Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

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Biological risk assessment and management

Summary of October 2020 Experts' Meeting on Strengthening Laboratory Biorisk Management

Submitted by the United States

Multilateral collaboration and international scientific exchanges can advance sound pathogen handling practices that underpin an effective global response to disease outbreaks. On October 20 and 27, 2020, the United States organized a meeting of experts to explore ways to bolster the existing international scientific foundation of laboratory biorisk management and strengthen public confidence that biological risks are managed appropriately. This paper summarizes the goals of the meeting and highlights recommendations that are relevant to topics in the current BWC intersessional process. The meeting report is included in the Annex.

Introduction

1. Sound pathogen handling practices, or "laboratory biorisk management," encompass biosafety, biocontainment, and laboratory biosecurity. Laboratory biorisk management is integral to the safe and effective prevention of and response to disease outbreaks. Sound practices are based on the best available scientific evidence for pathogen handling procedures. Openness regarding these practices can not only promote best practices but also build public confidence. Multilateral collaboration, including within the Biological and Toxin Weapons Convention (BWC), and scientific exchanges among laboratory experts can bolster biorisk management worldwide by building the requisite body of scientific evidence and sharing best practices. There are also opportunities to increase confidence that work is carried out with the utmost attention to biosafety and biosecurity, especially in light of the increasing numbers and sophistication of biological laboratories and their research. The BWC provides a unique forum to share information among States Parties, to receive input

from biocontainment laboratories about their biorisk management, and to encourage international collaboration between biorisk management experts.

2. In the current cycle of the intersessional program, MX2 discussion participants considered the implications of advances in science and technology for the BWC and available tools for biological risk assessment and management that align with developments in relevant fields. Several States Parties highlighted various approaches to managing risks in order to realize the benefits of biotechnology developments while also considering the potential for misuse for biological weapons development. For example, a working paper[1] submitted by Austria, Belgium, Chile, France, Germany, Iraq, Ireland, the Netherlands, Spain, and Thailand highlights the potential role of industrial standards for biorisk management, such as the recently established ISO35001, in BWC implementation. Communication with the laboratory community is one important factor in ensuring good governance of science and technology advances.

3. One group of experts whose experience is especially relevant to the work of the BWC includes the laboratorians that handle pathogens that pose a significant security or safety concern – given their experience and expertise in their research, in the risks and benefits of high containment laboratory work, and in existing safety and security practices and procedures. To gain insights from such experts, in October 2020 the United States hosted the G7 Experts' Meeting on Strengthening Laboratory Biorisk Management to explore how to advance evidence-based and transparent laboratory biorisk management practices.

4. The goal of the meeting was to solicit recommendations from the laboratory community—including laboratory directors, researchers, and those involved in overseeing safety and security measures—on how to advance the evidence base for and openness around biorisk management. The complete meeting report, which is included in the Annex, contains 11 recommendations developed by expert participants in their personal capacities. These recommendations focus on ways to improve pathogen handling practices so that they are based on the best available scientific evidence and on ways to advance openness about laboratory biorisk management. Three of these recommendations are directly relevant to the work that BWC States Parties are considering in MX2. The titles of these recommendations are below (See Annex for details of each recommendation):

- Recommendation #6: Laboratories to follow and/or harmonize with international guidelines for biosafety procedures;
- Recommendation #7: BWC CBMs to include BSL4 laboratory oversight (To accomplish this recommendation, the United States included a summary of BSL4 laboratory oversight preceding Form A, Part 1 as part of the 2021 CBM Submission);
- Recommendation #8: Containment labs to exchange best practices and lessons learned.

