

Center for Health Security

US-India Strategic Dialogue on Biosecurity

Report on the sixth dialogue session

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Center for Health Security

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EXECUTIVE SUMMARY

In February 2019, the Johns Hopkins Center for Health Security (“the Center”) hosted a dialogue on biosecurity between senior experts and leaders from the United States and the Republic of India. The purposes of this dialogue are to increase knowledge of prevention and response efforts for natural, deliberate, and accidental biological threats in India and the United States; to look for new synergies and share best practices and innovations; to examine opportunities for partnership and collaboration; to develop and deepen relationships between dialogue participants; and to identify issues that may warrant being brought to the attention of the Indian or US government.

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

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

The biosecurity dialogue took place nearly 6 months after the 2+2 meeting between the US Secretaries of State and Defense and their India counterparts in early September in New Delhi. That meeting reiterated both countries' commitments to "continue to lead global efforts to promote peace, prosperity, and security."¹ The threat of terrorism was exemplified just 1 week prior to the commencement of the biosecurity dialogue meeting, when a suicide bombing by a terrorist group killed 40 Indian security personnel in Kashmir.²

The Center convened senior thought leaders, scientists, public health practitioners, and medical experts from the US and India. Discussion topics included current and emerging biosecurity concerns, healthcare system preparedness for infectious disease outbreaks, industry and academic contributions to biosecurity, scientific advancements in animal biotechnology, and research and development in the context of national biosecurity. The diverse group of participants shared perspectives from government, academia, research, health care, and private industry and included subject matter experts in biosecurity, biosafety, the life sciences, medicine, and health care. Participants also conducted site visits at the National Institute of Animal Biotechnology (NIAB) and 2 biotechnology companies—Bharat Biotech and Biological E Limited—to learn about each organization's research priorities and programs. In accordance with the dialogue format, participants offered insights based on personal expertise and did not represent the government of either country in an official capacity.

Members of the Indian delegation included:

- Renu Swarup, PhD, Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India
- S. R. Rao, PhD, Advisor, Department of Biotechnology, Ministry of Science and Technology, Government of India
- Sudhanshu Vрати, PhD, Executive Director, Regional Centre for Biotechnology, Government of India
- Deepanwita Chattapadhyay, Chairman and CEO, IKP Knowledge Park
- Siddavattam Dayananda, PhD, Professor, Department of Animal Sciences, University of Hyderabad
- Prasanna Deshpande, Deputy Managing Director, Indian Immunologicals Ltd.
- Krishna M. Ella, PhD, Chairman and Managing Director, Bharat Biotech

- Randeep Guleria, MD, Director, All India Institute of Medical Science (AIIMS)
- Shashi Vardhan Kalivendi, Indian Institute of Chemical Technology
- Anand Kumar, PhD, Managing Director, Indian Immunologicals Ltd.
- Prathama S. Mainkar, Indian Institute of Chemical Technology
- Subeer Majumdar, PhD, Director, National Institute of Animal Biotechnology
- Rakesh K. Mishra, PhD, Director, Centre for Cellular and Molecular Biology
- Debashis Mitra, PhD, Director, Centre for DNA Fingerprinting and Diagnostics
- Panchapagesa (PM) Murali, PhD, Former President (ABLE), Jananom Private Limited
- Abhijit Poddar, PhD, Biosafety Support Unit, Department of Biotechnology, Ministry of Science and Technology, Government of India
- V. Siva Reddy, PhD, Chief Scientific Officer, Biosafety Support Unit, Government of India
- Ambassador Rakesh Sood, PhD, Observer Research Foundation
- Rajan Sriraman, Associate Vice President, Research and Development, Biological E Limited

Members of the American delegation were:

- Patrick Boyle, PhD, Head of Codebase, Ginkgo Bioworks
- David R. Franz, DVM, PhD, former Commander, US Army Medical Research Institute for Infectious Diseases
- Dan Hanfling, MD, Vice President, Technical Staff, In-Q-Tel
- Maureen O'Leary, PhD, MBA, CBSP, Director, Environmental Health & Safety, Dartmouth College
- Sumi Parenjape, PhD, Director, Technology Innovation, Vulcan, Inc.

Several observers from the United States and India also attended the meeting: **R. Emerson Tuttle**, Regional Science Manager, Biological Threat Reduction Program, Defense Threat Reduction Agency (DTRA); **Cassandra Peterson**, Project Lead for India, A&AS Support to DTRA; **Daniel Garcia**, Senior Laboratory Advisor, Division of Global Health Protection, US Centers for Disease Control and Prevention, US Department of Health and Human Services; **Ravi Kumar Gandham**, Scientist, National Institute of Animal Biotechnology; **Nagendra R. Hegde**, PhD, Scientist, National Institute of Animal Biotechnology; **Srinivas Kosaraju**, Senior Vice President, Quality Assurance and Regulatory Affairs, Biological E Limited; **Rajalakshmi Muralidharan**, PhD, Scientist, Department of Biotechnology, Ministry of Science and Technology, Government of India; and **AK Rawath**, Scientist, Department of Biotechnology, Ministry of Science and Technology, Government of India.

Participants also made 3 site visits during this year's dialogue. The first site visit, at the National Institute of Animal Biotechnology (NIAB), was led by **Subeer Majumdar**, PhD, Director, National Institute of Animal Biotechnology. The second site visit, at Bharat Biotech, was led by **Krishna M. Ella**, PhD, Chairman and Managing Director, Bharat Biotech. The third site visit, at Biological E Limited, was led by **Srinivas Kosaraju**, Senior Vice President, Quality Assurance and Regulatory Affairs, Biological E Limited. The purpose of these visits was to better understand each organization's priorities and programs.

During the 2-day dialogue meeting, several key topics and opportunities for collaboration were considered for possible future action, including:

- Organizing a jointly hosted side event at the 2019 Biological Weapons Convention;
- Developing a joint publication between US and Indian dialogue participants that highlights important findings and key themes that have emerged throughout the 6 dialogue sessions; this would ideally be published in a peer-reviewed journal and be publicly available;
- Completing a joint publication between US and Indian dialogue participants that compares and contrasts healthcare system preparedness and response policies and practices in each country; this would ideally be published in a peer-reviewed journal and be publicly available; and
- Establishing a formal partnership between the DBT-UNESCO Regional Centre for Biotechnology and the Center for Health Security to facilitate continued bilateral collaboration around studying, preventing, and mitigating biological threats of mutual concern.

