for executing rapid responses (i.e. developing MCMs) to quickly evolving biological threats, as well as the need for better tools to plan for biological emergencies. The potential value of collaboratively creating internationally accepted planning scenarios, such as the H1N1 influenza scenario developed by the US Centers for Disease Control & Prevention, was also discussed.

Remarks by Rear Admiral Kenneth Bernard

The discussion continued with reflections from Dr. Kenneth Bernard (United States Public Health Service, ret.; Member, Threat Reduction Advisory Committee, Department of Defense; former Special Assistant to the President for Security and Health on the National Security Council Staff, White House) on the evolution of the US's biodefense strategy. Dr. Bernard highlighted the events of September 11th and the subsequent anthrax attacks as watershed moments for biosecurity in the US, recalling how these emergencies catalyzed new collaborative efforts between the health and security sectors. Dr. Bernard also highlighted the importance of securing buy-in from political leadership on biosecurity issues, emphasizing the need for high-ranking personnel to raise the profile of biological threats in the US's national security portfolio. One theme of the subsequent group discussion was that strong political advocates are necessary but insufficient for successful policymaking in biosecurity; national leaders must also ensure that health and security budgets align with such policies.

White House Briefing: Global Health Security & Biodefense

Dialogue participants traveled to the White House for a discussion with Dr. Beth Cameron (Senior Director for Global Health Security & Biodefense, National Security Council) and Ms. Eleanor Celeste (Policy Analyst for Medical and Forensic Sciences, Office of Science and Technology Policy). Topics of discussion included the GHSA and approaches to successful interagency collaboration in biosecurity. Dr. Cameron and Ms. Celeste highlighted the merits of the Track II dialogue format in facilitating US-India collaboration on biosecurity and biosafety, and described how combining NSC's internal, interagency perspective on security threats with OSTP's strategy of soliciting expertise from diverse external stakeholders has given rise to a more comprehensive approach to biosecurity policymaking at the White House.

Another important topic raised during the White House session was the Joint External Evaluation (JEE), a tool designed to evaluate biological threat preparedness in support of the GHSA. Dr. Cameron described how the JEE process was working internationally, and the delegations discussed how the JEEs might be used to improve preparedness for epidemics. Dr. Cameron explained how the JEE could identify best practices from countries with considerably different public health infrastructures. Dr. Cameron praised India's valuable contributions to the GHSA Antimicrobial Resistance and Biosafety & Biosecurity action packages. She described the US experience in undergoing its own JEE, and she explored with participants whether India might consider pursuing a JEE or participating in JEEs of other countries as experts, noting its broad expertise in preparedness and response to emerging infectious diseases and transnational biosecurity threats.

From left to right: Beth Cameron, Indira Nath, David Hall, and S.R. Rao during White House meeting of the Dialogue

Biosecurity & Biosafety

Participants discussed national policies and frameworks for regulating biosafety. Participants from both nations discussed the importance of fostering positive work cultures in laboratories, but highlighted several challenges in inculcating such cultures in practice. Budget constraints often limit the ability of many research institutions to maintain stringent biosafety standards, particularly in smaller institutions with fewer personnel. Additionally, scientists are often required to juggle research, teaching, and mentoring responsibilities in addition to overseeing biosafety practices at their facilities. Participants suggested that such institutions might benefit from hiring and training dedicated biosafety officers, citing the need for a community of scientifically literate biosafety experts who can work collaboratively with practicing scientists. The World Health Organization, which is respected as a standards-setting organization in India, could play an important role in training officers for this purpose. Participants also examined US and Indian personnel reliability practices, identifying several strategies for mitigating the risks associated with personnel: soliciting references for new hires, annual performance assessments, self- and peer-reporting, background checks, character certificates, and supervision of new personnel. While such measures have proven reasonably effective in the US and India, both delegations noted that critical gaps in biosafety practice remain, including fear of reporting breaches of protocol, weak support systems for exposed lab personnel, and a lack of harmonization among international biosafety standards.