5. It was emphasized that various efforts to strengthen the existing evidence base of laboratory biorisk management practices are already underway and that a number of international fora and tools already exist to promote openness about the safe and secure management of pathogens. Laboratory biorisk management can thus be advanced by harnessing and amplifying ongoing multilateral collaboration and scientific exchanges. For instance, multilateral fora such as the World Health Organization (WHO), the Organization for Animal Health (OIE), the Global Partnership Against the Spread of Weapons and

[1] BWC/MSP/2020/MX.2/WP.2 - Biorisk management standards and their role in BTWC implementation - Submitted by Austria, Belgium, Chile, France, Germany, Iraq, Ireland, Netherlands, Spain and Thailand

Materials of Mass Destruction (GP), the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR), the International Organization for Standardization (ISO), and others all have important roles in the development and dissemination of safe and secure practices for pathogen handling. Further, international laboratory networks and professional societies can compare notes or lessons learned and partner to solve specific biorisk challenges as they arise. While this specific G7 meeting involved a limited number of experts, the recommendations and discussions about strengthening laboratory biorisk management are of relevance to all BWC States Parties. The United States welcomes international partnership to fulfill these recommendations as well as discussion among BWC States Parties about ways the Convention can reinforce the safe and secure handling of pathogens that have the potential to be misused as weapons.

Annex

Meeting Report: G7 Experts' Meeting on Strengthening Laboratory Biorisk Management (Virtual, 20th & 27th October 2020)

I. Executive Summary

1. Sound laboratory biorisk management is essential for an effective global response to biological threats. To this end, the United States hosted the G7 Experts' Meeting on Strengthening Laboratory Biorisk Management to explore how the G7 can advance evidence-based and transparent laboratory biorisk management practices. Public confidence depends on ensuring that laboratory biorisk management practices—which encompass biosafety, biocontainment, and laboratory biosecurity—are based on a sound foundation of research and are transparent to the international community. Work must be seen to be carried out with the utmost attention to biosafety and biosecurity. Efforts to further strengthen the existing evidence base of laboratory biorisk management practices are already underway, and many international forums and tools already exist to promote transparency about these practices. Expert participants developed 11 recommendations to advance these issues by harnessing and amplifying ongoing work, especially with respect to multilateral collaboration and scientific exchanges.

II. Recommendations

2. Experts from G7 countries discussed how evidence-based and transparent laboratory biorisk management practices and procedures can be advanced. The experts made the following recommendations:

Issue 1: Advance the evidence base of laboratory biorisk management practices and procedures

A. International experts' workshop(s) to develop a research agenda

3. Recommend that the G7 sponsor one or more international experts' workshops to identify and assess current evidence gaps in laboratory biorisk management at all laboratory levels and develop an agenda for applied biorisk research. The workshops should, where applicable, incorporate a "one health" approach and include experts from both developed and developing countries. The research agenda should take into account ongoing related efforts in G7 and Global Partnership countries and other venues, including cooperative projects with developing countries. Such workshops could be incorporated into existing relevant forums or build from previous efforts, for example the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR), Global Health Security Initiative (GHSI) Action Group (GHSAG), or World Health Organization's (WHO) Consultative Meeting on High/Maximum Containment Laboratories, and be linked with the international technical working group also recommended by this G7 experts' meeting (recommendation #2).

B. Ongoing international working group on evidence-based laboratory biorisk management

4. Begin an ongoing voluntary international technical working group on laboratory biorisk management composed of experts from a broad range of countries and varying levels of containment. The group should, where applicable, incorporate a "one health" approach and include laboratories, professional societies, government bodies, international organizations, and other organizations with relevant expertise. Building on the workshops recommended by this G7 experts' meeting (recommendation #1), the group should track real-time research needs, evaluate the evidence base of existing biorisk practices and applicable practices from other disciplines, conduct applied biorisk research, exchange information and related materials, and promote adoption of evidence-based best practices for laboratory biorisk management, for example, through publication of findings. Examples of issues to be addressed include methods of validation for biological material inactivation, effective use of personal protective equipment, development of training materials, establishing a biosafety culture, and laboratory decontamination.

C. Research agenda projects to be addressed in Global Partnership projects

5. Encourage Global Partnership member countries, in accordance with the Global Partnership's Biosecurity Deliverables, to address biological risk management and incorporate applied biorisk research in relevant Global Partnership Projects.

