

**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**

17 December 2020

English only

2020 Meeting

Geneva, 12-15 April 2021

**Meeting of Experts on Cooperation and Assistance,
with a Particular Focus on Strengthening Cooperation
and Assistance under Article X**

Geneva, 1-2 December 2020

Item 4 of the provisional agenda

**Consideration of the reports of the States Parties on their full and comprehensive
implementation of all provisions of Article X**

**Report on Implementation of Article X of the
Biological and Toxin Weapons Convention**

Submitted by the United States of America

Summary

The United States is fulfilling all of its obligations under the Biological and Toxin Weapons Convention (BTWC), including under Article X, and continues to invest significant resources in these efforts. In the 21st Century alone, the United States has invested over \$100 billion to strengthen national capacity in partner countries to prevent, detect, and respond to existing and emerging infectious disease threats, and to promote the advancement of the life sciences for peaceful uses.

The generosity of the American people is evident in the response to the COVID-19 pandemic. The United States Government has committed over \$1.6 billion in international assistance specifically aimed at fighting the pandemic and is deploying the full range of U.S. resources to contain and prevent the spread of COVID-19 across the globe. This funding is saving lives by improving public health education; strengthening healthcare facilities; and increasing laboratory, disease-surveillance, and rapid-response capacity in more than 120 countries.



I. Introduction

1. The United States places great importance on Article X implementation and continues to invest significant resources in these efforts. The Seventh Review Conference confirmed the importance of implementation of Article X and encouraged “States Parties to provide, at least biennially, appropriate information on how they implement this Article.” Such reporting is a central element of any effort to ensure that the obligations under Article X are being met by States Parties, both because they can facilitate understanding of successful approaches to assistance and identification of challenges, and because the vast majority of States Parties’ efforts on cooperation and assistance take place outside the formal confines of the BWC.

2. The United States strongly encourages all States Parties to the Convention to promptly submit reports on how they are implementing Article X obligations. This information will provide a more complete picture of the implementation of this article and will permit the international community to better prepare for future outbreaks of infectious diseases, regardless of origin.

3. The United States Government is the largest funder and implementer of global health programs worldwide, engaging in a wide range of cooperation and capacity-building assistance relevant to Article X, with a wide range of partners. The U.S. Government considers the promotion of global health, through cooperative activities, to be a prime example of Article X implementation, as it promotes scientific cooperation for peaceful purposes, promotes economic development, and serves as a vehicle for the exchange of scientific information, equipment, and materials. To guide our promotion of global health, the U.S. Government has issued several strategy and guidance documents, such as the National Biodefense Strategy (NBS) in 2018 and the Global Health Security Strategy (GHSS) in 2019. The NBS outlines a comprehensive U.S. Government approach to addressing biological threats domestically and internationally, while the GHSS guides U.S. Government efforts to enhance capacities of targeted countries to prevent, detect, and respond to infectious disease outbreaks. Furthermore, the United States often plays a key role in international responses to major disease outbreaks, including in response to COVID-19, the worst public health emergency in over a century.

4. The U.S. Government’s formal “assistance” programs and direct government-to-government engagement comprise only a portion of a much larger array of assistance and cooperation provided by the United States. U.S. activities and programs to promote the exchange, cooperation, and assistance that contribute to international cooperation are undertaken not only by the government, but also by individuals, industry, foundations, academia, and other non-governmental organizations. Indeed, most U.S. programs, and other efforts that strengthen global health, do not take place solely, or even primarily, in the BWC forum.

5. The breadth and scope of U.S. cooperation and assistance precludes a comprehensive listing of every program. Therefore, this report provides examples to illustrate the range and diversity of activities, and demonstrates the full commitment of the United States to Article X.

6. The remainder of the report is organized around the three basic obligations contained in Article X:

- (a) to facilitate the fullest possible exchange of information, equipment, and materials for peaceful purposes;
- (b) to cooperate in the development and application of the life sciences; and

(c) to implement the BWC in ways designed to avoid hampering the economic and technological development of States Parties or international co-operation in the field of peaceful bacteriological (biological) activities.

II. Bilateral, regional, and multilateral efforts to facilitate the fullest possible exchange of biological equipment, materials, and information for peaceful purposes

A. Facilitating global health

7. The COVID-19 pandemic reminds us that measures to limit vulnerability to infectious diseases, such as bolstering health care infrastructure, strengthening diagnostic capabilities, and developing new medical therapies, will benefit the response to an outbreak, regardless of its origin. Assisting States Parties in strengthening their national capacities to prevent, detect, and respond to infectious disease outbreaks is a direct contribution to the object and purpose of the BWC.

8. The United States Government is taking decisive action to build global health security capacity to respond to this, and future outbreaks, and is deploying the full range of its resources to contain and prevent the spread of COVID-19 and future pandemics across the globe. This effort builds upon decades of U.S. international investment in life-saving health and humanitarian assistance.

9. Furthermore, we continue to evaluate how best to support international efforts to facilitate rapid global access to COVID-19 vaccines and therapies, as we await completion of scientifically rigorous Phase III clinical trials and the United States Food and Drug Administration licensing or authorization of COVID-19 vaccines.

10. The United States' commitment to defeat this pandemic, and avoid future ones, is demonstrated through our numerous initiatives aiming to strengthen global health frameworks. We summarize some of these initiatives below.

B. Disease surveillance, detection, and response

11. The Global Health Security Agenda (GHSa), re-affirmed in 2018 and revised in 2019, is a catalyst for progress toward a world safe from global health threats posed by infectious diseases, whether caused naturally, deliberately, or accidentally. It is a collaborative multisectoral initiative of countries, regions, international organizations, and the non-governmental sector (including the private sector) to strengthen global health security.