The next meeting of the dialogue is tentatively scheduled for February 2020 in the United States.



US-India Delegation

INTRODUCTION

In February 2019, the Johns Hopkins Center for Health Security hosted a dialogue on biosecurity between senior experts and leaders from the United States and the Republic of India. The purposes of this dialogue are to increase knowledge of prevention and response efforts for natural, deliberate, and accidental biological threats in India and the United States; to look for new synergies and share best practices and innovations; to examine opportunities for partnership and collaboration; to develop and deepen relationships between dialogue participants; and to identify issues that may warrant being brought to the attention of the Indian or US government.

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

2016, November 2017, and September 2018, and in New Delhi, India, in February 2017 and February 2018. Each meeting was sponsored by the Project on Advanced Systems and Concepts for Countering WMD (PASCC, sponsored by the Defense Threat Reduction Agency, DTRA). The Department of Biotechnology of the Government of India's Ministry of Science and Technology has been an important collaborative partner in this effort, having expanded participation in the dialogue and assisted in developing content for meetings.

The biosecurity dialogue took place nearly 6 months after the 2+2 meeting that took place between the US Secretaries of State and Defense and their India counterparts in early September in New Delhi. This meeting reiterated both countries' commitments to "continue to lead global efforts to promote peace, prosperity, and security."¹ The threat of terrorism was exemplified just 1 week prior to the commencement of the biosecurity dialogue meeting, when a suicide bombing by a terrorist group killed 40 Indian security personnel in Kashmir.² Other recent developments in the past year, including India joining both the Australia Group and the Wassenaar Arrangement (both of which the United States is already member of), demonstrate both countries' continued commitment to improving biosecurity.

The meeting consisted of 2 dialogue sessions, 2 panel sessions, 1 working group session, 3 guest presentations, and 3 site visits. Each dialogue and panel session was preceded by brief opening remarks delivered by selected participants from each country; these remarks, in turn, set the stage for subsequent group dialogue. Discussion topics included current and emerging biosecurity concerns, healthcare system preparedness for infectious disease outbreaks, industry and academic contributions to biosecurity, scientific advancements in animal biotechnology, and research and development in the context of national biosecurity. Guest presentations included an overview of India's research priorities and progress in biotechnology, presented by **Dr. Renu Swarup**; an update from the US CDC on biosafety and biosecurity, presented by **Dr. Daniel Garcia**; and an overview of the role of Ginkgo Bioworks in biosecurity, presented by **Patrick Boyle**.

In addition to the invited participants and the Johns Hopkins Center for Health Security staff, several observers also attended the dialogue: **R. Emerson Tuttle**, Regional Science Manager, Biological Threat Reduction Program, Defense Threat Reduction Agency (DTRA); **Cassandra Peterson**, Project Lead for India, A&AS Support to DTRA; **Daniel Garcia**, Senior Laboratory Advisor, Division of Global Health Protection, US Centers for Disease Control and Prevention, US Department of Health and Human Services; **Ravi Kumar Gandham**, Scientist, National Institute of Animal Biotechnology; **Nagendra R. Hegde**, PhD, Scientist, National Institute of Animal Biotechnology; **Srinivas Kosaraju**,

Senior Vice President, Quality Assurance and Regulatory Affairs, Biological E Limited; **Rajalakshmi Muralidharan**, PhD, Scientist, Department of Biotechnology, Ministry of Science and Technology, Government of India; and **AK Rawath**, Scientist, Department of Biotechnology, Ministry of Science and Technology, Government of India.

CURRENT AND EMERGING BIOSECURITY CONCERNS

The dialogue opened with a discussion on current and emerging biosecurity concerns. Participants noted concerns that the changing dynamics occurring across the world, particularly in the Middle East, the South China Sea, and North Korea, could lead to increased political tensions and instability. Participants highlighted the importance of continued engagement between the United States and India, including through dialogues such as the India-US Biosecurity Dialogue, in strengthening relationships and helping to address growing threats. The importance of these relationships was emphasized in the recent US National Security Strategy,³ which specifically talks about engagement and cooperation in the Indo-Pacific region. One of the priority actions listed includes deepening the United States' "strategic partnership with India and support its leadership role in Indian Ocean security and throughout the border region."³

Participants also highlighted the need for increased regulatory frameworks to keep up with the rapidly expanding field of biotechnology. Some of the areas noted as needing potential increased regulation included big data, artificial intelligence, and synthetic biology. For example, participants highlighted the recent germ-line genetic modification by a Chinese scientist, which led to international concern in the scientific community.

Remarks by Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science & Technology, Government of India

Dr. Swarup provided an overview of India's research priorities and progress in the biotechnology field. Some of the successes highlighted by Dr. Swarup included increased government engagement with industry and the private sector (eg, public-private partnerships); increased multisectoral and international collaboration on biosecurity issues; policy development around the application of biotechnology; and an ever-growing capacity to conduct research and product development in universities, government, and other sectors in India. The Department of Biotechnology has also supported start-up companies that work in the biotechnology sphere, greatly increasing national innovation capacities. For example, they have recently launched a national biopharma mission, in collaboration with the World Bank, aimed at making available the infrastructure needed by small start-ups to move forward with their research.

Remarks by Daniel Garcia, Senior Laboratory Advisor, Division of Global Health Protection, US Centers for Disease Control and Prevention

Dr. Garcia provided an update on CDC-supported biosafety and biosecurity initiatives in India, including the National Laboratory Strengthening Initiative, which is working toward developing a tiered national laboratory network, and an initiative to map laboratory capacities and biorisk practices. Dr. Garcia also spoke of US CDC efforts in training on biosafety and anthrax surveillance.

HEALTHCARE SYSTEM PREPAREDNESS FOR INFECTIOUS DISEASE OUTBREAKS

An outbreak of H1N1 in India that was occurring during the same period as the dialogue session helped reinforce the importance of continued discussions on how to improve healthcare system preparedness for infectious disease outbreaks. Participants noted India has had challenges in responding to this outbreak, which had sickened more than 6,700 people by early February.⁴ In particular, lack of awareness among physicians in diagnosing and hospitalizing patients with influenza was noted as one cause of increases in mortality during these types of outbreaks. India has developed training modules for physicians on when to suspect highly pathogenic influenza, such as H5N1, and how to isolate and treat these patients while preventing continued transmission. Despite efforts to train the physician workforce on these issues, the level of preparedness for these issues wanes after outbreaks resolve. Participants echoed the importance of being proactive and not reactive when it comes to healthcare system preparedness efforts, and the need for healthcare to be considered a national security priority. One participant highlighted 5 critical capacities that should be in place to be able to quickly and effectively respond to an outbreak: creating the ability to establish situation awareness; the ability to readily define outbreak characteristics; how best to interrupt the transmission process; ensuring the availability of on-demand manufacturing; and establishing logistics and distribution models to understand where needs and resources are.