D. Groups to sponsor forums on evidence-based laboratory biorisk management

6. Encourage relevant professional societies, industry groups, other relevant research communities, and government bodies to sponsor forums on evidence-based best practices for laboratory biorisk management.

E. Research groups to incorporate applied biorisk research topics

7. Encourage international laboratory networks and research alliances, for instance the Group of High Containment Laboratory Directors (GOHLD), the Biosafety Level 4 Zoonotic Laboratory Network (BSL4Znet), the Global African Swine Fever Research Alliance, the GHSI GHSAG Laboratory Network, and similar groups, to incorporate applied biorisk research topics identified in international experts' workshops (recommendation #1) and working group(s) (recommendation #2) into their work programs.

Issue 2: Advance transparency about laboratory biorisk management practices and procedures

F. Laboratories to follow and/or harmonize with international guidelines for biosafety procedures

8. Encourage all laboratories, including in G7 countries, handling infectious agents or toxins that pose a significant risk if released, to demonstrate that they meet high standards for safe management of such materials by following or meeting relevant international guidelines (e.g. World Health Organization Biosafety Manual and the World Organization for Animal Health guidelines, etc.), international standards (e.g. International Organization for Standardization (ISO) Standard 35001, etc.), or equivalent national or regional guidelines (e.g. the Canadian Biosafety Standards and Guidelines, the Biosafety in Microbiological and Biomedical Laboratories (BMBL), relevant European Directives, e.g. 2000/54/EC, etc.). Encourage consideration of harmonization of such guidelines for safe handling of infectious agents and toxins.

Recognizing that serious resource constraints and other challenges preclude adoption and implementation of existing laboratory guidelines and standards in certain settings, G7 countries (including through the Global Partnership) should continue to support efforts to identify locally sustainable, appropriate, and effective laboratory biorisk solutions that do not compromise biosafety and biosecurity in low-resource environments.

G. BTWC CBMs to include BSL4 laboratory oversight

9. Recommend that G7 and Global Partnership countries include a brief description of maximum containment/BSL4 laboratory oversight measures in the Biological and Toxin Weapons Convention (BTWC) confidence-building measure reports (e.g., if applicable, the name of the relevant registration and oversight system for the laboratory, a naming of other laboratory biorisk management oversight systems such as an institutional biosafety committee). Recommend that G7 countries encourage other BTWC States Parties possessing a maximum containment laboratory do the same. Encourage G7 and Global Partnership countries, consistent with national regulatory requirements, to explore making publicly accessible appropriate portions of the BTWC confidence-building measure reports (e.g., Form E that provides information on national measures for biosafety and biosecurity).

H. Containment labs to exchange best practices and lessons learned

10. Encourage maximum containment laboratories in G7 countries, together with similar laboratories in other countries and consistent with regulatory and legal requirements, to promote transparency about laboratory biorisk management through regular exchange of best practices and lessons learned in relevant areas such as laboratory incidents, work with new or emerging diseases, and community engagement. This could be done through existing laboratory networks, as well as new research alliances, utilizing peer review procedures as well as scientific and biosafety exchanges. Encourage similar exchanges at other laboratory containment levels.

I. Exchange lessons learned, plans, and appropriate information for laboratory biorisk management

11. Encourage appropriate bodies in G7 and Global Partnership countries to exchange information with each other, on a case by case basis as appropriate and consistent with applicable legal requirements, relevant to laboratory biorisk management planning for new and existing laboratories in order to improve and promote consistency for laboratory biorisk solutions. This can foster scientific collaboration and peer exchanges as well as strengthen laboratory biorisk management by encouraging planners to leverage expertise already available within laboratory networks to help ensure that future work is carried out at the appropriate biosafety levels.

J. Relevant groups to develop and disseminate best practices

12. Urge professional societies, industry groups, laboratory networks, and other relevant research communities to develop and disseminate best practices, such as local community liaison arrangements, for transparency about laboratory biorisk management.