Department of State Briefing: 2016 Biological Weapons Convention Review Conference

Participants received a briefing from Dr. Meg Flanagan (Department of State) regarding recent developments from the 2016 Biological Weapons Convention (BWC) Review Conference. Dr. Flanagan outlined recent efforts to improve communication between scientific experts and

diplomats, strengthen the BWC implementation support unit, and enhance the authority afforded to political meetings of States Parties. Dr. Flanagan also described a joint US-India proposal that calls for national legislation to regulate transfers as specified in Article III of the BWC, which prohibits the transfer, manufacture, and acquisition of designated agents, toxins, weapons, equipment, and delivery mechanisms.[7] Dialogue participants received an update on the United Nations Secretary-General's Mechanism (UNSGM) for Investigation of Alleged Use of Chemical and Biological Weapons, which permits the Secretary-General to "carry out investigations in response to reports that may be brought to his attention by any Member State concerning the possible use of chemical and bacteriological (biological) or toxin weapons that may constitute a violation of the Geneva Protocol."[8] Dr. Flanagan reported that this year's BWC conference will examine whether UNSGM is an adequate tool for investigating allegations of biological weapons use.

Countering Biology as a Deliberate Threat

The delegations next examined the unique considerations associated with countering deliberate misuses of biological agents. Participants reviewed the comparative importance of critical capabilities needed to launch an effective response to such events, including strong surveillance systems, environmental sampling tools, diagnostics for rapid clinical testing, MCMs for mass prophylaxis, trained and prepared healthcare workforces, hospital beds, respirators, and biocontainment units. Additionally, post-attack recovery was highlighted as an area of concern requiring serious consideration from both nations. Recalling earlier discussions of MCMs, participants also revisited the challenge of financing MCM research and development for priority threats. Both delegations discussed the merits of adopting national biosecurity policies that differentiate between EIDs and acts of bioterrorism, noting that the lack of distinction often complicates efforts to ensure MCM preparedness for low-probability, high-consequence events.

Participants discussed financial and policy-related requirements for efficient institutional responses to deliberate threats. Several participants underscored the importance of securing buy-in from political leaders, and noted that there is considerable value in employing a dedicated cadre of policy experts to ensure that agency budgets align with national biosecurity policies and threat prioritizations. Speakers from both countries also discussed the potential benefits of setting a top-of-government strategic approach to biosecurity threats: that is, having national governments articulate preparedness and response priorities around specific biological threats, and funding targeted research efforts in support of those needs. Without such strategic requirement setting – particularly in the case of MCMs lacking a strong commercial market – research and development for particular biological threats becomes far more uncertain.

Remarks by Dr. Ronald K. Hann, Jr.

Dialogue participants next received a briefing from Dr. Ronald K. Hann, Jr., Director of the Chemical and Biological Technologies Department at the Defense Threat Reduction Agency (DTRA). Dr. Hann described several ongoing DTRA-led efforts in biodefense, citing India as a key strategic partner with tremendous capabilities in defense-related research and development. Key priorities for DTRA in this realm include point-of-need and point-of-care diagnostics, early warning capabilities for potential biological attacks, enhanced decontamination technologies, and improved prediction strategies for infectious disease outbreaks across the world. Participants acknowledged the importance of considering the host-pathogen-environmental nexus when

developing both medical and non-medical countermeasures against biological threats. Indeed, the US and India both share interests in answering fundamental bioscience questions, including many related to the biology of dangerous pathogens, as well as those surrounding transmission dynamics of pathogens in the environment and in laboratories (e.g. aerosolization).