Participants also emphasized the importance of vaccine development, which was described as being the best defense against infectious diseases. Hyderabad is one of the epicenters for vaccine development, including serving as the location for the Serum Institute of India, the largest vaccine manufacturer in the world by doses produced and sold.⁵ Participants did note the continued challenge in incentivizing vaccine manufacturing companies to create vaccines that are not currently needed but that might be paramount during the response to an outbreak. Creating funds to overcome this hurdle and stockpile vaccines could dramatically increase preparedness, as the United States has done through the creation of the Biomedical Advanced Research and

Development Authority (BARDA), which provides funding to help advance research to the development phase, and the US Strategic National Stockpile, which provides funding for medical countermeasure (MCM) stockpiling. One participant noted that similar issues exist in the hospitals, where hospital administrators and staff are asked to invest and participate in preparedness efforts for an event that might never happen. Platforms to screen monoclonal antibodies for the development of MCMs and the stockpiling of polyclonal serums were also noted as innovative ways of increasing preparedness. Finally, as many participants noted, risk communication efforts are a key component of preparedness, as community resistance to interventions such as vaccination could significantly hinder an outbreak response.

INDUSTRY AND ACADEMIC CONTRIBUTIONS TO BIOSECURITY—THE LEADING EDGE OF SCIENCE

During this panel session, Indian experts from industry and academia highlighted numerous research priorities, including the need for additional research on antifungals and multidrug resistant pathogens, and for better technologies to quickly detect infectious disease threats. One concern raised was the increasing risk of dual-use research with the advancement of technology, where research conducted with good intentions could also be used nefariously. For example, one participant noted that there is a lot of research currently being conducted on the respiratory microbiome, which could introduce the risk of nefarious actors using this information to increase the respiratory transmissibility of a pathogen. However, panelists cautioned that the risks and benefits of science must be weighed and that there must be ways to communicate to the public about these risks in ways that will not alarm them.

The need for public-private partnerships was also highlighted, including between academic and industry partners, as many universities spend time and effort creating technologies, but rarely have industry partners who are able to carry those technologies forward. Additional communication is needed between industry and academia, to help ensure that new technologies and molecules that are developed have useful and feasible healthcare and public health applications.

THE LATEST IN SCIENTIFIC ADVANCEMENTS IN ANIMAL BIOTECHNOLOGY

On the second day of the dialogue meeting, participants visited the National Institute for Animal Biotechnology (NIAB). The visit began with an overview and description of NIAB's research priorities and programs by Dr. Subeer S. Majumdar, the Director of NIAB. Dr. Majumdar spoke of how NIAB uses emerging biomedical and biotechnological research to solve problems affecting animal health and productivity. This includes infectious diseases that might have an impact on animal welfare, such

as brucellosis, Japanese encephalitis, bovine tuberculosis, leptospirosis, tick-borne diseases, Newcastle disease, and toxoplasmosis; ways of improving animal fecundity and nutrition; and genetics and genomics. Some of the specific biosecurity concerns raised included the risk for zoonosis in human populations, the risk of antimicrobial resistance perpetuated by the use of antibiotics in animals, and the possibility of terrorist attacks using pathogens that could affect food supplies.

Dr. Majumdar's presentation was followed by a panel session, in which dialogue participants brought up numerous other concerns related to animals, including those used in research and farming. Some issues included the need for better biosafety practices in animal research facilities, particularly the handling of samples and the containment and disposal of experimental animals, and the growing concern about bovine tuberculosis in humans. Other challenges specific to India's agricultural practices that were highlighted were the inability to slaughter sick cattle, which are often left out on the street; poor quarantine capacities in smaller farms; farms that allow interfacing with other wildlife; and the illegal importation of animal vaccines. During the panel session, participants were also briefed on a new research facility that will open in Kansas, USA, called the National Bio and Agro-Defense Facility (NBAF). This facility will have expanded capabilities and will be driven by intentional and unintentional threats, and it will have BSL-3 and BSL-4 laboratories.

RESEARCH AND DEVELOPMENT IN THE CONTEXT OF NATIONAL BIOSECURITY—RISKS AND CHALLENGES

Research and development are profoundly important to India and the United States for biotechnological advancement, but recent events, including the use of CRISPR to make a genetically edited baby (as noted previously), have raised many questions about how best to govern the growing landscape of biotechnology. Additionally, the number of people working on biological organisms has dramatically increased in the past few decades, further challenging how this emerging field will be regulated.

One participant highlighted the similarities between the regulation concerns for genetic engineering with those that arose after the emergence of IVF technologies in the 1970s. During this time in the United States, an ethics board was appointed, which eventually determined that it was ethically acceptable, but there was a lot of debate around the issue. Cloning and stem cell research has also been hotly debated in the United States, including the banning of federal funding for research using embryonic stem cells. However, this participant also noted that the main lever of control for this type of research has been on acquisition and funding and not on the actual banning of research. As technology continues to advance, these challenges will continue to emerge and will require engagement and collaboration among various stakeholders, including

government, industry, academic institutions, and the public. Ideally, these issues would be addressed similarly across the globe but will be challenged by differing cultural and government views on ethics.

Remarks by Patrick Boyle, Head of Codebase, Ginkgo Bioworks

Dr. Boyle provided an overview of the role of Ginkgo Bioworks in biosecurity. Some of the projects noted included engineering microbes to fix nitrogen in the soil, lab-grown cannabis, the use of machine learning to identify engineered versus nonengineered DNA, and designing pills with the *E. coli* bacteria with the hopes of treating phenylketonuria (PKU).

SITE VISITS: BHARAT BIOTECH AND BIOLOGICAL E LIMITED

On the second day of the dialogue meeting, participants traveled to Bharat Biotech and Biological E Limited to learn more about each company's research priorities and contributions to global health security. Bharat Biotech's vision is to "offer affordable, safe and effective healthcare solutions to combat mankind's dreaded illnesses and to thus eradicate or at least control their occurrence in the years to come."⁶ The company was started in 1996 and has delivered more than 3 billion doses of vaccine across the world, including vaccines for hepatitis B, rotavirus, and typhoid.⁶ The site visit at Bharat Biotech was led by Krishna M. Ella, PhD, Chairman and Managing Director.