12. The revised GHSa framework (hereafter GHSa 2024) sets a global target for implementation of global health security objectives, seeking to drive robust commitments, action, and accountability. GHSa 2024 includes a renewed vision, mission, core principles, and mandate. It also establishes new and updated structures to enhance coordination, including a secretariat function, task forces, and revised Action Package working groups.

13. Under GHSa 2024, nations make concrete commitments to elevate the priority of global health security and improve their capacity to prevent, detect, and respond to infectious diseases as a national priority. GHSa members provide support for implementation through advocacy, collaboration, information sharing, and technical assistance. The U.S. is a leading voice on the GHSa 2024 Steering Group, as the chair of the Accountability and Results Task Force, the Stakeholder Engagement Task Force, and the Laboratory Action Package Working

Group, in addition to being a member of several other Task Forces and Action Package Working Groups.

14. The GHSA 2024 target is to have more than 100 countries with improved capacities complete an evaluation of health security capacity, undertake planning and resource mobilization to address gaps, and begin the process of implementing activities to achieve improvements in at least five technical areas by 2024. To do so, the United States Government, through the United States Agency for International Development (USAID); the United States Department of Health and Human Services, including the Centers for Disease Control and Prevention (CDC); the United States Department of Agriculture; the United States Department of Defense; and the United States Department of State, is working with ministries of health, agriculture, environment, and other key stakeholders in partner countries to strengthen capacities to detect viruses with pandemic potential, improve laboratory capacity to support surveillance, strengthen response to disease outbreaks, and provide education on biosafety and biosecurity.

15. The CDC is the United States' primary agency for disease detection. It works in partnership with countries to develop sustainable capacities to support disease surveillance and response activities. The CDC collaborates with public health agencies, health ministry counterparts, non-governmental organizations, and others worldwide to address known and unknown global health threats. The CDC Center for Global Health's Division of Global Health Protection provides capacity-building, training, and educational support to other countries through its Global Disease Detection Program (GDD), Emergency Response and Recovery Branch (ERRB), and Field Epidemiology Training Program (FETP). The CDC has also created a cross-agency rapid response team for international deployment, and CDC staff are often involved in international response efforts. Thanks to decades of global cooperation to control diseases, the CDC has built a strong foundation upon which to address the coronavirus pandemic.

16. Through CDC's Global Emergency and Alert Response Service (GEARS), 30-40 public health events are monitored per day worldwide, and 139 events of public health importance were tracked during 2019. Over 350 CDC experts are ready to deploy globally in response to a public health emergency through GEARS. In 2019, GEARS mobilized 177 staff to more than 32 countries to support outbreak response and to provide public health expertise, logging more than 8,234 combined days of deployment. In response to the COVID-19 pandemic, the CDC developed disease specific guidelines to streamline the Rapid Response Team (RRT) operations for CDC staff working outside the United States. In support of the WHO and worldwide health professionals, the CDC also developed the COVID-19 National Rapid Response Teams Online Learning Package (<https://extranet.who.int/hslp/training/enrol/index.php?id=327>).

17. Through programs such as the FETP, the CDC works with partners across the world to develop a global workforce of field epidemiologists. Since its inception in 1980, the CDC has helped train more than 16,000 epidemiologists in more than 70 countries. In 2019, FETP residents and graduates played key roles in responding to major health threats, including the Ebola outbreak in the Democratic Republic of the Congo and Uganda, the acute encephalitis outbreak in India, and the HIV/AIDS outbreak in Pakistan. In 2019, CDC-trained disease "detectives" investigated more than 272 threats across the globe. During the COVID-19 pandemic, FETP graduates are playing a critical role by strengthening the public health workforce and expanding regional and global disease detection networks available during crises. In Kenya, for example, FETP graduates are managing the COVID-19 Emergency Operations Center and its rapid response team. Dr. Ahmed, Kenya FETP Resident Advisor, noted that "[w]ithout Kenya FETP's response to COVID-19, there would have been heartbreak, and the response would have been very difficult. All of the COVID-19 task forces

are run by FETP graduates, and the heads of most EOC (Emergency Operations Centers) are graduates.”

18. Another example of the CDC’s support to other countries is the Public Health Emergency Management (PHEM) Fellowship. This program builds public health emergency management capacity throughout the world through a three-month training program at CDC’s headquarters, which focuses on emergency management principles and effective functioning of emergency operations centers. Approximately 100 fellows from 35 countries have completed the program since its inception in 2013. PHEM Fellowship alumni have facilitated the expansion of public health emergency management within their countries and have returned to their home countries to assume key roles in public health. Examples of roles fellows have taken on after their training include China CDC’s Director of the Public Health Emergency Center; Kenya’s Ministry of Health Director of the Disaster Risk Management Unit; and Thailand’s Manager of the Emergency Operation Center in the Ministry of Public Health Department of Disease Control.

19. The National Institutes of Health (NIH), the United States’ medical research agency, includes 27 Institutes and Centers, and is a component of the U.S. Department of Health and Human Services. Within the National Institute of Allergy and Infectious Diseases (NIAID), the Centers of Excellence for Influenza Research and Surveillance (CEIRS) program is a collaborative network of centers that provide the information and public health tools needed to control the impact of epidemic influenza and the threat of pandemic influenza.