Regional Contingencies & Potential Areas of Partnership

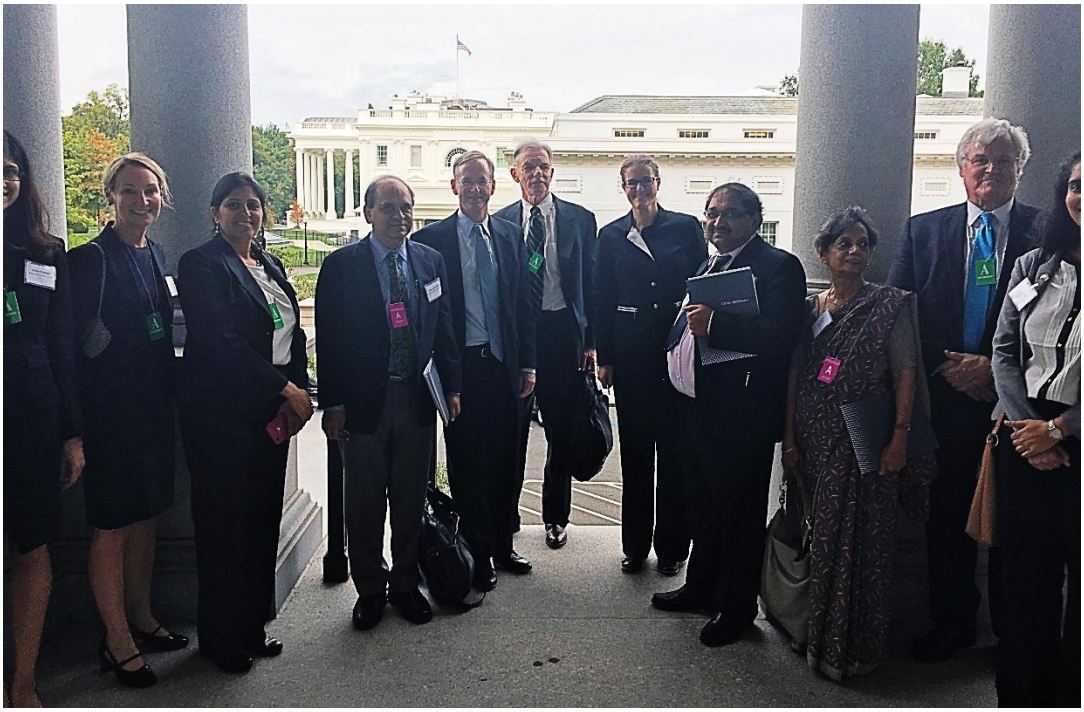
Participants agreed that bilateral partnership between the US and India could strongly enhance biothreat preparedness and response capabilities in both nations. There was also a shared sense that international relationships could be quite valuable in helping policymaking around various biosecurity, biosafety, and biotechnology-related contingencies. In fact, the Indian delegates recognized "a definite synergy" between India's biosecurity needs and American capacities for policy research.

Delegates acknowledged the importance of horizon scanning and forward thinking in assessing the risks associated with biological threats and emerging biotechnologies, citing the speed and facility with which they evolve, and reiterating the importance of global collaborative approaches to threat mitigation. In this vein, participants noted that international science engagement is an oft-underestimated – albeit very powerful – diplomatic tool, pointing out that multilateral scientific organizations have immense capacities to work cooperatively, notwithstanding historical tensions between member states. Though efforts like the Ronald Reagan-Indira Gandhi Science and Technology Initiative have bridged gaps in international scientific cooperation, both delegations cited lingering difficulties in fostering collaboration between their respective science and security communities. Still, given that the US and India already enjoy strong collaborative military partnerships, participants suggested building on these existing partnerships to include joint biosecurity and disaster management exercises.

Future Directions

Participants from both nations expressed great interest in continuing the dialogue and organizing a second meeting in New Delhi, India in February 2017. Delegates identified several potential subjects for discussion at this meeting. These include, but are not limited to: developing planning scenarios around biological threats of mutual concern; best practices around dual-use science risk mitigation; comparative risk assessments for biological threats; strategies for early outbreak detection; identifying incentives for advanced development of medical countermeasures; criteria for building BSL-3 and BSL-4 laboratories; and applications of microbial forensics in outbreak investigations.

Additionally, several participants suggested further exploration of the JEE process, envisioning the future of biosafety practice at high-containment facilities, and engaging with strategic partners in government (e.g. budgetary authorities and national security policymakers) to raise the profile of the dialogue further and ensure that biosecurity remains a key priority in both nations.