Participants also visited Biological E Limited, another leader in vaccines and pharmaceuticals. Biological E Limited was established in 1953 and is "committed to improving the quality of human life by enabling people to do more, feel better and live longer."⁷ The company is one of the world's largest producers of tetanus vaccine and is a leader in snake antivenin. The site visit was led by Srinivas Kosaraju, Senior Vice President, Quality Assurance and Regulatory Affairs.

WORKING SESSION: INDIA-US BIOSECURITY DIALOGUE LESSONS AND RECOMMENDATIONS—A JOINT COLLABORATIVE MANUSCRIPT

During this working session, dialogue participants highlighted the various themes that have emerged over the past dialogue sessions. Some of these themes include biosafety and personnel reliability, early warning and detection, dual-use research of concern, One Health, medical care during outbreaks, and concerns with emerging biotechnologies. This working session was the first step to developing a jointly written manuscript that will highlight why nongovernment dialogues are important forums for sharing challenges and lessons learned and developing recommendations for biosecurity.

FUTURE PRIORITIES FOR ENGAGEMENT

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

- Organizing a jointly hosted side event at the 2019 Biological Weapons Convention;
- Continuing to develop a joint publication between US and Indian dialogue participants that highlights important findings and key themes that have emerged throughout the 5 dialogue sessions; this would ideally be published in a peer-reviewed journal and be publicly available;
- Completing a joint publication between US and Indian dialogue participants that compares and contrasts healthcare system preparedness and response policies and practices in each country; this would ideally be published in a peer-reviewed journal and be publicly available; and
- Establishing a formal partnership between the DBT-UNESCO Regional Centre for Biotechnology and the Center for Health Security to facilitate continued bilateral collaboration around studying, preventing, and mitigating biological threats of mutual concern.

REFERENCES

1. U.S. Department of State. Joint Statement on the Inaugural U.S.-India 2+2 Ministerial Dialogue. September 6, 2018. <https://www.state.gov/joint-statement-on-the-inaugural-u-s-india-22-ministerial-dialogue/>. Accessed May 9, 2019.
2. Masih N. India and Pakistan hold talks after nearly going to war. *Washington Post* March 14, 2019. https://www.washingtonpost.com/world/india-and-pakistan-make-nice-after-nearly-going-to-war/2019/03/14/f022b5c6-45c7-11e9-94ab-d2dda3c0df52_story.html?noredirect=on&utm_term=.e7697dd61a22. Accessed May 9, 2019.
3. The White House. National Security Strategy of the United States of America. December 2017. <https://www.whitehouse.gov/wp-content/uploads/2017/12/NSS-Final-12-18-2017-0905.pdf>. Accessed May 9, 2019.
4. Sharma S. With 6,700 cases and 226 deaths, spike in swine flu triggers health alarm. *Hindustan Times* February 7, 2019. <https://www.hindustantimes.com/india-news/sharp-spike-in-swine-flu-triggers-health-alarm/story-wUQFH40Xktbk2S1Su26rO.html>. Accessed May 9, 2019.
5. Serum Institute of India. https://www.seruminstitute.com/about_us.php. Accessed May 9, 2019.
6. Bharat Biotech. <https://www.bharatbiotech.com/vision.html>. Accessed May 9, 2019.
7. Biological E Limited. http://www.biologicale.com/management_team.html. Accessed May 9, 2019.

APPENDIX A: DIALOGUE PARTICIPANTS' BIOGRAPHIES

Patrick Boyle, PhD

Patrick Boyle is the head of Codebase at Ginkgo Bioworks, a Boston-based synthetic biology company that makes and sells engineered organisms. Patrick is responsible for Ginkgo's Codebase, the company's complete portfolio of reusable biological assets. Codebase includes novel strains, enzymes, genetic parts, and diverse genetic repositories, including millions of engineered DNA sequences. Codebase is being developed, maintained, and leveraged by Ginkgo's organism engineers via dozens of strain engineering projects. Prior to leading Codebase, Patrick founded the design group at Ginkgo, which now produces hundreds of millions of base pairs of DNA designs each year to support Ginkgo's projects. At present, more than 30% of the world's DNA synthesis is performed for work at Ginkgo.

Patrick also participates in a number of efforts related to the broader development of synthetic biology and biosecurity. This includes a fellowship in the Johns Hopkins University Center for Health Security Initiative, serving as a technical advisor to the Synthetic Biology for Military Environments program for the Department of Defense, and co-authoring the 2018 *Biodefense in the Age of Synthetic Biology* report by the National Academies of Sciences, Engineering, and Medicine. Patrick received his PhD from Harvard Medical School in 2012, developing synthetic biology applications in bacteria, yeast, and plants in the lab of Dr. Pamela Silver. He received an SB in biology from the Massachusetts Institute of Technology in 2006.

Srivari Chandrasekhar, PhD

Srivari Chandrasekhar is director, CSIR (Council of Scientific and Industrial Research), Indian Institute of Chemical Technology, Ministry of Science & Technology, Government of India. His noteworthy contributions in the total synthesis of architecturally diverse natural products are well-reflected in the total synthesis of 35 natural products, which include an acinar morphogenetic inhibitor, Fusarisatin A, molecule with anticancer activity through tubulin inhibition, Rhazinal, neuro-protective natural product Stachybotrin C, anticancer molecule pladienolide, molecule with CNS activity, Kainic acid, prostacyclin analogue Beraprost, Bedaquiline (both R and S isomers) anti-TB compound, Azumamide E, Bengazole, Arenamide, Tubulysin, Spirastellolide B, Hyacinthacene A1, (-)-Spongidepsin with absolute stereo control. All these achievements were accomplished while developing new C–C bond formation reactions using organo-catalysis and carbocycles derived from carbohydrates. Another research field has been the identification of novel peptido-mimetics, wherein

the research group of Dr. Chandrasekhar has synthesized β -sugar amino acids, norbornene-based, aminoxy acids of furanoses, and nucleoside-based amino acids and demonstrated that these monomers in various combinations of oligomerization resulted in predefined secondary structures, including nanotubes.