K. Share experiences in biorisk management training among universities, professional groups

13. Encourage G7 countries to promote training, education, and exchange of knowledge and experience in biorisk management through university laboratories and professional networks, both nationally and internationally, as an important foundation for transparency about biorisk management practices.

III. Discussion Summary

Welcome

Dr. Gerald Parker (United States)

14. Dr. Parker welcomed participants for engaging on the critical subject of strengthening laboratory biorisk management, describing the goal of the meeting as launching a process to improve the existing evidence base and transparency in laboratory biorisk management practices. He reminded participants that laboratory biorisk management practices include a suite of measures to ensure the safe and secure handling of hazardous biological materials.

Issue I: How can G7 countries advance scientifically sound laboratory biorisk management practices and procedures?

Chairs: Dr. Gerald Parker (United States) and Dr. Robert Hawley (United States)

Discussion Questions:

- How can existing efforts to identify and fill evidence gaps be advanced?
- What new steps can G7 countries take to further applied biorisk research?
- How can scientifically sound laboratory biorisk management practices be promoted worldwide?

Framing discussion

15. Dr. Robert Hawley noted relevant evidence gaps in applied biorisk management, ongoing efforts to fill them, and models for international research coordination. He described the existing framework of laboratory biorisk management as a discipline, referencing the standard ISO 35001, Biorisk Management for Laboratories and Other Related Organisations description: "management system approach enables an organization to effectively identify, assess, control, and evaluate the biosafety and biosecurity risks inherent in its activities." He noted that many laboratory biorisk management tools already exist across a range of veterinary, clinical, diagnostic, and research laboratories at various biosafety levels, including the World Health Organization Laboratory Biosafety Manual, the Canadian Biosafety Standards and Guidelines, and U.S. Biosafety in Microbiological and Biomedical Laboratories among other national guidelines and standards.

16. Dr. Hawley emphasized the special importance of scientifically sound practices, or biorisk management practices that are supported by scientific evidence, from peer-reviewed research or otherwise validated, reproducible research. In addition to scientifically sound practices being effective safety measures, they provide assurance to the researcher and the public, provide credibility for biosafety professionals, and provide an opportunity for enhanced dialogue between researchers and biosafety professionals. Dr. Hawley provided examples of such scientifically sound practices arising from applied biorisk research, including research undertaken for the COVID19 pandemic response surrounding the effectiveness of fabric masks, SARS-CoV-2 surface stability, incubation, and bioaerosol spread as well as examples from equipment biosafety procedures and laboratory incidents. He emphasized the benefits of sharing this research and data, particularly for laboratory incidents and sociology that can improve the overall management system.

17. Dr. Hawley provided examples of ongoing work to identify existing evidence gaps in laboratory biorisk management, including the findings of a 2019 U.S. Workshop on Applied Biosafety Research, which identified the following categories for potential future research: evidence based evaluation of elements within the hierarchy of controls; scientific basis to prevent pathogen exposure and infection; empirical basis for incidents - human factors and equipment reliability; evaluation of risk assessment and management methods; and sociology of laboratory biorisk management. He emphasized the role of a safety culture and climate, which can be advanced by sociological evidence surrounding personnel behavior, training, and organization culture and climate. Other examples include work by the World Organization for Animal Health to develop a Biosafety Research Road Map or intramural research programs, like the U.S. Centers for Disease Control and Prevention's Laboratory Safety Science and Innovation Intramural Research Fund Program or the U.S. Department of Defense's Scientific Gaps in Biorisk Research Program.

18. Dr. Hawley emphasized the importance of international coordination, which leverages global expertise, strengths, and resources in addition to fostering international collaboration and promoting dissemination of scientifically sound practices. He provided examples of such international research coordination, including the Nuclear Forensics International Technical Working Group, the Chemical Forensics International Technical Working Group, the Transatlantic Taskforce on Antimicrobial Resistance, and peer-reviewed journals, such as Forensic Genomics.