From left to right: Heema Sharma, Maureen O'Leary, Jaishree Garhyan, Rakesh Bhatnagar, Tom Inglesby, David R. Franz, Beth Cameron, S.R. Rao, Indira Nath, Parney Albright, Sanjana Ravi

Appendix A: Dialogue Participants

Penrose (Parney) C. ALBRIGHT, PhD

Dr. Albright joined HRL in 2014 after serving as director and associate director at large, Lawrence Livermore National Laboratory, and senior advisor, Office of the Director of National Intelligence (ODNI), Intelligence Advanced Research Projects Activity (IARPA), where he supported IARPA as well as ODNI senior leadership on a variety of issues.

Before he joined LLNL, Dr. Albright served from August 2005 to November 2009 as president and vice-chairman of the board of Civitas Group, LLC. He led the analytic team in support of the first Quadrennial Homeland Security Review, and he led the development and publication of a comprehensive Biodefense Net Assessment under DHS sponsorship.

In October 2003 Dr. Albright was confirmed by the Senate as Assistant Secretary of Homeland Security in the Department of Homeland Security. He served in that position until July 2005. His responsibilities included developing the multiyear strategic planning guidance and budget execution for the complete portfolio of programs comprising the Science and Technology Directorate. Dr. Albright served as principal scientific advisor to the secretary of Homeland Security on issues associated with science, technology, and the threat of biological, nuclear, and chemical terrorism. On these issues he served as the department's primary representative to other US government agencies, the Homeland Security Council, the National Security Council, the Office of Science and Technology Policy, and foreign governments.

Between January 2002 and the startup of the Department of Homeland Security, Dr. Albright concurrently held the positions of senior director for research and development in the Office of Homeland Security and assistant director for homeland and national security in the Office of Science and Technology Policy. He was the lead official in the White House responsible for providing advice to the Executive Office of the President on science and technology issues surrounding homeland security and on the threat of biological, nuclear, and chemical terrorism. In July 2002, he was asked to lead the planning for the Chemical, Biological, Radiological, and Nuclear Directorate of the proposed Department of Homeland Security; this later evolved into the Science and Technology Directorate.

Between 1999 and being asked to serve in the White House after the events of September 11, 2001, Dr. Albright worked in the Advanced Technology Office at the Defense Advanced Research Projects Agency (DARPA). While there, he developed and managed programs associated with special operations, intelligence collection, molecular biology, communications, and maritime operations.

From 1986 until joining DARPA, Dr. Albright worked at the federally funded Institute for Defense Analyses (IDA). While there, he became an internationally recognized expert on ballistic and cruise missile defense systems; space-based infrared and launch detection systems; and weapons and sensor system design and analysis.

He has authored several policy papers for internal or public consumption, primarily in the areas of homeland and national security. He has also been the author of numerous technical publications and briefings, in both the open and classified literature, primarily in the areas of statistical physics, infrared phenomenology, space-based tactical warning and attack assessment systems, intelligence collection systems, and ballistic and cruise missile defense systems.

Dr. Albright received his bachelor's degree in physics from the George Washington University (1979), and his master's and doctorate in physics from the University of Maryland (1982 and in 1985, respectively).

Rakesh BHATNAGAR, PhD

Dr. 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, identification of potential vaccine and drug targets and development of improved and safe vaccine and therapeutics for these infections diseases. His research group aims towards covering a wide breadth of both fundamental as well as applied sciences. Fundamental research includes exploration of phenomena like programmed cell death and two component signal transaction in Bacillus anthracis: and deciphering novel virulence determinants in Mycobacterium tuberculosis. His vision is to investigate these process 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 confer significant protection against virulent spore challenge in mice, guinea pigs, New Zealand white rabbits and rhesus macaques. The vaccine has successfully undergone pre-clinical toxicity studies and Phase I and II human clinical trials. Therapeutics development includes developing a bi-specific monoclonal antibody against the two anthrax toxins and his group is currently working towards development of a cognate single chain antibody which will also target the two toxins simultaneously, as well as humanizing it In Brucella infection biology, his group is working towards development of a recombinant vaccine and identification of 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, Fellow at the National Academy of Sciences, Fellow at the Indian Academy of Sciences, Fellow at the Indian National Sciences Academy. His laboratory has been ranked 7th among the top ten eminent researchers publishing commendable research papers on anthrax, where the top 6 were from Institute Pasteur, Harvard, NIH and USAMRID. Dr. Bhatnagar is recipient of President of India award for the innovation.