Dr. Chandrasekhar has for the first time identified polyethylene glycol (PEG) as a recyclable solvent for organo-metallic reactions, wherein both the solvent and catalyst can be recycled. This unprecedented report triggered various research programs using PEG as a solvent in different parts of the world. Some of the reactions worth mentioning using PEG as a solvent are: Heck reaction in PEG, Sharpless asymmetric dihydroxylation (was performed for the first time in PEG), PtO₂ recycle, and H₂ absorption studies. This work has found direct applications in developing non-infringing technologies for APIs.

Dr. Chandrasekhar received his PhD in organic chemistry from Osmania University.

Deepanwita Chattopadhyay

Deepanwita Chattopadhyay, chairman and CEO of IKP Knowledge Park, developed the first Life Science Research Park in India, in Hyderabad. She pioneered a Hardware Product Incubator and Makerspace, IKP EDEN, in Bangalore and works with Indian and global partners to nurture and fund more than 300 innovators and early startups. Ms. Chattopadhyay is an electronics engineer by training and worked in the Telecom Advisory Division of ICICI Bank before being deputed to IKP Knowledge Park as CEO in 2000. In 2018 she was named one of the “Top Women Achievers of the Year 2017 in Asia” by AsiaOne Business Magazine and “Women of the Decade in Life Sciences & Innovation” by the Women Economic Forum.

Ms. Chattopadhyay is the founding chairman of Support Elders Pvt. Ltd. She is a director on the boards of IKP Trust and IKP Investment Management Company and the president of IKP EDEN. She is a member of the governing councils of the Lucknow Biotech Park, IIT Hyderabad i-TIC Incubator, NCCS Atal Incubation Centre, Pune, and SRIX Incubator, Warangal, and a member of several government committees, including the Committee of the Prime Minister’s Fellowship for Doctoral Research and the DBT Committee on Biotech Parks.

Anita Cicero, JD

Anita Cicero is the deputy director at the Johns Hopkins Center for Health Security and a visiting faculty member at the Johns Hopkins Bloomberg School of Public Health. She

is a lawyer with over 27 years of experience. Ms. Cicero works closely with the Center director to lead strategic and budget planning and program development. She is also an associate editor of the journal *Health Security*, the leading peer-reviewed journal in this field.

Ms. Cicero has greatly expanded the Center's efforts in epidemic preparedness policy, global catastrophic biological risk issues, and international programs to engage other countries and regions in collaborative efforts to address biosecurity threats. 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 the People's Republic of China, Kuwait, the Kingdom of Saudi Arabia, India, Singapore, Malaysia, Thailand, Philippines, and Indonesia.

Ms. Cicero has authored or co-authored a number of widely cited articles and reports on biosecurity policy, pandemic preparedness, nuclear 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.

Siddavattam Dayananda, PhD

Siddavattam Dayananda is a professor, Department of Animal Sciences, School of Life Sciences, University of Hyderabad. His laboratory is interested in understanding evolutionary aspects of phosphotriesterases (organophosphate hydrolase, OPH), involved in hydrolysis of triester linkage found in structurally diverse group of organophosphate insecticides and nerve gases. His research has shown for the first time the transposons-like organization of triesterase coding (opd) gene in *Flavobacterium*

sp. Further research on horizontal gene transfer (HGT)/ lateral transfer (LT) of degradative traits, especially the OPH coding opd gene clusters among soil bacteria has demonstrated HGT of opd plasmid (pCMS1) among soil bacteria.

His research also focuses on transport of prefolded proteins across the bacterial membrane (Twin Arginine Translocation, TAT pathway). He has shown the existence of Twin Arginine (Tat motif) motif in the signal sequence of OPH and elucidated its role in membrane targeting in *Brevundimonas diminuta*. He is currently working to gain further insights into the physiological role of OPH in the native soil bacterium and the molecular checkpoints during the translocation process.

His laboratory has been developing a number of bioremediation strategies useful in leather processing, insect control, and detection and decontamination of nerve agents, in collaboration with DRDE, Gwalior, the laboratory of Prof. C. K Mitra, and the laboratory of Prof. Aparna Dutta Gupta.

He received his PhD from S. V. University, Tirupati.

Krishna Ella, PhD

Krishna Ella graduated from the University of Hawaii, received a PhD from the University of Wisconsin-Madison, and served at the Medical University of South Carolina-Charleston. Dr. Ella returned to India 1997 and started Bharat Biotech, which focuses on working on human vaccines.

Dr. Ella ensured that Bharat Biotech successfully developed and launched the world's most affordable vaccine for rotavirus, and the world's first clinically proven and WHO-prequalified typhoid conjugate vaccine (TCV). Bharat Biotech, under Dr. Ella's leadership, was the first company to file global patents for vaccines for chikungunya and Zika viruses and continues to achieve major milestones in the development of these vaccines. India's first BSL-3 production facility is being established for the manufacture of Sabin's IPV as per GAPIII requirements. In addition, Dr. Ella facilitated the establishment of the world's second BSL3+Ag facility at Biovet Private Limited, Bangalore.

Bharat Biotech has received a grant of \$68.6 million from the Bill and Melinda Gates Foundation for the Rotavac project and indirect funding of \$45 Million for Typbar TCV for conducting effective and efficacy studies. Bharat Biotech has partnered with the University of Maryland and Oxford University and is working on NTS vaccines in collaboration with the University of Maryland for use in African countries.

Dr. Ella is a member of numerous committees involved in shaping India's science education and policy, including his current role on prominent Government of India bodies as a member of the Scientific Advisory Committee to the Union Cabinet (SAC-C), the Governing Body, Council of Scientific & Industrial Research (CSIR), and the Technology, Information, Forecasting & Assessment Council (TIFAC).

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 with Ambassador Ron Lehman 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.

Ravi Kumar Gandham, VPPS

Ravi Gandham completed a BVSc & AH at the College of Veterinary Science, Tirupati, Andhra Pradesh Agricultural University; an MSc (dairying) in animal genetics and breeding from National Dairy Research Institute, Karnal; and a PhD in animal genetics from Indian Veterinary Research Institute, Izatnagar, Bareilly. He underwent training at the School of Informatics, Indiana University Purdue University Indianapolis, in the field of computational biology and genomics. He joined NIAB in 2018.