20. The NIH/NIAID Centers for Research in Emerging Infectious Diseases (CREID) program aims to improve pandemic preparedness through the establishment of a coordinated network of researchers across the globe. The global network involves multidisciplinary investigations into how and where viruses and other pathogens emerge from wildlife and spillover to cause disease in people.

21. The United States Agency for International Development (USAID) supports health programs in partner countries, advances health research and innovation, and transfers new technologies. These activities are done through its own programmatic work and in coordination with other donors and portfolio partner countries to prevent avoidable outbreaks, detect infectious disease threats early, and respond rapidly and effectively when outbreaks occur. Additionally, other USAID global health programs support health systems strengthening, including building surveillance and laboratory capacities that have applications for global health security. Furthermore, USAID’s Bureau for Humanitarian Assistance (BHA), in collaboration with USAID’s Bureau for Global Health, are involved in large-scale international outbreak responses. In 2019, USAID expanded efforts to respond to an ongoing Ebola Virus Disease outbreak in the Democratic Republic of the Congo, in coordination with the CDC and the Department of State, providing more than \$266 million to support emergency response since the outbreak began in August 2018.

22. USAID’s Global Health Security (GHS) program focuses on building capacities across more than 10 technical areas critical to address the threat of zoonotic and other epidemic-prone infectious disease threats and are regularly assessed through the independent Joint External Evaluation of Health Security tool. USAID works collaboratively with other United States Government partners in 19 “intensive focus” countries, as well as in other countries that are highly vulnerable to infectious disease threats and/or represent hotspots where the risks of spillover, amplification, and spread of zoonosis is greatest. All USAID GHS activities are grounded in a “One Health” approach that brings together the animal, human, and environmental health sectors to address the burden of disease. These investments strengthen public health systems — efforts crucial to saving lives and building resilient local partners and allies — and build the knowledge base necessary to better understand, prevent, and mitigate the spillover of zoonotic pathogens to human populations and the spread of antimicrobial resistance generated from livestock.

23. The COVID-19 pandemic, and the increasing threats from emerging zoonosis, highlight the critical need for continued investments in combating zoonotic disease, such as those supported through USAID's GHS Program, especially efforts that directly reduce the spillover of animal disease threats in communities. USAID has designed a new project — STOP Spillover — that will use the information gathered through previous projects to focus on known viruses that often cause outbreaks around the world that result in significant public health and economic impact.

24. USAID's Association of Southeast Asian Nations (ASEAN) Health Futures Initiative is investing over \$87 million in assistance to fight COVID-19 and future zoonotic disease outbreaks. This initiative is supporting the ASEAN Public Health Emergency Coordination System, a robust public health network that supports coordination between existing national systems, as well as data transparency and legal measures so ASEAN countries can respond as a region to emerging public health crises and help prevent the future outbreaks. Additionally, the One Health Workforce-Next Generation Project will transform the multisectoral health workforce and help ASEAN countries prepare for, prevent, detect, and respond to public health emergencies.

25. The United States Department of Agriculture (USDA) Agricultural Research Service (ARS) is actively engaged in implementing research programs that help prevent, detect, or improve surveillance of plant and animal diseases, including emerging diseases and zoonotic agents that pose a threat to human health. ARS also actively collaborates with international partners worldwide on research projects dedicated to supporting disease surveillance programs for transboundary animal diseases. ARS is one of the founding members of the Global Foot-and-Mouth Research Alliance (GFRA) and the Global African Swine Fever Research Alliance (GARA) and is an active member of the global network of expertise on animal influenza (OFFLU), which supports the Food and Agriculture Organization of the United Nations (FAO) and World Organization for Animal Health (OIE) global efforts to control and eradicate transboundary animal diseases that affect the health of animals and people worldwide. ARS also partners with the American Biosafety Association (ABSA) to conduct biosafety training relevant to agriculture to many national and international participants at a biennial symposium.

26. The USDA Animal and Plant Health Inspection Service (APHIS) manages overseas capacity building for agricultural safeguarding, including: 1) emergency preparedness and response, and 2) prevention and control of transboundary animal diseases, particularly highly pathogenic avian influenza and African swine fever. These programs advance food security by promoting animal health (e.g., improved diagnostic laboratory and disease management techniques), developing local food supply chains, and teaching farmland and watershed management. This leads to sustainable improvements in animal and plant health infrastructure and reduced pest and disease risk. The programming also promotes cooperation with international organizations and their scientific and regulatory personnel, leading to enhanced capacity building and regulatory development. APHIS has expertise and programs in animal and plant disease, surveillance, exclusion, information systems, emergency response, and vaccination and delivers this expertise internationally to more than 100 countries.

27. APHIS also operates the National Veterinary Services Laboratories (NVSL), which provides high quality diagnostic services in support of animal health worldwide. NVSL serves as an OIE and FAO reference laboratory and actively collaborates with international partners to support animal disease surveillance and diagnostic testing programs. NVSL is an active member of OFFLU, which supports the FAO and OIE global efforts to control and eradicate transboundary animal diseases that affect the health of animals and people worldwide and is an OIE Collaborating Centre for Diagnosis of Animal Diseases.