Pawan K. DHAR, PhD

Pawan K. Dhar is professor and head, Synthetic Biology Group, School of Biotechnology, Jawaharlal Nehru University, New Delhi. Prior to this, Prof. Dhar held faculty positions at RIKEN Genomics Sciences Centre, Bioinformatics Institute Singapore, Keio University, Kyoto

University, and Manipal University. Prof. Dhar received his PhD in 1993 from Banaras Hindu University, Varanasi, for his work on human genetics.

Prof. Dhar's lab is known for their work in making synthetic peptides and proteins for therapeutic applications. The synthetic proteome project that Prof. Dhar heads has a goal of building a novel drug discovery pipeline from sequences that are traditionally considered "junk." Prof. Dhar's dream is to transform the drug discovery space by offering a robust and untapped innovation pipeline using synthetic biology approaches.

As a part of social outreach, Prof. Dhar recently created the first Indian synthetic biology network, centered on responsible innovation, by bringing together scientists, students, and funding managers. Prof. Dhar has organized hands-on workshops and conferences, including the pre-iGEM competition, and serves on the external board of referees for the European Science Foundation and the Task Force of the Indian Govt. Marine Biotechnology Program.

David R. FRANZ, DVM, PhD

Dr. Franz served in the U.S. Army Medical Research and Materiel Command for 23 of 27 years on active duty and retired as colonel. He served as commander of the U.S. 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). He 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

Dr. 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 USA BSL-3s 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 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 and presented in Asia-Pacific biosafety association meetings in the past.

Gigi GRONVALL, PhD

Gigi Gronvall is a senior associate at the UPMC Center for Health Security and an associate professor at the University of Pittsburgh School of Medicine and Graduate School of Public Health. She is an immunologist by training. Dr. Gronvall's work 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. In a recent project, she identified gaps in international norms that govern biosafety and the response to laboratory errors. And in ongoing work funded through the Global Health Security Agenda, she is working with the ministries of health in Togo and Benin to develop national policies for biosafety, biosecurity, and infectious waste management.
Dr. Gronvall is the author of the book *Synthetic Biology: Safety, Security, and Promise*, to be 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. She is also the author of *Preparing for Bioterrorism: The Alfred P. Sloan Foundation's Leadership in Biosecurity,* which describes 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 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 made recommendations for future DoD actions in response to disease outbreaks.

Dr. Gronvall served as the science advisor for the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism; she has testified before Congress about the safety and security of high-containment biological laboratories in the United States; and she has served on 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 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.

Margaret A. HAMBURG, MD

Dr. Hamburg is an internationally recognized leader in public health and medicine. She is the former commissioner of the U.S. Food and Drug Administration (FDA), having stepped down from that role in April 2015 after almost 6 years of service. As FDA commissioner she was known for advancing regulatory science, streamlining and modernizing FDA's regulatory pathways, and globalization of the agency. Before joining the FDA, Dr. Hamburg was founding vice president and senior scientist at the Nuclear Threat Initiative, a foundation dedicated to reducing nuclear, chemical, and biological threats. Previous government positions include assistant secretary for planning and evaluation, US Department of Health and Human Services; health commissioner for New York City; and assistant director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health.

Dr. Hamburg earned her BA from Harvard College and her MD from Harvard Medical School and completed her medical residency at Weill Cornell Medical Center. She is a fellow of the American Association for the Advancement of Science and the American College of Physicians and is an elected member of the Council on Foreign Relations and the National Academy of Sciences, where she now serves as foreign secretary. Dr. Hamburg currently sits on the board of the Commonwealth Fund, the Simons Foundation, the Urban Institute, and the American Museum of Natural History. She is also a member of the Harvard University Global Advisory Council and the Scientific Advisory Committee for the Gates Foundation. She is the recipient of numerous awards and several honorary degrees.

