

Ninth Review Conference 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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Item 11 of the provisional agenda

Consideration of issues identified in the review of the operation of the Convention as provided for in its Article XII and any possible consensus follow-up action

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

Submitted by the United States of America

I. Background

1. The United States is firmly committed to fulfilling all its obligations under the Biological and Toxin Weapons Convention (BWC), including those under Article X. 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 requested States Parties to report on their fulfillment of their Article X obligations, in order to produce a more complete picture of its implementation.
2. The United States has worked collaboratively with the international community to pursue shared goals related to Article X, including, inter alia:
 - Contributing to the advancement of life sciences for peaceful purposes;
 - Building sound, appropriate regulatory and oversight systems at all levels to ensure the safe and peaceful application of dual-use materials and technologies;
 - Effectively implementing our obligations under the BWC and United Nations Security Council Resolution (UNSCR) 1540;
 - Advancing educational and collaborative opportunities for the international scientific community; and
 - Improving global health security through preventing, detecting, and responding effectively to infectious disease, whether naturally occurring, deliberate, or accidental.

II. General perspectives on the implementation of Article X

3. The United States places great importance on the effective implementation of X of the Biological Weapons Convention (BWC) and invests billions of dollars in international cooperation and assistance programs. U.S. efforts aim to strengthen global health capacities to counter biological threats of all types – whether natural, accidental, or deliberate in origin – that could affect human, animal, or plant health.
4. Since our last report in 2020, the United States Government has committed over \$2.4 billion in international health, humanitarian, and economic 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.¹

5. As the largest funder and implementer of global health programs worldwide, the United States Government engages in a wide range of cooperation and capacity-building assistance relevant to Article X. These efforts save lives by enhancing public health education; bolstering healthcare facilities; and building laboratory, disease-surveillance, and rapid-response capabilities in over 120 countries.

6. Additionally, the United States is by far the largest and most reliable contributor to crisis response and humanitarian action through WHO, UNICEF, the World Food Program, and dozens of other international organizations. Our support enables these organizations to fight disease and ultimately, protect lives. The United States is also one of the largest funders of basic and applied research in the life sciences. U.S. funding supports such work not only in the United States but around the world.

7. Official assistance programs and bilateral engagements 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 relevant international exchanges, cooperation, and support are undertaken not only by the federal government, but also by state and local governments, individuals, industry, foundations, academia, and other non-governmental organizations. Accordingly, most U.S. programs and related efforts that strengthen global health or promote international exchange and advances in the life sciences for peaceful purposes do not take place solely, or even primarily, specifically under the auspices of the BWC.

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

9. The remainder of the report addresses the U.S. response to COVID-19 and then is organized around the three basic obligations contained in Article X:

- To facilitate the fullest possible exchange of information, equipment, and materials for peaceful purposes;
- To cooperate in the further development and application of the life sciences for prevention of disease and other peaceful purposes;
- 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.

III. Response to the Covid-19 Pandemic

10. Our experience combatting a pandemic for the last several years has amply illustrated the need to limit vulnerability to infectious diseases, including through bolstering health care infrastructure, strengthening diagnostic capabilities, and developing new vaccines, therapeutics, and diagnostics that are essential to outbreak response. Assisting States Parties in strengthening their national capacities to prevent, detect, and respond to infectious disease outbreaks is a direct contribution to the objectives and purposes of the BWC and is an important element of how the United States implements its obligations under Article X of the Convention.

11. The United States Government continues to take decisive action to build global health security capacity to respond to this and future outbreaks. We are deploying the full range of our capabilities to respond to COVID-19 and prevent future outbreaks around the globe from becoming pandemics. This effort builds upon decades of U.S. international life-saving health and humanitarian assistance. The United States and its international partners together donated COVID-19 vaccines to the world to end the pandemic. In partnership with COVID-19 Vaccines Global Access (COVAX), and through bilateral agreements, the U.S. has

¹ “Foreign Assistance for Coronavirus (COVID-19),” United States Department of State, <https://www.state.gov/foreign-assistance-for-coronavirus-covid-19/>.

provided more than 610 million doses of the COVID-19 vaccine to 115 countries and economies. Furthermore, the U.S. continues to support international efforts to expedite global access to COVID-19 vaccines and therapies. We also continue to support international efforts to expedite global access to COVID-19 medical countermeasures (MCMs). Several scientifically rigorous Phase III clinical trials have led to emergency use authorization and then licensing of COVID-19 vaccines and therapies by the United States Food and Drug Administration and other rigorous regulatory authorities, such as the European Medicines Agency. MCM development and clinical trials continue with the goal of expanding options available to prevent infections, as well as to improve treatment of patients with COVID-19.