28. The NVSL has conducted diagnostic testing, produced and distributed diagnostic reagents, and provided proficiency test panels for international partners on a range of diseases, including brucellosis, tuberculosis, glanders, dourine, piroplasmiasis, avian influenza, and Newcastle disease. NVSL has worked internationally to build capacity and harmonize methods through activities such as participating in the North American Animal Health Laboratory Network (NAAHLN); collaborating with Canada and Mexico to address bovine tuberculosis and brucellosis; publishing genomic data for agents and diseases including SARS-CoV-2, *Streptococcus equi zooepidemicus*, *Mycobacterium bovis*, vesicular stomatitis virus, and Newcastle disease; and providing scientific expertise and support to international partners by serving as subject matter experts on OIE, FAO, and OFFLU committees. NVSL actively shares knowledge on animal disease and diagnostic topics through publication of scientific advances in peer-reviewed journals and through participation in and presentations at international forums such as the WHO Consultation and Information Meeting on Composition of Influenza Virus Vaccines, the International Alliance for Biological Standardization annual meeting, and the Joint Annual Meetings of the National Reference Laboratories for Avian Influenza and Newcastle Disease of European Union Member States.

29. The U.S. Department of Defense (DoD) Defense Threat Reduction Agency's Biological Threat Reduction Program (BTRP), previously known as the Cooperative Biological Engagement Program (CBEP), funds capacity-building efforts to strengthen partner countries' biosecurity, surveillance, and response capabilities and is a component of the DoD's broader Cooperative Threat Reduction (CTR) Program. DoD's Global Emerging Infections Surveillance and Response System (GEIS) provides technical and funding support for DoD and partner organizations' surveillance, research and development, outbreak response, and local capacity-building and helps support Army and Navy laboratories that are located in multiple foreign partner countries.

30. The Armed Forces Health Surveillance Branch's Global Emerging Infections Surveillance Section (AFHSB-GEIS) enhances health protection through an integrated worldwide military laboratory network that conducts emerging infectious disease surveillance. GEIS provides direction, funding, and oversight to this laboratory network, which works with more than 50 international partners based in all regions of the world. These partners conduct disease surveillance and rapid outbreak response, perform innovative pathogen discovery activities, and enhance coordination and collaboration efforts between DoD agencies and international partners to facilitate information sharing and early detection of emerging infectious disease threats. AFHSB-GEIS encourages its partners to present and publish their findings in medical journals, global health security publications, and at scientific meetings and to comply with the International Health Regulations.

31. In fiscal year 2018, AFHSB-GEIS distributed more than \$58 million to military laboratories to support a range of emerging infectious disease surveillance projects in collaboration with international partners. The projects addressed four focus areas, including enteric infections, respiratory infections (including providing input to the WHO influenza vaccine strain selection process), febrile and vector borne infections, and antimicrobial resistant infections (to include resistant *Neisseria gonorrhoea*). The U.S. DoD is collaborating with many countries in the fight against COVID-19. For example, in Georgia scientists trained through the DoD CTR Program are now working in the National Center for Disease Control and Public Health (NCDC) at the CTR-constructed Richard Lugar Center and developed a Real-Time Polymerase Chain Reaction (RT-PCR) diagnostic testing capability for COVID-19. This diagnostic testing capability enabled Georgia to implement the WHO advice for diagnostic testing to inform outbreak control. Georgian Prime Minister Giorgi Gakharia visited the Lugar Center on June 24, 2020 and highlighted its enormous contribution to Georgia's fight against the COVID-19 pandemic, adding that it is due to the

professionalism and enormous efforts of the Center's staff that the country's epidemiological situation is currently under control.

32. Finally, the United States Government made a voluntary contribution to the International Atomic Energy Agency (IAEA) of \$11 million to support the global response to COVID-19. This contribution supports the provision of testing kits that include a RT-PCR diagnostic system, which detects the presence of viral genetic material to confirm whether a patient has been infected, and relevant biosafety equipment, including cabinets and hoods. The IAEA has so far delivered more than 1,260 consignments of these diagnostic kits to 123 countries.

C. Capacity enhancement and global health security

33. The Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services manages cooperative agreements with partner countries and international organizations to strengthen core public health emergency preparedness and response capacities abroad. ASPR works through these partnerships to strengthen emergency preparedness and response by building surveillance networks, strengthening laboratory diagnostic capacity, training personnel, and improving communication capacities within the Ministries of Health of partner countries.

34. ASPR also leads U.S. engagement in the Global Health Security Initiative (GHSI). GHSI is an informal network formed in 2001 to ensure health-sector exchange and coordination of practices in confronting risks to global health posed by chemical, biological, and radio-nuclear threats, as well as by pandemic influenza. The member countries/organizations of the GHSI are Canada, France, Germany, Italy, Japan, Mexico, the United Kingdom, the United States, and the European Commission, with the WHO serving as a technical advisor. The GHSI partners hold an annual meeting of Health Ministers to foster dialogue on topical policy issues and promote collaboration. Other initiatives involving senior health officials, as well as policy, technical, and scientific personnel, take place on a regular basis and focus on risk management, communications, chemical events, radio-nuclear threats, pandemic influenza, and global laboratory cooperation.

D. Other improvements in global health

35. The United States has been a major contributor to the Global Fund to Fight AIDS, Tuberculosis, and Malaria, as well as several other multilateral health organizations, including the Joint United Nations Program on HIV/AIDS (UNAIDS), the World Health Organization (WHO), the International AIDS Vaccine Initiative (IAVI), and Gavi, the Vaccine Alliance. The United States Government is a leading supporter of Gavi, contributing \$580 million for 2018 and 2019, and in June 2020, an additional commitment of \$1.16 billion, for fiscal years 2020 through 2023, towards the prevention of the spread of infectious diseases worldwide. This funding will strengthen the global vaccine infrastructure that could serve as a foundation for future COVID-19 vaccination efforts.