William P. HOSTYN, MS

Mr. 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. The 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 D.C. 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 three 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, 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 B.S. in Organizational Management from Colorado Christian University, a M.S. in Public Administration from Troy State University and a M.S. 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 director of the UPMC Center for Health Security, a nongovernmental organization dedicated to protecting people's health from the consequences of epidemics and disasters and to ensuring that communities are resilient to those challenges. He is an associate professor of Medicine and Public Health at the University of Pittsburgh Schools of Medicine and Public Health.

Dr. Inglesby's work is internationally recognized in the fields of public health preparedness, pandemic flu and epidemic planning, and biosecurity. 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 chair of the National Advisory Council of the Robert Wood Johnson Foundation National Health Security Preparedness Index. He is a member of the External Laboratory Safety Workgroup appointed by the CDC Director that is examining the biosafety practices of the CDC, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA). He is on the Advisory Committee to the Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary of Preparedness and Response of the Department of Health and Human Services. He has also served on committees of the Defense Science Board and the National Academies of Sciences and in an advisory capacity to DHS and DARPA.

During the past 15 years, Dr. Inglesby has authored or co-authored more than 90 peer-reviewed articles, reports, and editorials on a range of issues related to health and security. He is editor-in-chief of the journal *Health Security*, which he helped to establish 14 years ago as the first peer-reviewed journal in its field, under its original title, *Biosecurity and Bioterrorism*. 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 public health preparedness and biosecurity. He is regularly consulted by major news outlets for his expertise. He is also on 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.

Ambassador Ronald F. LEHMAN, II

The Honorable Ronald F. Lehman II is the counselor to the director of Lawrence Livermore National Laboratory. He is also the chair of the US Department of Defense Threat Reduction Advisory Committee (TRAC) and recently co-chaired the National Academy of Sciences' study on the future of Cooperative Threat Reduction. Since 1996, Dr. Lehman has been the chairman of the governing board of the International Science and Technology Center, a 39-nation intergovernmental organization. He was Director of the 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.

In past years, he served on the Presidential Advisory Board on Proliferation Policy, on the State Department's International Security Advisory Board, as chair of the NATO High Level Group, on the governing board of the US Institute of Peace, and as a US representative to a number of United Nations disarmament and review conferences. Dr. Lehman formerly co-chaired the Policy Advisory Group on nonproliferation for the US Senate Foreign Relations Committee. He was on the Defense Science Board Task Forces on Globalization and Security, on Tritium, on Global Strike, and on Defense against Biological Weapons. He is currently on the National Research Council Committee on US Air Force Strategic Deterrence Military Capabilities in the 21st Century and served on the National Research Council's Committee on Science, Technology, and Health Aspects of the Foreign Policy Agenda of the United States and on its Committee on Alternative Technologies to Replace Anti-Personnel Landmines.
Dr. Lehman was detailed to the administrator of the National Nuclear Security Administration as counterterrorism coordinator after the September 11, 2001, attacks. For the Department of Energy, he was the US-Snezhinsk Working Group Co-Chair for the Joint Russian-American

Steering Committee on the Nuclear Cities Initiative. He served on the advisory panel for USSTRATCOM's Global Innovation and Strategy Center. He was on the Council on Foreign Relations Independent Task Force on the US Nuclear Posture. He was a public affairs fellow at the Hoover Institution on War, Revolution, and Peace at Stanford University and an adjunct professor at Georgetown University.

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

Indira NATH, MD

Indira Nath is former senior professor and head, Department of Biotechnology, All India Institute of Medical Sciences, and former Raja Ramanna fellow and emeritus professor, National Institute of Pathology (ICMR), New Delhi, India; director of Lepra Research Centre, Hyderabad, India; dean, Medical School, AIMST, Sungai Petani, Malaysia. She received an MBBS 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. She continues to be on committees of the Indian Council of Medical Research and Department of Biotechnology as well as selection committees for faculty/directors of national institutions. She is on the Governing Body of Institute of Life Sciences and the Institute Body and Academic committee of the newly formed All India Institute of Medical Sciences, Rishikesh, India.