12. The U.S. commitment to bring COVID-19 under control and to undertake preparedness measures to prevent or counter future outbreaks of pandemic concern is demonstrated through numerous initiatives aiming to strengthen global health frameworks and improve clinical research response capacity in partnership with other nations and with multilateral institutions, including the WHO. Some of these initiatives are described below:

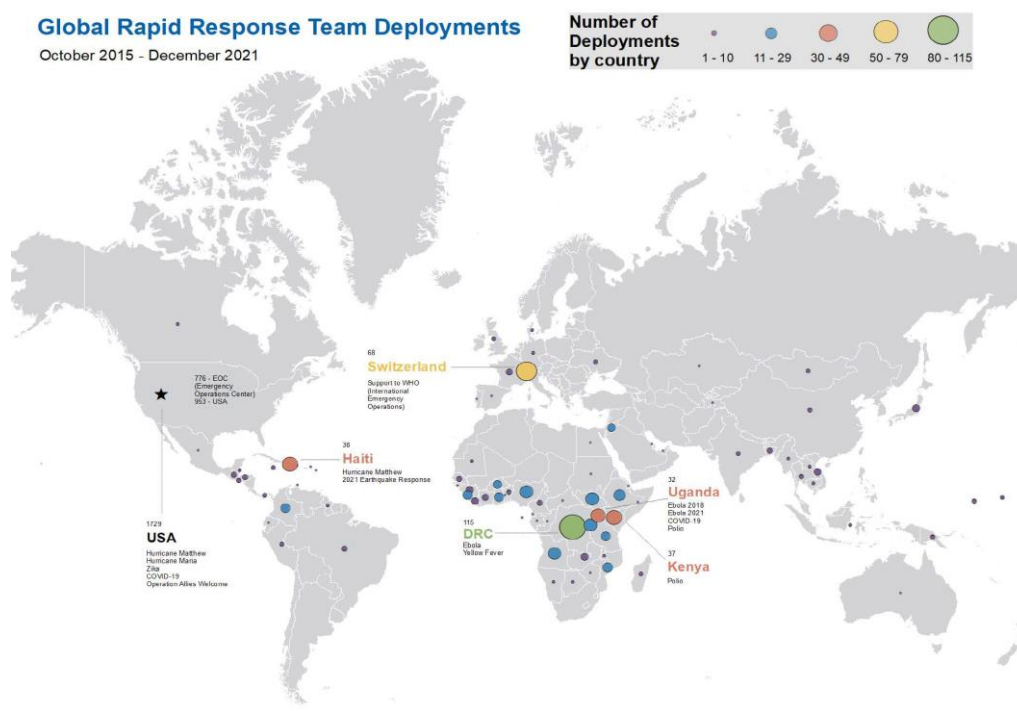
- The COVID-19 pandemic has highlighted the need for expanded manufacturing infrastructure, capability, and workforce to produce vaccines. In this context, helping other countries enhance their own capabilities to produce vaccines in turn helps the entire world combat health threats. That is why our experts in the Biomedical Advanced Research and Development Authority (BARDA) in the Administration for Strategic Preparedness and Response (ASPR, U.S. Department of Health and Human Services) are collaborating with governments around the world to develop manufacturing capability to produce vaccines in their home countries. The most recent example is the Republic of South Africa, where vaccine manufacturing companies have identified a shortage of experienced technical experts as an obstacle to in-country production; this need led the South African Medical Research Council (SAMRC) to collaborate with BARDA's Division of Pharmaceuticals Countermeasure Infrastructure (PCI) on a current Good Manufacturing Practices (cGMP) train-the-trainers program. With BARDA's participation and support, this training began in July 2022. Members of South African universities, upon completion of the course, will establish their own program in South Africa to train other professionals from their own country as well as elsewhere in Africa through the SAMRC. The ripple effects of this program will enhance the ability of entire nations to bring infectious disease threats under control more quickly, in the process reinforcing global health security.
- The U.S. Department of Defense (DOD) is also collaborating with many countries in the fight against COVID-19. For example, in Georgia scientists trained through the DOD Cooperative Threat Reduction (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 21 June 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 was under control.
- The investments of the Fogarty International Center at the U.S. National Institutes of Health (NIH) in the scientific workforce and collaborative networks enabled researchers around the world to quickly respond to COVID-19. Past and current grantees and trainees played major roles in the research response to the pandemic in their countries including China, Haiti, Peru, and South Africa, while also providing expert analysis to policymakers. Fogarty grantee Dr. Christian Happi of Nigeria was the first to sequence the full COVID-19 viral genome in Africa and continues to lead the scientific response to the pandemic in his country. Recently, Fogarty further supported this powerful research network by awarding \$3.3 million in administrative supplements to support research on unique scientific questions and research training activities related to COVID-19.