E. Facilitating national implementation of the BWC

36. Implementation of the BWC's Articles III and IV help States Parties prevent the misuse of the life sciences and biotechnology as they fulfill their Article X undertakings to facilitate exchange for peaceful purposes. Indeed, effective national implementation measures by States Parties are a key means of achieving the aims of Article X. Through a range of assistance and cooperation activities, the United States works with other BWC States

Parties to implement the Convention. During the last two years, we worked with Armenia, Ethiopia, Georgia, India, Kenya, Malaysia, Philippines, Singapore, South Africa, Sri Lanka, and Ukraine to raise awareness and train professionals to manage biological risks. In 2020, U.S. State Department funding was made available to create a database on national implementation by States Parties and to provide further direct assistance to Parties on implementing the Convention. This project is the subject of a U.S. working paper to be submitted to Meeting of Experts 3.

37. A key area of BWC implementation is Article III, obligating States Parties not to transfer biological weapons. The U.S. Department of State's Export Control and Related Border Security (EXBS) Program works with partner countries to develop ways to prevent the proliferation of weapons of mass destruction (WMD) and help to develop effective national strategic trade control systems in countries that possess, produce, or supply strategic items, as well as in countries through which such items are most likely to transit. To achieve this goal, the EXBS Program works with partner governments to identify regulatory and institutional gaps and strengthen partner countries' legal authorities and institutional capabilities. The EXBS Program provides a wide range of technical assistance including executive exchanges, training workshops, provision of detection equipment, and specialized training for border control and enforcement agencies.

38. The EXBS Program is active in over 50 countries and draws on the expertise and cooperation of a range of U.S. Government departments and agencies, the private sector, and domestic and international nongovernmental organizations to provide legal, licensing, and enforcement training, along with information systems and equipment. By strengthening the capacity of trade and border control systems, the EXBS Program helps partner countries adhere to the guidelines of multilateral export control regimes and meet their obligations and commitments to important international initiatives, including BWC Article III, United Nations Security Council Resolution (UNSCR) 1540, and the Proliferation Security Initiative.

39. Building on years of work with critical partner countries to address the greatest threats at land, sea, and air borders, our EXBS Program is now providing those partners with the training and guidance needed to effectively and safely manage points of entry in the COVID-19 environment. Through delivery of tailored instructional materials, operational guidance, and other assistance, we are helping to ensure partners have the expertise needed to manage the movement of people and goods across borders, while stopping those items that threaten global security.

G. Threat reduction

40. A related area is assistance and cooperation on efforts to reduce the threat posed by biological agents and toxins. The Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP) is an international initiative aimed at preventing the proliferation of chemical, biological, radiological, and nuclear weapons and related materials. Biological threat reduction programs that support the GP's Biosecurity Sub-Working Group (BSWG) have, over decades, collectively invested significant resources to build biosecurity and bio-surveillance capabilities in countries with significant vulnerabilities and weak capacity to contain disease outbreaks. This has included capacity building to ensure safe and secure sample collection, storage, inactivation, and waste processing, as well as accurate and sufficient testing and reporting of disease outbreaks. These efforts result in a decreased likelihood that actors with ill intentions may acquire dangerous samples and an increase in the ability to prevent sustained outbreaks and the further spread of diseases. This has been demonstrated during the COVID-19 pandemic, where U.S. biosecurity threat reduction programs have contributed to global response efforts by continuing to build and adapt

programming to protect life, enhance international security, and help prevent future catastrophes.

41. Under the U.S. Presidency of the GP in 2020, the U.S. Department of State has provided leadership in its co-chairmanship, with Denmark, of the Biosecurity Sub-Working Group (BSWG). In this role, the U.S. has facilitated GP discussion focused on understanding how COVID-19 has changed the biosecurity threat landscape and biosecurity programmatic priorities for the future and on the pressing trends in bioterrorism and the burgeoning biosecurity threats associated with advancements in various technologies. Under the U.S. Presidency, the BSWG has agreed to develop and implement a holistic Signature Initiative to mitigate biological threats collectively with concrete activities advancing shared objectives and priorities that are well-coordinated across the BSWG and partner nations. This approach has the potential to enable tremendous positive threat reduction impact, leveraging resources and expertise of a great number of nations towards the same goals. The activities within the Signature Initiative will align programming in this dynamic threat environment, further promote the five key “deliverables” adopted by member countries to guide partner’s efforts to strengthen biosecurity and reduce biological threats, and increase coordination across international threat reduction programs.

42. The U.S. Department of State’s Biosecurity Engagement Program (BEP) works in partnership with countries primarily in Eastern Europe, the Middle East, North Africa, South Asia, Southeast Asia, and Sub-Saharan Africa to promote safe, secure, and sustainable biological capabilities. BEP utilizes a multisectoral approach to biological threat reduction and engages government stakeholders in the public health, animal health, and law enforcement sectors, as well as academia and industry, to mitigate the threat posed by biological agents. Recent activities include promoting multisectoral coordination in the Middle East, North Africa, and sub-Saharan Africa: enhancing biosecurity regulatory frameworks in the Middle East, North Africa, and Southeast Asia; and improving biorisk management practices in the Middle East, North Africa, South Asia, Southeast Asia, and Sub-Saharan Africa. Many of BEP’s past efforts with partner countries around the world have helped build capacity and capabilities that are currently being utilized to respond to the COVID-19 pandemic.

43. Additionally, BEP has focused some of its current biological security assistance efforts to aid in partner countries’ response to COVID-19. Some of its programs include increasing safe and secure diagnostic capacity; improving laboratory infection prevention control and hazardous waste management; providing technical assistance for proper sample handling and use of personal protective equipment; and teaching government officials, laboratorians, and academics how to accurately and effectively communicate the risks from COVID-19.