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), co-chair IAP on Responsible Research Conduct (2012), chair of Health and Wellbeing programme of International Council for Science (ICSU) (2012-2016). She was conferred civil awards, notably: Padmashri, India (1999); Chevalier Ordre National du Merite, France (2003); Silver Banner, Tuscany, Italy (2003).
Scientific recognition brought her both national and international awards, some notable ones being Raja Ramanna Fellowship (2010-14) , 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 fellow of the Indian National Science Academy, Delhi; National Academy of Sciences (India), Allahabad (1988); Indian Academy of Sciences, Bangalore (1990); National Academy of Medical Sciences (India) (1992); Royal College of Pathology (1992); and the Academy of Sciences for the Developing World (TWAS) (1995). She was conferred a DSc (hc) 2002, by Pierre and Marie Curie University, Paris, France.

Maureen O'LEARY, PhD, MBA

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-elect of ABSA.

S. R. RAO, PhD

S. R. Rao, PhD, is advisor, Department of Biotechnology (DBT), 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 engineering 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 which 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

Ms. Ravi is a senior analyst at the UPMC Center for Health Security. 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. In that vein, 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. In 2014 and 2015, she helped plan the first ever strategic dialogues on biosecurity policy among the United States, Singapore, Malaysia, and Indonesia. 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.

Appendix B: Meeting Agenda

INDIA - US STRATEGIC DIALOGUE ON BIOSECURITY

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20-21 September, 2016
The Ritz-Carlton
1250 Hayes St.
Arlington, Virginia 22202

20 SEPTEMBER 2016

08:30 – 09: 00 **Light Breakfast, Coffee/Tea, Plaza A**

09:00 – 09: 30 **Welcome, Goals for Meeting, and Introductions, Plaza B**

Dr. Tom Inglesby, Director, UPMC Center for Health Security

Anita Cicero, JD, Deputy Director, UPMC Center for Health Security

09:30 – 10:45 **Dialogue Session One: Priorities, Strengths & Challenges in National Biosecurity**

During this opening session, we will discuss what each country views as its leading concerns, greatest strengths, and most important challenges relating to biosecurity. In your view, what biological threats are of greatest concern to each country? How have each country's distinct histories shaped these priorities? Are there distinctions between how each country considers natural vs. deliberate biological threats? Is there a difference between how each country approaches and manages well known and more common infectious diseases (e.g. HIV, TB, hepatitis) vs acute novel events (e.g. SARS, novel flu strains, Ebola, Zika)? With respect to emerging biological threats, what has caused great concern or surprise in recent years? One representative from each country will provide opening remarks (5-10 minutes) on this topic, followed by a discussion by all participants.

Opening Remarks: Dr. Indira Nath & Dr. David Franz

10:45 - 11: 00 **Coffee Break, Plaza B Foyer**

11:00 – 12:15 **Dialogue Session Two: Medical Countermeasures, Emerging Biotechnology and Risk Assessment**

Emerging biotechnologies are widely recognized as being highly beneficial for medicine, health, agriculture, and for national economies. These powerful developments are accompanied by the potential for both better medical countermeasures as well as increased risks for the potential for deliberate misuse of biotechnology. How do the US and India see the future of biotechnology changing the ability to develop medical countermeasures for biological threats? What are the national concerns related to new risks that could emerge from biotechnology? What is your government's process for risk assessment(s) to evaluate and compare these risks? How is your country's risk assessment process linked to a process for

managing and addressing biological risks? Are there areas of potential collaboration between the US and India on any of these issues? A representative from each country will provide opening remarks (5-10 minutes) on this topic, followed by a discussion by all participants.