IV. Efforts to facilitate the fullest possible exchange of biological equipment, materials and information for peaceful purposes

A. Disease surveillance, detection, and response

13. The Center for Disease Control and Prevention (CDC) is the United States' lead agency for disease detection. It works in partnership with countries to develop sustainable capacities for disease surveillance and response activities, including establishing or strengthening centers called national public health institutes. 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, Emergency Response and Recovery Branch, 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 including helping countries improve the linkages and coordination within the public health workforce through national public health institutes.

14. Through CDC's Global Emergency and Alert Response Service (GEARS), up to 40 public health events are monitored per day worldwide. Since its inception in 2007, it has reported more than 1,800 events (over 1,200 of which were of international importance), including 189 different diseases in over 240 countries and territories. Over 500 CDC experts are ready to deploy globally in response to a public health emergency through GEARS.² In response to the COVID-19 pandemic, the CDC developed disease-specific guidelines to streamline Rapid Response Team 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.³



² The map is from “Global Emergency Alert and Response Service (GEARS), Centers for Disease Control and Prevention, March 3, 2022.

³ “Health Security Learning Platform in the Context of the IHR - RRT Learning Programme for COVID-19,” <https://extranet.who.int/hslp/training/course/index.php?categoryid=60>.

15. 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 21,000 public health workers epidemiologists in more than 80 countries.

16. Another example of the CDC's support to other countries is through the Public Health Emergency Management (PHEM) Fellowship managed by the Division of Emergency Operations, Global Emergency Management Capacity Development Team.⁴ Established in 2013, the 3-month program, based at CDC Headquarters in Atlanta, Georgia, aims to build and nurture a global network of trained experts to establish public health emergency management programs and public health emergency operations centers (PHEOCs) in their respective countries. 152 fellows from 40 countries have completed the program. PHEM Fellowship alumni have played key roles in the expansion of public health emergency management within their countries. Overall, they have assumed leadership positions in public health responses to threats such as polio, Ebola, measles, and COVID-19. Examples of PHEM Fellowship alumni roles include Incident Managers for national responses in Burkina Faso, Cameroon, Liberia, and Japan. Some graduates have provided support to other countries. Nigeria, for example, hosted delegates from the Zambian National Public Health Institute to share best practices on establishing a national PHEOC and PHEM program. Examples of leadership roles fellows have taken on after their training include 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.

17. 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 and the Global African Swine Fever Research Alliance 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 (WOAH) 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 to conduct biosafety training relevant to agriculture to many national and international participants at a biennial symposium.

18. 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.

19. APHIS also regulates animal vaccines and diagnostic products for diseases that affect both animals and people worldwide. APHIS' Center for Veterinary Biologics (CVB) is a World Organization for Animal Health collaborating center for animal vaccine approvals, provides annual guidance to worldwide partners via the Institute for International Cooperation in Animal Biologics and is a member of the Veterinary International Conference

⁴ "Public Health Emergency Management Fellowship," Centers for Disease Control and Prevention, <https://www.cdc.gov/cpr/eoc/EmergencyManagementFellowship.htm> .

on Harmonization to harmonize international requirements for veterinary product registration.

20. APHIS also operates the National Veterinary Services Laboratories (NVSL), which provides high quality diagnostic services in support of animal health worldwide. The NVSL serves as a WOA and FAO reference laboratory and actively collaborates with international partners to support animal disease surveillance and diagnostic testing programs. NVSL has recently partnered with eight international institutions for surveillance and timely detection of high-consequence animal and zoonotic diseases.