Facilitated discussion

19. In the discussion sessions, the following points were noted:

- The necessity to be responsive to real-time research needs and priorities, which requires agility both in biorisk research funding (for example, to identify surrogates during an ongoing outbreak) and in laboratory capabilities (for example, to modularly adapt laboratories for appropriate biosafety levels).
- The value of international coordination in linking institutions and their relevant capabilities to leverage research strengths and amplify the impact of limited financial resources.
- The importance of evidence-based biorisk management practices in both high and low resource settings, including scientifically sound practices tailored to the needs of diagnostic laboratories and research laboratories beyond G7 countries.
- The need for sustained international collaboration, in the form of consortiums or coalitions of the willing, particularly to continue important work beyond the outbreak of the day.
- The importance of peer partnerships in a professional community to leverage one another's expertise to fill biorisk research knowledge gaps and to freely and informally exchange information without fear of repercussion.
- The success of the BSL4Znet international laboratory network in exchanging lessons learned and collaborating to address practical, real-world issues.
- The value of rapid and accurate sharing of information, especially to leverage ongoing research efforts with emerging or new diseases.
- The need for inclusive venues where laboratory directors and others can share information about applied biorisk research, through peer-reviewed publications or sharing protocols. Such a venue could broaden the input for identifying evidence gaps, distribute the research needed to fill those gaps, and facilitate sustained

international communication lines between scientists, biosafety experts, and biorisk policy officials.

- The importance of raising awareness and building from other relevant initiatives in order to identify approaches that have been successful and could be adapted or applied to a variety of settings, including low-resource, diagnostic, or field settings.
- The necessity of realizing the "One Health" approach while identifying evidence gaps and how to fill them. One successful example from the agricultural disease discipline is the Group of High Containment Laboratory Directors (GOHLD) that have developed Guidelines for Livestock Biosafety Manual Development as well as facilitated scientific exchanges and collaborations.
- The need to identify where there are evidence gaps in laboratory biorisk management in a structured way, similar to Master Question Lists or Gap Analysis developed for other scientific topics. The following evidence gaps were noted: inactivation procedures, decontamination, sociological studies to support biosafety culture, root cause analysis of laboratory incidents, and validation procedures.
- The utility of building from existing laboratory networks, including BSL4Znet, to compare lessons learned, share information, reduce duplication, and identify ways to sustain international communication and to increase the impact of limited resources.

Issue II. How can the G7 countries advance transparency about laboratory biorisk management practices?

Chairs: Dr. Gerald Parker (United States) and Dr. David Franz (United States)

Discussion Questions:

- How can existing efforts to share laboratory biorisk management practices be advanced?
- What new steps can G7 countries take to further transparency about biorisk management within the professional community?
- How can openness about laboratory biorisk management be promoted worldwide?

Framing discussion:

20. Dr. David Franz provided a presentation on relevant forms of transparency, ongoing efforts, and ways to promote best practices surrounding transparency about laboratory biorisk management. He said that transparency about biorisk management can build confidence that work is carried out safely and securely, that it goes beyond regulations and public disclosures, that it begins with enlightened leadership, and that it can take many forms.

21. He provided examples of existing international exchanges that can promote transparency about laboratory biorisk management. These include groups of laboratory networks, like the Group of High Containment Laboratory Directors (GOHLD), the Biosafety Level 4 Zoonotic Laboratory Network (BSL4Znet), or the Veterinary Biocontained Facility Network for Excellence in Animal Infectious Disease Research and Experimentation (VetBioNet). Dr. Franz highlighted that these networks can also involve shared laboratory access, which can both increase safety and reduce the perceived need for new high containment labs. Such exchanges also included international meetings, like the World

Health Organization's 2017 Consultative Meeting on High/Maximum Containment Laboratories Networking. Dr. Franz emphasized the importance of international scientific collaboration in furthering transparency, referencing the following collaborations: Global African Swine Fever Research Alliance, Global Foot-and-Mouth Disease Research Alliance, and the Emerging and Dangerous Pathogen Laboratory Network (EDPLN).