Dr. Gandham is experienced in the field of animal genomics and computational biology. He is a computational and experimental biologist who has handled several

externally funded projects. He worked on host pathogen interaction to delineate molecular pathogenesis using high-throughput genomics and proteomics approaches and assembled several genomes of pathogens. The results from the analysis of RNA-seq, miRNA-seq, and proteomics data were validated through Real Time, Western Blot, or Dual Luciferase assay. The signature molecules identified are now being studied through CRISPR/Cas9 knockout studies. His research interests at NIAB are host-pathogen interaction, genomics, and functional studies.

Gigi Gronvall, PhD

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

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

Dr. Gronvall is the author of the book *Synthetic Biology: Safety, Security, and Promise*, 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 alumnus of the European Union Visitors Program, a competitive program designed to increase mutual understanding between professionals and future leaders from non-EU countries and their EU counterparts, and the Council on Foreign Relations Term Member Program.

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

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

Randeep Guleria, MD

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

Dan Hanfling, MD

Dan Hanfling is vice president, Technical Staff, at In-Q-Tel, specifically working with B. Next, the IQT Lab exploring the national security implications of epidemics and

outbreak events and how to detect and quench them. He currently serves as the co-chair of the National Academy of Sciences Forum on Medical and Public Health Preparedness for Catastrophic Events.

Dr. Hanfling previously served as a special advisor in the US Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response (ASPR), focused chiefly on the National Healthcare Preparedness Program. He spent 18 years as principal consultant to the Inova Health System on matters related to emergency preparedness and response and was instrumental in founding one of the nation's first healthcare coalitions, the Northern Virginia Hospital Alliance, in October 2002. He also served as a contributing scholar at the Johns Hopkins Bloomberg School of Public Health Center for Health Security.

He continues in his role 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. He is clinical professor of emergency medicine at George Washington University and adjunct faculty at the George Mason University School of Public Policy.

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 and continues to practice in the emergency department at the Inova Regional Trauma Center.

Nagendra R. Hegde, PhD

Nagendra R. Hegde completed BVSc (1989) and MVSc degrees (1992; veterinary microbiology and public health, virology) at the University of Agricultural Sciences, Bangalore, India, and a PhD (1998; veterinary & biomedical sciences, immunology) from the University of Nebraska. He worked as a postdoctoral fellow and then as a research assistant professor at the Oregon Health & Science University. Before joining NIAB in 2017, he was a group leader and then the associate director of Ella Foundation, Hyderabad, India.

Dr. Hegde's research experience spans veterinary virology, immunology, and microbiology. His major contribution has been in virology, where he has worked on epidemiology, genomics, diagnosis, and prevention as well as interaction with host cells

of animal (as well as human) DNA and RNA viruses. In immunology, he has worked on bovine major histocompatibility complex (MHC) and cell-mediated immunity (CMI). In microbiology, he has worked on epidemiology, diagnosis, and preventive measures for bovine mastitis-causing pathogens. His research interests are to understand the epidemiology, genomics, and biology of important livestock diseases, to devise protective measures for these diseases, and to elucidate fundamentals of immunological responses.

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.

Srinivas Kosaraju, PhD

Srinivas Kosaraju is senior vice president, QA&RA, Biological E. Limited in Hyderabad, India.

Anand Kumar, PhD

Anand Kumar is managing director, Indian Immunologicals Ltd, Hyderabad, India, and has over 25 years of experience in the biotechnology / pharma industry.

Indian Immunologicals Ltd, a subsidiary company of the National Dairy Development Board (NDDB), is the largest veterinary vaccine company in India and the third largest human vaccine company in India. He is a whole time director on the board of IIL and is also a director at its subsidiary Pristine Biologicals NZ Ltd. Prior to IIL, Dr. Kumar worked as associate vice president of biotech operations at Wockhardt Ltd.

He has worked for more than a decade outside India for companies such as Pfizer Global Manufacturing in Australia and Schering Plough Animal Health in New Zealand. He also had a brief stint as investment manager-biotech with the New Zealand government.

Dr. Kumar is a member of the National Biotechnology Expert Committee with FICCI and CII, and he is a member of the National Pharmaceutical Committee with CII. He was an executive committee member of the Parenteral Drug Association (PDA), Australia, and currently is on the expert panel on analytical methods related to vaccines with the Indian Pharmacopoeia (IP). He served as an expert volunteer with United States Pharmacopoeia (USP) during the period 2010-2015. He has been a speaker at various international forums.

Dr. Kumar undertook Senior Management Development Programme at the Indian Institute of Management, Ahmedabad. He has vast experience in various fields

related to the biotech/ vaccine industry, including project management, bioprocess manufacturing, advanced fill finish processes, technology transfer, quality control, quality assurance, R&D, cold chain management, TQM, industrial safety, and biosecurity. He has actively contributed to the commercialization of various recombinant biotech products including hepatitis B vaccine, recombinant human insulin, erythropoietin, insulin glargine, interferon, and epidermal growth factor. He has handled products belonging to all 3 major expression systems such as yeast, bacteria, and mammalian cells.

Dr. Kumar has a PhD in microbiology from Indian Council of Medical Research (ICMR).

Subeer Majumdar, PhD

Subeer Majumdar is presently the director of the National Institute of Animal Biotechnology (NIAB) at Hyderabad, India. NIAB aims to harness novel and emerging biotechnological avenues for taking up research in cutting edge areas aimed at improving animal health and productivity. Dr. Majumdar's major research interest lies in differential genomics and functional genomics to dissect molecular mechanisms underlying endocrine and paracrine regulation of germ cell division and differentiation. This work is continued with his students at the National Institute of Immunology (NII), where he worked before joining NIAB. He is involved in development and use of transgenic technology for making transgenic animal models of diseases and also transgenic farm animals for generating therapeutic proteins for animals and humans in the milk of farmed animals. He is also working on livestock genomics for developing SNP chips to select and conserve pure breeds of native cattle in India. Dr. Majumdar is utilizing shRNA to generate transgenic animals for studies of functional genomics. Because of his long-term involvement with generation of transgenic animals, his interest lies in biosecurity and biosafety related to such advances in biotechnology.

Diane Meyer, RN, MPH

Diane Meyer is a senior analyst at the Johns Hopkins Center for Health Security and a research associate at the Johns Hopkins Bloomberg School of Public Health. She is an associate editor of the peer-reviewed journal *Health Security*. Her primary research interests include emerging infectious diseases, improving outbreak preparedness and response, response to humanitarian crises, and hospital preparedness. At the Center, Ms. Meyer contributes to a number of different projects that focus on public health, including improving health sector resilience to infectious diseases, improving public communication during public health emergencies, and improving outbreak response.