21. 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, Newcastle disease and African swine fever. 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, Newcastle disease, and African swine fever; and providing scientific expertise and support to international partners by serving as subject matter experts on WOA, 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.

22. The Armed Forces Health Surveillance Branch's Global Emerging Infections Surveillance Section (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. 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.

23. GEIS 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*).

B. International collaboration and exchange programs for scientific research

24. The United States views programs that promote science education, train young scientists, and provide opportunities for international researcher-to-researcher collaborations as essential to the fulfillment of our Article X obligations. Such programs are mutually beneficial for all participating countries and contribute to the furtherance of scientific progress.

25. The Department of State's Office of Science and Technology Cooperation (OSTC) implements capacity-building programs and engages with partner nations in dialogue on a range of scientific policy issues. More than 50 bilateral and multilateral science and technology agreements provide a framework for international collaboration on scientific endeavors. Among other efforts, OSTC implements the Science Envoy Program, through which eminent U.S. scientists and engineers build peer-to-peer connections with the scientific

communities in partner countries, promote science education, and identify opportunities for ongoing bilateral cooperation.

26. The Department of Health and Human Services supports extensive international research, training, and scientific exchange programs, including:

- The National Institute for Allergy and Infectious Diseases (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. The Institute published the NIAID Pandemic Preparedness Plan in December 2021, outlining its strategy to target ‘prototype’ and priority pathogens, using a preemptive approach designed to identify viral threats before they emerge. Strengthened capacity to detect, characterize, and respond to emerging pathogens with pandemic potential is a primary defense against future emerging or re-emerging infectious diseases growing from isolated outbreaks to global pandemics.
- NIAID’s 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. The Fogarty International Center at the National Institutes of Health is dedicated to advancing the Institutes’ mission by supporting and facilitating global health research conducted by U.S. and international investigators, building partnerships between health research institutions in the U.S. and abroad, and training the next generation of scientists to address global health needs. More than 7,500 individuals from 132 countries have trained through Fogarty programs since 1989.
- NIAID Global Infectious Disease Research Administration Development Award for low- and middle-income countries’ 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 low- and middle-income countries, the world is better enabled to undertake international collaborations that are essential to assure emerging or re-emerging diseases are rapidly investigated to develop urgently needed medical countermeasures. The National Cancer Institute’s Short Term Scientist Exchange Program facilitates scientific interactions between non-U.S. scientists and researchers at NCI.
- 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.

27. 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 drought tolerant rice varieties, the biophysical impact of water availability on cocoa, the identification of genes associated with wheat improvement and disease resistance, and risk management of livestock diseases. FAS programs also promote U.S. international cooperation on other mutually beneficial applications of life sciences, such as biotechnology for improving crop traits.

28. 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 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.

C. Capacity enhancement and global health security

29. The United States is a founding member of the Global Health Security Agenda (GHSA), a multilateral initiative launched in 2014 by 20 countries to accelerate compliance with the 2005 International Health Regulations (IHR). The IHRs, a legally binding instrument now adopted by 196 countries, aims to strengthen country-level capabilities needed to prevent, detect, and respond to health emergencies. From its inception, GHSA has been a catalyst for progress to protect the world from global health threats posed by infectious diseases, whether caused naturally, deliberately, or accidentally. This collaborative multisectoral initiative now includes 70 countries, international organizations, non-governmental organizations, and the private sector with the objective of strengthening global health security.

30. Agencies across the United States Government work with ministries of health, agriculture, environment, and other key stakeholders in partner countries to expand capabilities to detect viral pathogens with pandemic potential, improve laboratory surveillance, strengthen disease response, and educate on biosafety and biosecurity.

31. As part of the U.S. commitment to global health security, the U.S. government also partners bilaterally with countries to enhance capacities in health security. These partner countries receive U.S. government program funding and technical assistance and engage with the U.S. government health teams to implement global health security activities. As a key principle, these partnerships work to ensure that all capacities will be sustained by the partner country.

32. U.S. departments and agencies partnered with more than 40 countries in 2021 to provide coordinated operational and technical assistance to build their health security capacities. The list of partner countries receiving intensive support from the U.S. government in 2021 includes Bangladesh, Burkina Faso, Cameroon, Côte d'Ivoire, Democratic Republic of Congo, Ethiopia, Guinea, India, Indonesia, Kenya, Liberia, Mali, Nigeria, Pakistan, Senegal, Sierra Leone, Tanzania, Uganda, and Vietnam.