44. The U.S. Department of State’s Office of Weapons of Mass Destruction Terrorism (WMDT) works with foreign partners to establish, strengthen, and maintain their capabilities to deter, detect, defeat, and respond to terrorist attempts to acquire or use chemical, biological, radioactive, or nuclear materials. WMDT works with partners to enhance partner capacity in five key areas: material and information security; investigative capabilities; legislation & prosecution; national, regional, and international information sharing and cooperation; and technical support and expertise. WMDT recently collaborated with the Department of Defense’s BTRP to assist a partner country in its efforts to inform and draft its BWC implementing legislation enabling a whole-of-government approach, and WMDT expects continued collaborative engagement.

45. The Department of Defense’s CTR and BTRP implement sustainable projects to reduce the proliferation of biological weapons (BW), BW components, and BW-related technologies and expertise against the U.S. homeland, U.S. forces abroad, and U.S. allies and partners. BTRP also seeks to facilitate the detection and reporting of diseases caused by

especially dangerous pathogens (EDPs). To achieve its mission, BTRP assists partner nations and regional organizations in their efforts to improve their biosafety, biosecurity, and biosurveillance capabilities. This includes such activities as: 1) helping partner nations identify, consolidate, and secure collections of EDPs to prevent their sale, theft, diversion, or accidental release; and 2) improving national capacities to rapidly and accurately detect, diagnose, and report outbreaks of EDPs, in accordance with international reporting requirements and in support of international nonproliferation agreements. BTRP also establishes and enhances international research partnerships between the U.S. and scientists throughout Africa, Central, South and Southeast Asia, East and Central Europe, and the Middle East. BTRP continues to support training programs in partner countries focused on: enhancing the skills essential for effective biosurveillance programs; promoting a culture of safe, secure, and responsible life science research; promoting a One Health approach to health security; and fostering cooperation between health and security sectors to strengthen multi-sectoral capacities to quickly identify, report, and diagnose an unusual biological event. BTRP works with partner countries to identify, prioritize, and address capability and capacity gaps. For example, BTRP has provided diagnostic laboratory renovation, equipment, and training support in several African countries and partnered with countries in the Caucasus to implement an electronic disease surveillance system to facilitate rapid detection, diagnosis, and reporting of infectious disease outbreaks.

46. Through the DoD CTR Program's long history of supporting partner countries' biosurveillance capabilities, BTRP has demonstrably helped prepare partner countries to detect, diagnose, and report infectious disease outbreaks. While the BTRP mission is focused on reducing threats associated with weapons of mass destruction, the same knowledge, skills, and capabilities are relevant for countering natural outbreaks and pandemics, such as COVID-19. BTRP improves biosurveillance through multiple lines of effort that have been utilized by partner countries in their response to COVID-19, including:

- Constructing, renovating, and equipping laboratory facilities leading national and regional COVID-19 testing efforts.
- Standing up Public Health Emergency Operations Centers (PHEOCs). BTRP has helped equip and train professionals to run 24-hour PHEOCs that are coordinating national-level COVID-19 responses. The PHEOC in Senegal, for example, is playing a critical role coordinating that country's efforts to minimize the impact of COVID-19.
- Training and building knowledge. Previous trainings provided by BTRP or supported by BTRP in partnership with other agencies or organizations, such as through Field Epidemiology Training Programs (FETPs), have prepared public health experts to lead national COVID-19 outbreak investigation and diagnostics. For example, partners at Chulalongkorn University in Thailand were the first to detect and isolate COVID-19 infections outside of China. During its normal threat reduction cooperation activities, BTRP provides limited personal protective equipment and diagnostic equipment to foreign partners.

III. Contributions to the development and application of scientific discoveries in the life sciences

47. The United States has long been a global leader in life sciences research, leading the world in global research and development spending. The United States Government provides the support and environment that enables scientists to participate in and foster the exchange of ideas that advances knowledge sharing in the life sciences. American universities, biotech companies, and individual biologists also drive both basic science and its application. In the United States, the private sector funds and performs most of the research and development

(R&D) overall, as well as most of the applied research and experimental development. Higher education institutions represent the second-largest performer of R&D overall and also perform the largest share of basic research. While federal R&D funding of basic research has increased since 2000, the proportion of R&D funded by the private sector remains higher.

48. American colleges and universities also engage in joint research collaborations with colleagues across the globe and educate many of the world's emerging scientists through undergraduate, graduate, and post-graduate training. The United States attracts the largest number of international students in the world. The number of international students in the United States set an all-time high in the 2018/19 academic year, the fourth consecutive year with more than one million international students; over 50% of them are pursuing science, technology, engineering, and math (STEM) fields.

49. The National Science Foundation (NSF), an independent federal agency with a budget in 2019 of \$8.1 billion, promotes international activities and fosters institutional frameworks that facilitate international cooperation in research and education. These activities are widely distributed across the world and range from work in the world's most advanced science and engineering laboratories to observation of physical, biological, and human phenomena around the globe. In response to the COVID-19 pandemic, the NSF has to date funded more than 945 grants totaling \$137 million. The NSF is specifically supporting fast-track, fundamental, and transformational research activity associated with improving our understanding of SARS-CoV-2, the virus responsible for causing the COVID-19; developing a predictive understanding of the spread of the virus; and enabling approaches that mitigate the negative impacts of COVID-19 on public health, society and the economy.