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

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

Rakesh Mishra, PhD

Rakesh K. Mishra is a scientist specializing in genomics and epigenetics. Dr. Mishra is currently the director of the Centre for Cellular and Molecular Biology in Hyderabad, India, and heads the Genome Organisation and Nuclear Architecture Lab at CCMB. He is an elected fellow of the Indian National Academy of Science, New Delhi, the Indian Academy of Sciences, the National Academy of Sciences, and the Andhra Pradesh Academy of Sciences. He is also a life member of the Proteomics Society, India.

Dr. Mishra obtained his masters in chemistry and PhD in organic chemistry from the University of Allahabad and was appointed director of CCMB by CSIR, assuming charge in 2016. Dr. Mishra has edited and contributed a chapter to the book, *Chromosomes to Genome*. Dr. Mishra had previously held postdoctoral positions at the Molecular Biophysics Unit, Indian Institute of Science, Bangalore, University of Bordeaux, France, and University of Geneva, Switzerland, prior to joining CSIR-CCMB in 2001.

Debashis Mitra, PhD

Debashis Mitra is director, Centre for DNA Fingerprinting and Diagnostics (CDFD), in Hyderabad, India.

Panchapagesa (P.M.) Murali, PhD

Panchapagesa Murali is the former president of Jananom Private Limited. He has been an entrepreneur for many decades, with many first of its kind innovations in biotechnology. He received his PhD in microbiology and microbial technology from Madurai Kamaraj University.

Rajalakshmi Muralidharan

Rajalakshmi Muralidharan is a scientist-F at the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India.

Maureen O'Leary, PhD, MBA, CBSP

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

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

Sumi Parenjape, PhD, MPH

Sumi Parenjape is director, Technology Innovation, Vulcan, Inc. Dr. Parenjape received her PhD in biological and biomedical sciences and her MPH from the University of California, San Diego.

Abhijit Poddar, PhD

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

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

S. R. Rao, PhD

S. R. Rao is senior adviser, Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India. He holds a PhD in mycology and plant pathology from Indian Agricultural Research Institute, New Delhi. He was visiting scientist in Tottori University, Japan, and at Waite Agricultural Experimental Station, Adelaide, Australia, and has specialized in molecular pathology. He served in various positions in the Department of Biotechnology, Ministry of Science and Technology, Government of India, since 1989 and was actively involved in several sophisticated biotech infrastructure facilities, research resources, forging bilateral collaboration with Asian and /European countries, introduction of golden rice for research in India, new beginning in veterinary biotechnology, biosecurity systems, formulation of national biotech policies, strategic planning, and investment matters. He served or is serving as a member of several technical committees of the Government of India and academic and research councils of universities and institutions.

Currently, he is responsible for regulation of genetically engineering products as scientific member secretary of statutory body, namely Review Committee on Genetic Manipulation (RCGM), operational for scientific risk assessment and management under the Environmental Protection Act 1986 of India. He is also member of the Genetic Engineering Appraisal Committee (GEAC), a statutory body for environmental release of living modified organisms (LMOs), and chairman of the Scientific Panel on GM Foods of Food Safety Standards Authority of India (FSSAI), dealing with risk assessment of imported of GM foods.

He specializes in core and cross-sectoral policy issues of biotechnology policy, development, regulation, safety, biosecurity, public-private partnership, international relations, biotech R&D innovation and development, and public concerns and consensus building. He is founder and editorial board member of *Asian Biotechnology Development Review* (ABDR), has published more than 40 research papers in national/ international journals, and has made several presentations in various national and international conferences. The current areas of his work are formulating national policy

and regulatory framework on bio-innovations through genome editing technology and reforms in agriculture, food, and biopharma regulations and infrastructure.

V. Siva Reddy, PhD

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

Ambassador Rakesh Sood, PhD

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

Rajan Sriraman, PhD

Rajan Sriraman is Associate Vice President in R&D at Biological E. LTD.

Renu Swarup, PhD

Renu Swarup is secretary at the Department of Biotechnology (DBT), Government of India. She holds a PhD degree in genetics and plant engineering, and completed her postdoctoral studies at the John Innes Centre, Norwich, UK. Her career at DBT started in 1989 when she joined the department as a science manager. Currently, Dr. Swarup is also a managing director of the Biotechnology Industry Research Assistance Council (BIRAC), a public company that promotes innovative research in biotechnology with a special focus on startups and small and medium enterprises.

At DBT, Dr. Swarup was part of several initiatives. As a science manager, she worked on policy planning and implementation. She also heads the National Bioresource Development Board and is involved in development, funding, and monitoring of programs in the area of energy biosciences, bioresource development and utilization and plant biotechnology, tissue culture, and other biomass associated programs. She was also instrumental in the formation of the first Biotechnology Vision in 2001, the National Biotechnology Development Strategy in 2007, and the second strategy in the year 2015, where she served as the member secretary of the expert committee.

Dr. Swarup has been a fervent supporter of women scientists and has been closely involved in several initiatives related to women and science. She is credited with initiating the Biotechnology Career Advancement for Women Scientists (BioCARE), a DBT initiative. She was also a member of the task force on Women in Science, constituted by the Scientific Advisory Committee to the Prime Minister. Over the years, she has been the winner of several awards and honors including, the Bio-Spectrum Person of the Year Award in 2012 and National Entrepreneurship Award in 2017.

Sudhanshu Vrati, PhD

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

APPENDIX B: MEETING AGENDA

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

*February 21-22, 2019
Hyder Mahal II Room
ITC Kakatiya, Hyderabad, India*

India-United States Biosecurity Dialogue AGENDA

DAY 1: FEBRUARY 21

8:30-9:00 **Breakfast in ITC Kakatiya Coffee Shop**

9:00-9:25 **Welcome, Introductions, Goals for Meeting**

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

9:25-9:45 **Remarks by Ambassador Rakesh Sood, Distinguished Fellow
Observer Research Foundation, Tom Inglesby, Director, Johns
Hopkins Center for Health Security**

Topic: Current and Emerging Biosecurity Concerns

In this opening session, presenters will provide remarks (10 minutes each) on what they think are the most concerning biological threats in their respective countries and the major efforts being made to address them. Topics addressed will include: How do biosecurity leaders in both countries see the latest international developments in biology and biotechnology? What new risks have emerged? How do the life sciences interact with each country's overall security concerns? What might have changed since the last meeting of the dialogue in September 2018?