33. The United States Agency for International Development (USAID) implements the Global Health Security (GHS) Program in partner countries to prevent avoidable outbreaks, detect infectious disease threats early, and respond rapidly and effectively when outbreaks occur. Other USAID global health programs support synergistic health systems strengthening, including building surveillance and laboratory capacities that also increase capacities for global health security. Furthermore, USAID leads U.S. responses to large-scale international outbreaks.

34. USAID's GHS Program collaborates with partner countries and the global community to build better preparedness for future health threats. The Program focuses on building capacities across sectors and multiple technical areas critical to address emerging infectious disease threats, to understand and address risks posed by diseases spilling over from animals to humans and causing epidemics; strengthening national laboratories and disease surveillance systems; improving risk communications in communities; training the next generation of "One Health" workers; addressing the rising threat of antimicrobial resistance; identifying and understanding risks from new and emerging diseases; and supporting vaccine development for high consequence diseases.

35. USAID works collaboratively with other United States Government agencies in 30 countries, which are highly vulnerable to infectious disease threats and/or represent hotspots where the risks of spillover, amplification, and risk of animal-to-human transmission (zoonosis) is greatest. All USAID GHS activities implement the "One Health" approach that brings together the animal, human, and environmental health sectors to address the burden of disease. These investments reinforce public and animal 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.

36. Since 2020, USAID has greatly increased its investments in global health security and its GHS Program has launched new projects, including:

- STOP Spillover, which is strengthening capacities to increase our understanding of spillover of known high consequence viruses such as Ebola virus, to develop and implement interventions in communities to reduce contact with animals and risk of infection.
- TRANSFORM, which is working with farmers and the private sector to improve animal health to reduce emerging infectious diseases and antimicrobial resistance in livestock on farms and in markets in Asia and Africa.
- DEEP VZN, which is strengthening country capacities to detect new viruses in wildlife and understand where, when, and how they spillover from animals to humans.

37. These efforts, combined with others, are supporting countries to be better prepared to detect and prevent future epidemics and pandemics.

38. The Assistant Secretary Administration for Strategic Preparedness and Response (ASPR) at 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.

39. 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.

40. The Federal Select Agent Program (FSAP) is jointly implemented by the Centers for Disease Control and Prevention's Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service's Division of Agricultural Select Agents and Toxins. FSAP promotes laboratory biosafety and security practices at the international level. FSAP assists federal partners in assessing biosafety/security of international select agent research sponsored by the U.S. government as a condition of funding. Since 2005, FSAP has conducted 76 international assessments to determine equivalencies to U.S. select agent regulations and standards for foreign laboratory operations. FSAP also provides tailored technical assistance to help advance global biosafety and biosecurity to international audiences. FSAP staff have recently been engaged with the Egyptian Civil Sector to discuss and update their existing biosafety and biosecurity directives, regulations, and organizational structure. FSAP is hoping to continue to augment its existing international outreach efforts so that it can help enhance biosafety and biosecurity in the global arena. That means preventing disease spread, promoting safe laboratories, and applying scientific expertise to peaceful purposes.

D. Other improvements in global health

41. 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, the World Health Organization, the International AIDS Vaccine Initiative, and Gavi, the Vaccine Alliance. Through the U.S. President's Emergency Plan for AIDS Relief, the U.S. government has invested nearly \$100 billion in the global HIV/AIDS response, the largest commitment by any nation to address a

single disease in history, saving 21 million lives, preventing millions of HIV infections, and accelerating progress toward controlling the global HIV/AIDS pandemic in more than 50 countries. The United States Government is a leading supporter of Gavi, contributing over \$7 billion since 2001, 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.

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

42. The United States has long been a global leader in life sciences research, leading the 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 perform the largest share of basic research. American colleges and universities also engage in joint research 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.

43. The National Institutes of Health (NIH) spearheaded the rapid research response to the COVID-19 pandemic, pioneering safe, effective vaccines and therapeutics in partnership with industry, BARDA, and other agencies. NIH carries out cutting-edge scientific investigations and funds a large proportion of medical research carried out in academic and medical institutions. Within the NIH, the Centers of Excellence for Influenza Research and Response program is a collaborative network of centers that provides the information and research response tools needed to control the impact of epidemic influenza and the threat of pandemic influenza and other respiratory viruses, including SARS-CoV-2. The expeditious development and deployment of vaccines, therapeutics, and diagnostics, in response to the COVID-19 pandemic, with successful vaccines reaching populations less than a year after the severe acute respiratory system coronavirus 2 (SARS-CoV-2) was identified, was based on many years of research in several fields, much of it supported or carried out by NIAID and other centers and institutes of the NIH, working with many partners. NIAID is leading on efforts to develop a "prototype pathogen" approach to develop MCMs against the estimated 26 virus families including species known to infect humans, with the goal of further reducing the time required to deploy safe and efficacious MCMs against pathogens with pandemic potential.