22. Dr. Franz provided examples of international biosafety and biosecurity partnerships that advance transparency. These included U.S. National Academy Committee on International Security and Arms Control - International Biosecurity Dialogues, Chatham House's Sustainable Laboratory Initiative and other bilateral laboratory capacity building partnerships. The Sustainable Laboratory Initiative, in particular, is working to tailor biorisk management practices to be safe, sustainable, and context appropriate. He also highlighted the role that accreditation processes and international standards can play in providing assurances that work is being carried out safely and securely. Beyond certification, the process and the relationships during the accreditation process have long-lasting transparency benefits. Examples of such measures included the ISO35001 Biorisk Management for Laboratories, the American Biological Safety Association (ABSA) International's Laboratory Accreditation Program, and the Biological and Toxin Weapons Convention's Confidence-Building Measures.

23. Dr. Franz summarized the ways in which international exchanges promote openness about laboratory biorisk management, namely by leveraging global experiences and lessons learned, fostering international collaboration, promoting best practices in transparency, and opening lines of communication between like-minded professionals. He referenced several existing forums that could promote best practices in transparency about laboratory biorisk management. These forums included international working groups, like International Experts Group of Biosafety & Biosecurity Regulators (IEGBBR), the Global Partnership Biological Security Working Group (GP/BSWG), or the International Veterinary Biosafety Workgroup (IVBW). Professional societies, including the American Biological Safety Association (ABSA) International and the International Federation of Biosafety Associations (IFBA), are also venues to reach a wide audience across many countries.

Facilitated discussion

24. In the discussion sessions, the following points were noted.

- The importance of involving scientists and policy makers in dialogues about transparency in laboratory biorisk management in addition to the biosafety community, including by raising awareness through editorials in scientific journals or by promoting policies that encourage openness.
- The role that international and regional collaboration can play in sharing information about laboratory biorisk management, ensuring work is conducted safely, and leveraging existing resources to maximize existing investments in high containment laboratories.
- The need to engage practitioners (BSL3 and BSL4 staff) as well as to leverage already existing laboratory networks, while including countries beyond the G7 either in multilateral exchanges or bilaterally.
- The importance of communicating about laboratory biorisk management practices already in place with the local community and the public, which can be strengthened by training scientists in communication and by encouraging journalists with scientific backgrounds.

- The need for non-punitive laboratory incident reporting so that the incident, impact, and lessons learned can be shared without repercussions or fear of the "black eye phenomenon." Ways to facilitate this include anonymizing reporting data, normalizing the sharing of negative results, and fostering open communications with oversight bodies.
- The necessity of community engagement and public relations to build trust by sharing information about high containment laboratory safety both about work already completed and work being planned. The value of laboratories sharing experiences about approaches to local community engagement, both in terms of the work being performed and in terms of the measures to ensure that work is carried out safely and securely.
- The value in engaging laboratories beyond the G7, either other high containment laboratories or laboratories that handle similar pathogens, to share best practices. Key tools to this engagement include translations into local languages and capacity building initiatives that foster sustainability in contexts where resources are constrained.
- The value of international standards as a way to promote transparency, while also acknowledging that different settings have different resources, capabilities, and national standards that should be taken into account.
- The need to involve partner countries during the development process to ensure biorisk management tools are useful in a broad range of settings.
- The important role that professional societies (for example, ABSA, the American Society for Microbiology, etc.) and international consortiums can play in transparency about laboratory biorisk management, including through peer exchanges.

IV. Developing Recommendations

Chair: Dr. Gerald Parker (United States)

25. Drawing from the framing discussions, the organizers prepared draft recommendations for review by the active participants. Based on these discussions, revised recommendations were distributed to the group for their review and final changes made. (The resulting recommendations are contained in this report.) Dr. Parker noted that some recommendations might be implemented as Global Partnership projects; others might be more suitable as initiatives under the Biological and Toxin Weapons Convention or in other venues outside these two particular settings.