50. The U.S. Department of State's Office of Science and Technology Cooperation (STC) negotiates science and technology agreements, facilitates technical cooperation under those agreements, and engages with allies and partners on a range of science, technology, and innovation issues. Currently, the United States is party to more than 50 bilateral and multilateral science and technology agreements that provide frameworks for scientific collaboration. Among other efforts, STC implements the U.S. Science Envoy Program, through which eminent U.S. scientists and engineers build connections with the scientific communities in partner countries, promote science education, and identify opportunities for ongoing bilateral cooperation. STC also administers the Embassy Science Fellows Program, which dispatches U.S. government scientists to U.S. embassies for temporary assignments related to environment, science, technology, health, and other issues that have significant positive impact on host countries.

51. The National Academies of Sciences, Engineering, and Medicine, in cooperation with sponsoring federal laboratories and other research organizations, conducts the National Research Council Research Associateship Programs, which have supported the research of more than 14,000 scientists and engineers from all over the globe since their establishment in 1954. The goal of these programs is to provide advanced training and collaborative research opportunities for highly qualified postdoctoral and visiting scientists, while enhancing the research conducted in federal laboratories and affiliated institutions.

52. The Department of Health and Human Services supports many international research, training, and scientific exchange programs, including, inter alia:

(a) NIH/NIAID supports global research and research training through multiple collaborative research initiatives that engage counterpart foreign institutions. Some research programs also facilitate global pandemic preparedness by fostering global research collaboration, which enables strengthening of infectious disease research capabilities worldwide.

(b) NIH/NIAID International Centers of Excellence in Research program fosters research of mutual benefit in disease-endemic countries through partnerships that engage

U.S. and foreign scientists who participate in scientific research and training both in the U.S. and overseas.

(c) NIAID Global Infectious Disease Research Administration Development Award for low- and middle-income countries' (LMICs) institutions provides advanced training in the management of NIH grants to assure the efficient implementation of NIAID-funded research of importance to address disease outbreaks. The overall intent of the initiative is to support the training of senior science administrators so they can serve as institutional grant management leaders. With such skills in place, particularly in LMICs, the world is better enabled to undertake international collaborations that are essential to assure emerging or re-emerging diseases are rapidly investigated in order to develop urgently needed medical countermeasures.

(d) The NIH/National Cancer Institute (NCI)'s Short Term Scientist Exchange Program facilitates scientific interactions between non-U.S. scientists and researchers at NCI.

(e) The Food and Drug Administration (FDA)'s Foreign National Training Program enables researchers from foreign countries to initiate and conduct research that complements projects at the FDA's National Center for Toxicological Research.

(f) The CDC's Epidemic Intelligence Service (EIS) is a two-year training program for health and veterinary professionals interested in applied epidemiology. Primarily a domestic program for the training of "Disease Detectives", the EIS programs also accepts a limited number of non-U.S. citizens each year.

(g) The CDC's Field Epidemiology Training Program (FETP)

53. The Department of Defense provides an opportunity for U.S. military and civilian scientists to conduct research in foreign government laboratories and for foreign military and civilian scientists to work in U.S. Department of Defense laboratories, through the Engineer and Scientist Exchange Program. The Department has signed with 16 countries formal international agreements with reciprocal working arrangements for scientists in governmental and defense organizations.

54. The Foreign Agricultural Service (FAS) links U.S. agriculture to the world to promote American agricultural products and exports. FAS implements USDA international fellowship programs and non-emergency assistance programs that mutually benefit the United States and partner countries to help facilitate agriculture-led economic growth and increase participation in international agricultural trade. These FAS programs link U.S. and foreign scientists, policymakers, and other stakeholders to address shared priorities, including, but not limited to, trade-related aspects of plant and animal health and food safety. For example, recent participants in the FAS Borlaug Fellowship Program and Cochran Fellowship Program have worked on combating aflatoxin, African swine fever, brucellosis, fall armyworm, Johne's disease, and additional diseases and pests of economic importance in the food and agriculture sector. FAS programs also promote U.S. international cooperation on other mutually beneficial applications of life sciences, such as biotechnology for improving crop traits.

55. Additionally, many nongovernmental organizations and foundations based in the United States promote engagement among scientists from around the world. Some of these entities explicitly sponsor the scientific development of foreign researchers; other nongovernmental organizations host scientific exchanges and fora to bring scientists together to share best practices and lessons learned and to highlight the role of science in society. One noteworthy example is the Intel International Science and Engineering Fair (ISEF), a program of the Society for Science and the Public. ISEF is the world's largest pre-college science competition, with \$4 million in awards, judged by doctoral-level scientists. The 2019 ISEF featured over 1,800 young scientists selected from 423 affiliate fairs in more than 80

countries, regions, and territories. In addition to the top winners, approximately 600 finalists received awards and prizes for their innovative research. The American Society for Microbiology (ASM) also has a robust program to engage international partners and foster collaboration and partnership; its premier event, ASM Microbe, is the largest gathering of microbiologists from across the globe and provides a forum to explore the full scope of microbiology. The 2020 ASM Microbe Online enabled participants to explore research from peers with thousands of e-posters, hear from experts in the field during live keynotes, and access track-related content with a curated selection of on-demand sessions. ASM also regularly hosts conferences focusing on specialized areas, including clinical virology, biodefense, and emerging infectious diseases.