44. Also essential to pandemic preparedness is improved medical research capacity everywhere viruses could arise. The United States Government is engaged in both bilateral and multilateral partnerships to build or bolster research capacity where it is most needed. For example, the NIH / Centers for Research in Emerging Infectious Diseases (CREID) program aims to improve pandemic preparedness through the establishment of a coordinated network of emerging and re-emerging viral infectious disease researchers in regions around the globe where emerging and re-emerging viral infectious disease outbreaks are likely to occur. Multidisciplinary teams of investigators conduct pathogen/host/vector surveillance, study pathogen transmission dynamics, pathogenesis, and host immunologic responses, and develop reagents and diagnostic tools for improved detection for important emerging pathogens. The CREID Network aims to develop a framework and infrastructure that will enhance domestic and international research capacities to respond quickly and effectively to future outbreaks.

45. NIAID was able to call on the existing HIV/AIDS Clinical Trials Networks (HCTN) to facilitate clinical research in the emergency response to COVID-19 and is supporting additional efforts to coordinate clinical research and ensure that new outbreaks are met with well-planned, sufficiently powered research rather than the plethora of small, inconclusive efforts that bedeviled early response to SARS-CoV-2.

46. The National Science Foundation (NSF), an independent federal agency with a 2021 budget of \$8.8 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.

47. The National Academies of Sciences, Engineering, and Medicine's International Networks and Cooperation Theme is a key resource and mechanism for U.S. government agencies, public interest foundations, science, engineering, and medical organizations, and the Academies themselves for new international engagements, participation in international organizations, and sustained engagement with international counterparts on important topics.⁵

48. DOD provides an opportunity for U.S. military and civilian scientists to conduct research in foreign government laboratories and for foreign military and civilian counterparts 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. Additionally, many non-governmental 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 non-governmental 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 \$8 million in awards, judged by doctoral-level scientists.⁶ Each year more than 1,800 ninth through twelfth graders earn the right to compete at Regeneron ISEF and can win cash awards, scholarships, internships, and other prizes by participating at a Society-affiliated local, regional, state, or national science fair. 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 2022 event gathered over 4,500 attendees. The 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.

49. In the spirit of transparency in science, the United States supports "open access" – the principle of making government-funded research results broadly available and 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 and without delay. In August 2022, the White House's Office of Science and Technology Policy directed all federal departments and agencies to update their public access policies as soon as possible, and no later than December 31st, 2025, to make publications and their supporting data resulting from federally funded research publicly accessible and waiving the optional 12-month embargo that had been allowed by the original 2013 "open access" memorandum. The 2013 memorandum directed all federal departments and agencies with more than \$100 million in annual research and development expenditures to develop a plan to support increased public access to the results of federally funded research but allowed a 12-month embargo from public access. The optional embargo period limited access of federally funded research results to only those able to pay for it or who have privileged access through

⁵ "International Networks and Cooperation," National Academies of Sciences, Engineering, and Medicine, <https://www.nationalacademies.org/networks/international-networks-and-cooperation>.

⁶ "Regeneron ISEF Awards," Society for Science, <https://www.societyforscience.org/isef/awards/>.

libraries or other institutions. The new guidance acknowledges that financial means and privileged access must never be the pre-requisites to realizing the benefits of federally funded research that the scientific community deserves.

50. 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.

51. 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.

52. Researchers are turning to the most powerful high-performance computing resources available to gain a better understanding of COVID-19. In early March 2020, 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 is bringing together the U.S. government, industry, and academic leaders to provide access to the world's most powerful high-performance computing resources in support of COVID-19 research.⁷

VI. Efforts to avoid hampering the economic and technological development of states parties or international co-operation in the field of peaceful bacteriological (biological) activities

A. Facilitating National Implementation of the Convention

53. 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.