Discussion of recommendations

26. During the development of recommendations, the following areas were identified for future consideration:

- The specific mechanisms of implementing each recommendation, including how to link these efforts with ongoing work and how to ensure they receive sustained attention.
- The way in which recommendations #1, #2, and #3 would be connected and the methods of work, for example whether topic-specific working groups or scenario-based approaches would be useful.

- Ways in which to involve BSL2 laboratories and diagnostic laboratories in the recommendations surrounding issue 1 (evidence-based laboratory biorisk management).
- Ways in which to widely disseminate the work envisioned in recommendations surrounding issue 1 (evidence-based laboratory biorisk management).
- The importance of involving key entities, especially international organizations involved in biorisk management (for example OIE), outside of the G7 expert participants in this meeting in advancing the recommendations of the report.

V. Participants

Chair and Speaker Biographies

Gerald W. Parker, Jr., DVM, Ph.D.

27. Dr. Parker is the Associate Dean for Global One Health at the College of Veterinary Medicine & Biomedical Sciences and Director for the Pandemic & Biosecurity Policy Program at the Scowcroft Institute of International Affairs within the Bush School of Government and Public Service. Dr. Parker also serves as a senior advisor for the Assistant Secretary for Preparedness and Response on detail as a special government employee at the Department of Health and Human Services. Parker is a member of several advisory boards, including the Texas Task Force on Infectious Disease Preparedness and Response for the Governor, ex officio member for the Bi-partisan Commission for Biodefense, and the National Science Advisory Board for Biosecurity for the National Institutes of Health. Prior to his appointment to Texas A&M University, Dr. Parker's service included more than 26 years on active duty leading military medical research and development programs and organizations. He is a former Commander and Deputy Commander, U.S. Army Medical Research Institute of Infectious Diseases. Dr. Parker held senior executive level positions at the Department of Homeland Security, the Department of Health and Human Services (HHS) and the Department of Defense (DOD), including serving as the Principal Deputy Assistant Secretary for Preparedness and Response at HHS, and Deputy Assistant Secretary of Defense for Chemical and Biological Defense at DOD. Dr. Parker graduated from Texas A&M's College of Veterinary Medicine, Baylor College of Medicine Graduate School of Biomedical Sciences, and the Industrial College of the Armed Forces.

Robert J. Hawley, Ph.D., RBP, SM(NRCM), CBSP

28. Dr. Hawley serves as an independent consultant in biological safety and security. He previously served as a Senior Advisor, Science, at the Midwest Research Institute Global in Frederick, Maryland and as Chief of the Safety and Radiation Protection Division at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick. He earned a Master's and Doctorate in Microbiology and has over 45 years of experience encompassing academics, clinical microbiology and biological safety and security. Dr. Hawley is a Registered and Certified Biological Safety Professional with the American Biological Safety Association International (ABSA) and has served as a Council Member and President of ABSA. He is also a member of American Society for Microbiology and New York Academy of Sciences. He has served on various national and international review and certification committees.

David R. Franz, DVM, Ph.D.

29. 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 was Chief Inspector on three United Nations Special Commission biological warfare inspection missions to Iraq. He also served as a member of the first two U.S.-U.K. teams that visited Russia in support of the Trilateral Joint Statement on Biological Weapons and as a member of the Trilateral Experts' Committee for biological weapons negotiations. The current focus of his activities relates to the role of international engagement in public health and the life sciences as a component of global security policy. Domestically he continues to encourage thoughtfulness when regulating research in the name of security, thereby minimizing negative impact on progress in the life sciences. Dr. Franz holds a D.V.M. from Kansas State University and a Ph.D. in Physiology from Baylor College of Medicine.

30. **Workshop Organizers:** The meetings were organized by Dr. Danielle Lohman (Department of State), assisted by Dr. Robert Mikulak (Department of State). Meeting support was provided by Kenneth Turner (Department of State), Amanda Moodie (National Defense University), and Dr. Kirsten Weand (Department of State).

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