Opening Remarks: Mr. S.R. Rao, Dr. Peggy Hamburg

12:15 – 13:15 **Lunch in the Ritz-Carlton**

13:15 – 14:15 **Dialogue Session Three: Strengthening the Response Nationally and Internationally to Natural Threats**

This discussion will explore national approaches for early detection and surveillance in response to new outbreaks, as well as opportunities to improve international collaboration on these issues. What are the most important systems in place for early detection of new outbreaks? 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. Rakesh Bhatnagar & Dr. Tom Inglesby

14:15 – 15:00 **Reflections on US Biodefense Strategy, followed by Q&A**

Presentation by Rear *Admiral Kenneth Bernard* (USPHS, Ret.), *Member, Threat Reduction Advisory Committee (DoD), former Special Assistant to the President for Security and Health on the National Security Council (NSC) Staff at the White House*

15:00 – 15: 30 **Travel by shuttle bus to the White House in Washington, DC**

16:00 – 17:15 **Meeting with Dr. Beth Cameron, Senior Director for Global Health Security and Biodefense, National Security Council**

17: 15 **Walk to dinner.**

18:00 **Biosecurity Dialogue Dinner at iCi Restaurant**
Sofitel, 806 15th Street NW, Washington, DC 20005

20:00 **Travel by shuttle bus to the Ritz-Carlton, Arlington, VA**

INDIA-US STRATEGIC DIALOGUE ON BIOSECURITY – DAY 2

21 SEPTEMBER, 2016

08:30 – 09: 00 **Light Breakfast, Coffee/Tea, Plaza A**

09:00 – 10:15 **Dialogue Session Four: Biosecurity & Biosafety, Plaza B**

This session will focus on biosecurity and 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? To what extent does your country track (via national registry or other means) labs that work on high consequence pathogens/select agents? How do research scientists in your countries regard current biosafety rules and guidelines? Are the guidelines sufficient? Have they discouraged research on high consequence pathogens? How much regulatory oversight is provided – do you think it is too much or too little? Do you employ "personnel reliability" programs in labs that work on high consequence pathogens? How effective do people think these programs are? How do you ensure a laboratorian is "reliable" and not going to do something dangerous with a pathogen? A representative from each country will provide opening remarks (5-10minutes) on this topic, followed by a discussion by all participants.

Opening Remarks: Dr. Jaishree Garhyan & Dr. Maureen O'Leary

10:15 – 10:45 **Briefing about the 2016 Biological Weapons Convention Review Conference, representative of the US Department of State** *(invited)*

10:45 – 11:15 **Coffee Break, Plaza B Foyer**

11:15 - 12:30 **Discussion Session Five: Countering Biology as a Deliberate Threat**
In this discussion, there will be a focus on each country's approach to preparing for and responding to deliberate biological threats. What are the important elements of your country's plans to prepare for or respond to adversary use of biological weapons? How does the review conference of the Biological Weapons Convention factor into these preparations to counter deliberate threats? How would responsibilities be divided among Defense, Health and Disaster/ Emergency Management following biological weapons use? In the event of suspected use of biological weapons, what are the national response mechanisms? Do greatest concerns emanate from other countries, terrorist groups, or lone individuals? Could biological weapons events occur that aren't able to be attributed? A representative from each country will provide opening remarks (5-10minutes) on this topic, followed by a discussion by all participants.

Opening Remarks: Dr. Pawan Dhar & Dr. Parney Albright

12:30 – 13: 45 **Group Photo, followed by Lunch in Hotel Restaurant**

13:45 – 14:15 **Remarks by Dr. Ronald Hann, Jr.,** Director, Chemical and Biological Technologies Dept. at Defense Threat Reduction Agency *(invited)*

14:15 – 15:30 **Discussion Session Six: Regional Contingencies, Potential areas of partnership**

In this session, we will explore the potential for regional biological threats, and examine areas where India and the US may be able to work together to resolve regional contingencies with biosecurity implications. The discussion will include what natural, deliberate or accidental biological threats may benefit from collaboration or joint response. This discussion will also consider the role of collaborative relationships between scientists, public health practitioners, and the security community. Is there an opportunity for governmental agreements which could aid security and scientific collaboration between the two countries? 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. Indira Nath & Amb. Ronald Lehman

15:30 – 16: 00 **Proposals for Future Biosecurity Dialogue Topics**

Group discussion about topics for next biosecurity dialogue meeting in 2017.

16:00 **Meeting Adjourns**

Appendix C: References

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