54. In 2020, the U.S. State Department launched a project to create an electronic platform containing information on States Parties' implementation of the BWC. As a result, the Department of State awarded a grant to the United Nations Institute for Disarmament Research (UNIDIR) to develop this tool. We hope the platform will provide States Parties a rich depository of best implementation practices and assist them in their own efforts. In addition to the database, this funding supports projects to assist countries with BWC implementation challenges. The first of those pilot projects will take place in Kenya.

⁷ "The COVID-19 High Performance Computing (HPC) Consortium," <https://covid19-hpc-consortium.org/>.

B. Export Controls and Related Measures

55. 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 barred.

56. In the most recent period for which data is available, from October 1, 2021, to August 31, 2022, the U.S. exported \$49.6 billion worth of advanced technology products in the categories of biotechnology (\$16.5 billion) and life science (\$33.0 billion). Of the \$49.6 billion in combined U.S. exports in the biotechnology and life sciences, only about 0.1% (\$60.8 million) was subject to the U.S. Department of Commerce's license requirements.

57. 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 to further promote the fullest possible exchange of equipment, materials, and information.

58. 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.

59. Comprehensive and uniform regulations support long-term research and development collaborations. Predictable and robust legal and regulatory regimes are critical to promote investment. 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.

60. The U.S. Department of State's Export Control and Related Border Security (EXBS) Program works with partner countries to fulfill the Article III obligations, which calls States Parties not to transfer biological weapons. EXBS collaborates 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.

61. 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 non-governmental 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.

62. 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 manage points of entry effectively and safely 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.

B. Threat reduction

63. 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) has, for over a decade, collectively invested significant resources to build and strengthen capabilities in partner countries to prevent, detect, and respond to biological threats. This includes activities to strengthen biosafety and biosecurity practices and infrastructure, improve biosurveillance and disease detection capabilities, develop national and regional frameworks to identify and respond to biological incidents, and support biological nonproliferation efforts at the national and subnational level. These efforts result in a decreased likelihood that actors with ill intentions may acquire knowledge or material that could be used for malicious purposes, a decreased likelihood of accidental release of pathogens, and an increased 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.

64. Under the U.S. Presidency in 2020, the BSWG 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 GP member countries. Over the past two years, the U.S. has continued to support the Global Partnership's Biosecurity Signature Initiative to Mitigate Deliberate Biological Threats in Africa undertaken in collaboration with the Africa Centres for Disease Control and Prevention (Africa CDC). This includes involvement in working groups aimed at information sharing and project development focused on biosafety and biosecurity, national governance frameworks, disease detection and epidemic intelligence, and biological nonproliferation and supporting activities in these areas to strengthen the capacity of African partners to detect, prevent, and respond to biological threats. For example, the United States is supporting efforts to promote universalization and strengthen national implementation of the BWC and assisted in the establishment of the first Regional Center of Excellence for Biosafety and Biosecurity training for Africa CDC.

65. The U.S. Department of State's Bureau of International Security and Nonproliferation (ISN) has various programs that support biological threat reduction and biological nonproliferation efforts around the world. These programs operate closely together to strengthen global and multisectoral biosafety and biosecurity and proactively mitigate biological threat gaps and requirements. One example of collaboration is an effort in Southeast Asia to reduce the risks of pathogen spillover from animals to humans by developing implementable biosafety and biosecurity guidelines for high-risk points within the live animal supply chain in the region.

66. ISN's Biosecurity Engagement Program (BEP) works in partnership with nearly 40 countries around the world to promote and strengthen 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. For example, BEP collaborated with partners in Africa, the Middle East, and Southeast Asia to develop, implement, and operationalize sample management and inventory tools that ensure biological materials are safely and securely stored. In Southeast Asia, BEP supported efforts to develop policies and regulatory frameworks to strengthen biorisk management, implement biosafety and biosecurity best practices, and promote networking of regional and national laboratories across public health, animal health, and academic sectors. BEP also is working with countries in Africa and the Middle East to strengthen national and regional laboratory systems through the development of data, information, and sample sharing frameworks that can be used to better coordinate and communicate across sectors and between countries in the event of an outbreak. In the Middle East, BEP and its partners helped further develop emergency management systems and emergency management coordination to improve responses to biological incidents.