56. In the spirit of transparency in science, many United States institutions support “open access” – the principle of making research results broadly available, free of charge. Open access databases promote collaboration, facilitate the spread of expertise throughout the globe, and reduce the costs associated with distributing scientific information and sharing results. In furtherance of the goal to make the results of federally funded research more accessible, in February 2013 the White House Office of Science and Technology Policy directed all federal departments and agencies to develop plans to make published results of federally funded research freely available to the public within one year of publication. In accordance with this directive, the Departments of Agriculture, Defense, and Health and Human Services; the Department of Energy’s Office of Science; the National Aeronautics and Space Administration; the National Institute of Standards and Technology; the National Oceanic and Atmospheric Administration; and the National Science Foundation have all released plans to enhance public access to the results of research funded by these entities.

57. In addition, many U.S. colleges and universities have adopted open access policies requiring researchers to make publications available free of charge. A growing number of major U.S. institutions are also making undergraduate and even some graduate courses freely available online. The Johns Hopkins Bloomberg School of Public Health the Massachusetts Institute of Technology, Stanford University, and Yale University are among the U.S. universities providing free and open access to a variety of courses through their own websites or through online platforms such as Coursera or edX.

58. The Training Finder Real-time Affiliate Integrated Network (TRAIN) is funded in part by the CDC and managed by the Public Health Foundation (PHF), a private, non-profit organization. TRAIN is a web-based learning network for agencies and organizations that delivers, tracks, and shares trainings for professionals who protect the public’s health. The national TRAIN network is currently made up of 26 state health departments and three federal agencies (CDC, Medical Reserve Corps, and Veteran’s Health Administration) and is available worldwide. Each has its own online portal into the national TRAIN network that allows these agencies to share courses with a growing learning system of more than one million registered learners. TRAIN offers health professionals access to courses on a wide array of public health topics in a variety of formats, including classroom training, webinars, and online self-study options. Such online and distance learning opportunities enable the exchange of information between public health professionals and organizations and promote the development of public health workforces worldwide.

59. Researchers are turning to the most powerful high-performance computing resources available to gain a better understanding of COVID-19. In early March, NSF made all its computing resources accessible to the scientific community. NSF co-led the establishment of the COVID-19 High Performance Computing (HPC) Consortium, a new public-private consortium that will offer free computing time to researchers on their world-class machines.

IV. Efforts to avoid hampering economic or technological development or international cooperation in the life sciences for peaceful purposes

A. International trade

60. The United States is a leader in the healthcare, pharmaceutical, and medical devices markets and promotes many investment and trade initiatives to enhance international exchanges in these areas. In the most recent period for which data is available, from October 1, 2019 to July 31, 2020, the U.S. exported \$28.9 billion worth of advanced technology products in the categories of biotechnology (\$4.0 billion) and life science (\$24.9 billion).

61. The United States Government's export licensing system is designed to be fast, transparent, and effective in fulfilling BWC Article III and UNSCR 1540 obligations to guard against the risks of proliferation and terrorism, while minimizing the impact on international cooperation. In coordination with several other departments and agencies, the Department of Commerce's Bureau of Industry and Security (BIS) administers and enforces controls on the export of commercial items that can also be used in conventional arms, weapons of mass destruction, terrorist activities, or human rights abuses. However, a very low percentage of overall trade is subject to this licensing system and a much lower portion of that is actually barred. Of the \$28.9 billion in combined U.S. exports in the biotechnology and life sciences, only about 0.01% (\$2.9 million) was subject to the U.S. Department of Commerce's license requirements.

B. Overcoming impediments to ongoing exchanges and international cooperation

62. The United States believes that partnerships for capacity-building and other forms of assistance to partner nations, whether by governments, international organizations, academic institutions, or private industry, benefit both parties in terms of economic and scientific development and fulfilling commitments under the BWC. However, a number of obstacles to successful implementation of Article X could be reduced by recipient countries in order to further promote the fullest possible exchange of equipment, materials, and information.

63. Effective and predictable intellectual property right (IPR) regulations provide an important incentive for investments in innovation and facilitate exports around the world. The lack of effective protection and enforcement for IPR can dissuade those holding the rights from investing in a country and collaborating with their institutes or academies. Strengthening IPR regulations by ensuring that relevant laws are enforced and include rigorous penalties can deter potential traffickers, provide patent holders tools for defending against infringement, lower costs for manufacturers, and provide incentives for those holding the IPR to enter new markets.

64. Comprehensive and uniform regulations support long-term research and development collaborations. Unfortunately, regulatory agencies in many countries lack adequate training and resources to review patent and other regulatory applications in a timely and consistent manner, creating enormous backlogs, approval uncertainty, and market access delays. Predictable and robust legal and regulatory regimes are critical to promote investment.

65. High tariffs, taxes, and other fees also present significant market access barriers. These markups often increase the end-user price of medicines significantly, sometimes by more than 80 percent. Not only do such expenses unnecessarily increase drug costs to patients, but they also often slow product delivery. Non-tariff measures, such as customs

delays or rules of origin, are less visible impediments that can also make it difficult for the pharmaceutical or biotechnology industry, or academic or government programs, to provide equipment or materials to support collaborative efforts. Such delays can be a significant deterrent to ongoing commitments to provide assistance and resources.

V. Conclusion

66. International cooperation and exchange in the life sciences and biotechnology, including efforts to combat diseases like COVID-19, will continue to be a core objective for the United States of America, consistent with our obligations under Article X of the Biological Weapons Convention. The United States will continue to commit significant resources to support international cooperation to advance biological science for peaceful purposes; improve global health through the prevention, detection, and mitigation of disease; and develop relevant capacity worldwide. Furtherance of these aims has broad support across the full range of U.S. public and private institutions, including the United States Government, non-governmental organizations, industry, academic institutions, civil society, and the American people.