9:45-10:45

Dialogue Session One: Healthcare System Preparedness for Infectious Disease Outbreaks

Opening Remarks: Randeep Guleria, Director, All India Institute of Medical Sciences (AIIMS), and Dan Hanfling, Vice President, Technical Staff, In-Q-Tel

Brief Intervention: Sudhanshu Vрати, Executive Director, Regional Centre for Biotechnology (RCB), and Rajan Sriraman, Associate Vice President, Research and Development, Biological E. Limited

During this session, participants will discuss both India and US healthcare system preparedness for infectious disease outbreaks. Topics addressed might include: how to allocate scarce resources (eg, vaccines, ventilators) during an outbreak, the experience of AIIMS in managing infectious disease outbreaks, how AIIMS fits in to the larger approach to hospital preparedness in India, and any new policy or program updates in hospital preparedness. This will be followed by an update on a US-India joint collaborative manuscript on healthcare system preparedness in India and the US. Presentations will be followed by a group discussion.

10:45-11:00

Coffee Break

11:00-11:30

Remarks by Dr. Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science & Technology, Government of India

Topic: India's Research Priorities and Progress in Biotechnology
15-minute presentation followed by discussion with Dialogue participants

11:30-12:30

Panel Discussion One: Industry and Academic Contributions to Biosecurity—The Leading Edge of Science

Panelists: P. M. Murali, former President, Jananom Private Limited; Krishna M. Ella, Chairman & Managing Director, Bharat Biotech; Rakesh K. Mishra, Director, Centre for Cellular and Molecular Biology (CCMB); and Debashis Mitra, Director, Centre for DNA Fingerprinting and Diagnostics (CDFD)

During this panel, Indian experts from both academia and industry will discuss how their work in biotechnology enhances biosecurity (5-7 minutes each). Topics addressed will include: What do industry and academia bring to biosecurity? What are the latest technologies, and how do they strengthen biosecurity? Are industry and academia engaged enough in biosecurity? The panel will be followed by a group discussion.

12:30-13:30

Lunch and Group Photo

13:30-14:30

Travel/Check-in to National Institute of Animal Biotechnology

14:30-15:00

Remarks by Subeer S. Majumdar, Director, National Institute for Animal Biotechnology (NIAB)

Topic: Overview and Description of Research Priorities and Programs at NIAB

15:00-15:30

Tour, National Institute for Animal Biotechnology

15:30-16:30

Panel Discussion Two: The Latest in Scientific Advancements in Animal Biotechnology

Panelists: Nagendra R. Hegde, NIAB; Ravi Kumar Gandham, NIAB; and Dave Franz, former Commander, US Army Medical Research Institute of Infectious Diseases

During this panel discussion, researchers from NIAB will discuss (5-7 minutes each) their current research endeavors. Topics addressed will include: What are the latest scientific advances at NIAB? What are current approaches to biosafety and biosecurity in terms of controlled agents? What are the challenges of working with controlled agents? Dave Franz will provide an update on a national biocontainment facility that is currently being built in the US state of Kansas. The panel will be followed by a group discussion.

16:30-17:30

Return to Hotel

19:00

Dinner in ITC Kakatiya Deccan Pavilion

DAY 2: FEBRUARY 22

8:00-8:30 **Breakfast in ITC Kakatiya Coffee Shop**

8:30-8:45 **Remarks by Daniel Garcia, Senior Laboratory Advisor, Division of Global Health Protection, US Centers for Disease Control and Prevention**

Topic: Biosafety and Biosecurity—An Update from the US CDC

8:45-9:15 **Working Session: India-US Biosecurity Dialogue Lessons and Recommendations—A Joint Collaborative Manuscript**

Moderators: Gigi Kwik Gronvall, Senior Scholar, JHU Center for Health Security; Maureen O’Leary, Director, Environmental Health and Safety, Dartmouth College; V. Siva Reddy, Chief Scientific Officer, Biosafety Support Unit, Government of India; and Abhijit Poddar, Scientist, Biosafety Support Unit, Government of India

During this session, the moderators will provide an overview and update on a collaborative manuscript written by India and US Biosecurity Dialogue members, which summarizes findings and recommendations from the previous 5 dialogue sessions.

9:15-10:15 **Dialogue Session Two: Research and Development in the Context of National Biosecurity—Risks and Challenges**

Opening Remarks: S. R. Rao, DBT, and Sumi Paranjape, Director, Technology Innovation, Vulcan Inc.

Brief Intervention: Deepanwita Chattopadhyay, Chairman & CEO, IKP Knowledge Park; Anand Kumar, Managing Director, Indian Immunologicals Ltd.; and Siddavadam Dayanada, Professor, Department of Animal Sciences, University of Hyderabad

Research and development are profoundly important to India and the US for biotechnological advancement. However, recent events, such as the use of CRISPR by a Chinese scientist to make a genetically edited baby, and conferences, such as the Second International Summit on Human Genome Editing in Hong Kong,

have raised many questions about how best to govern the growing landscape of biotechnology. Topics addressed during this session might include: How do the US and India balance the opportunities and risks from biotechnology? What are the roles of researchers and government? Are we better able to manage risks from research funded by government vs. those funded by private companies? A representative from each country will provide opening remarks (5-7 minutes) on this topic, followed by a discussion with all participants.

10:15-10:30 **Remarks by Patrick Boyle, Head of Codebase, Ginkgo Bioworks**

Topic: The Role of Ginkgo Bioworks in Biosecurity

10:30-11:00 **Future Priorities for Engagement**

Opening Remarks: S. R. Rao, DBT, and Tom Inglesby, JHU Center for Health Security

What issues should be developed more deeply at the next meeting of the Dialogue in February 2020? How can we continue collaborations? Introductory speakers will provide opening remarks (3-5 minutes) on this topic, followed by a discussion by all participants.

11:00-12:00 **Travel to Bharat Biotech**

12:00-13:00 **Lunch at Bharat Biotech**

13:00-14:00 **Tour/Presentation: Bharat Biotech**

14:00-14:15 **Travel to Biological E Limited**

14:15-15:15 **Tour/Presentation: Biological E Limited**

15:15 **Meeting Adjourns; shuttle bus returns group to ITC Kakatiya**

16:30 **Arrive at ITC Kakatiya Hotel**

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