67. During the COVID-19 pandemic, BEP focused some of its biological security assistance efforts to aid in partner countries' response to COVID-19. Programs included increasing safe and secure COVID-19 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 communicate the risks of COVID-19 accurately and effectively. This work not only supported the COVID-19 response but built capabilities that can be used more broadly to address other biological threats. Similarly, many of BEP's past efforts with partner countries before the pandemic helped build capacity and capabilities that were utilized in response to the COVID-19 pandemic.

68. ISN'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 partner law enforcement and first responder communities 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 conducted workshops in Sub-Saharan Africa, North Africa, Southeast Asia, and the Middle East that have focused on strengthening biodefense policies and regulations, navigating contaminated crime scenes, and identifying and disrupting clandestine laboratories. Through the ASEAN Regional Forum (ARF), WMDT strengthened partners' coordination of international assistance and critical preparation and response procedures during a biological incident. WMDT's effort through the ARF also highlighted the nexus between law enforcement and biosecurity operations to develop or enhance capabilities to proactively identify, assess, and manage behaviors of concern which could put dangerous pathogens and other valuable biological materials at risk. WMDT in collaboration with ISN/BPS also collaborated multilaterally with the UN and international partners to promote and strengthen the operationalizing of the United Nations Secretary-General's Mechanism to investigate the alleged use of a biological weapon. 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.

69. The U.S. Department of Defense (DOD) Defense Threat Reduction Agency's Biological Threat Reduction Program (BTRP), a component of DOD's broader Cooperative Threat Reduction (CTR) Program, supports 31 partner nations as they seek to improve their capabilities to counter biological threats. The program focuses on the enhancement of partner country and regional biosafety, biosecurity, and biosurveillance capabilities by working cooperatively with foreign partners across Africa, Europe, the Middle East, and Asia. BTRP and these partners work together to identify, consolidate, and secure collections of pathogens as a means of preventing their sale, theft, diversion, or accidental release; enhance biosafety and biosecurity at vulnerable sites; and strengthen the capacity for public health and veterinary health systems to detect, diagnose, and report disease outbreaks rapidly and accurately, in accordance with international reporting requirements and in support of international nonproliferation agreements.

70. BTRP assistance and cooperation activities, like all other U.S.-supported programs, help to fulfill the U.S. commitment to BWC Article X through the peaceful exchange of scientific information, equipment, and materials. The focus of this program is to ensure that partner countries have properly trained staff and the ability to maintain and sustain their facilities. Once BTRP's assistance projects are completed, the partner countries own and operate their own facilities. Foreign partners are responsible for operating and sustaining the training and equipment provided by BTRP, including laboratory infrastructure.

71. 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. It 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.

72. Through the DOD CTR Program's long history of supporting partner countries' biosurveillance capabilities, BTRP has cooperated with key nations, international organizations, and other global health security donors for years to build sustainable biosurveillance capabilities with appropriate biosafety and biosecurity practices at national, regional, and global levels. These capabilities have helped bolster partner nations' abilities to quickly detect and diagnose 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. For example, BTRP supported the construction and modernization of a modular diagnostic laboratory (MDL) in the Republic of Guinea. The government of Guinea designated this MDL as the sole laboratory to handle and test all COVID-19 samples across the country. BTRP funded the certification and repair of biosafety cabinets at the MDL to promote enhanced biosafety and biosecurity standard operating procedures required to perform COVID-19 diagnostic activities.
- 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, was the epicenter for the country's efforts to combat COVID-19 and a key focal point for information sharing and diagnostic testing coordination for the West Africa region and the African Union Center for Disease Control and Prevention.
- Training and building knowledge. Previous trainings provided by BTRP or supported by BTRP in partnership with other agencies or organizations have prepared public health experts to lead national COVID-19 outbreak investigation and diagnostics. For example, partners at Chulalongkorn University in Thailand used BTRP-provided diagnostic equipment and training to determine the first COVID-19 case outside of China, resulting in early detection and reporting that the disease was spreading outside of China. BTRP continues to provide training to promote biosurveillance capacity building to increase partners' ability to successfully detect COVID-19 and other pathogens.

VII. Conclusion

73. International cooperation and exchange in the life sciences and biotechnology, including efforts to combat diseases like COVID-19, will continue to be a core mission for the United States, 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 prevent the proliferation of biological weapons. Furtherance of these aims has broad support across the full range of U.S. public and private institutions, including governments at all levels, non-governmental organizations, industry, academic institutions, civil society, and the American people.
