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

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

Submitted by the United States of America

Summary

The United States continues to be a global leader in providing assistance and cooperation, as called for by Article X of the BWC. This includes more than $10 billion in assistance for global health in 2017 alone, including through foreign assistance arrangements with more than 60 low- and middle-income countries; collaboration with, and training and education of, many thousands of foreign life scientists, health professionals, and students every year; and substantial cooperation with a large number of countries on global health security, biological threat reduction, and export controls, and nearly $50 billion in exports of items in the areas of life science and biotechnology over the past year.

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I. Introduction

1. The United States is firmly committed to fulfilling all of 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 Eighth Review Conference confirmed the importance of implementation of Article X and encouraged "States Parties to provide at least biannually appropriate information on how they implement this Article." Such reporting is an important element of any effort to ensure that the undertakings of Article X are being met, both because they can facilitate understanding of successful approaches and identification of challenges, and because the vast majority of States Parties' efforts to achieve these undertakings take place outside the formal confines of the BWC.

2. Article X embodies an international commitment to partnership, sharing of information, and the development and application of the life sciences for beneficial purposes. The United States and the international community have worked together collectively to pursue mutual goals related to Article X, including, *inter alia*:

(a) Contributing to the advancement of life sciences for peaceful purposes;

(b) Building sound, appropriate regulatory and oversight systems at all levels to ensure the safe and peaceful application of dual-use materials and technologies;

(c) Effectively implementing our obligations under the BWC and United Nations Security Council Resolution (UNSCR) 1540;

(d) Advancing educational and collaborative opportunities for the international scientific community; and

(e) Improving global health security through preventing, detecting, and responding effectively to infectious disease, whether naturally occurring, deliberate, or accidental.

3. The United States Government is the largest funder and implementer of global health programs worldwide. U.S. funding for global health grew to more than $10 billion in 2017, and we provide direct support in the area of global health to more than 60 low- and middle-income countries through bilateral foreign assistance arrangements, The United States also engages in a wide range of other cooperation and capacity-building assistance relevant to Article X, with a very wide range of partners. It is important to recognize, however, that formal "assistance" programs and direct government-to-government engagement comprise only a part of a much larger undertaking. In the United States, activities and programs to promote exchange, cooperation, and assistance that contribute to our implementation of Article X are undertaken not only by the United States Government, but also by individuals, industry, foundations, academia, and other non-governmental organizations. This is consistent with the provisions of Article X, which calls on States Parties to "facilitate" exchange in the life sciences for peaceful purposes. Many projects are multi-sectoral and involve collaboration between the United States Government and other organizations.

4. The large number of U.S. programs and other efforts underway that contribute to the implementation of Article X do not take place solely, or even primarily, in the BWC forum. The programs and activities conducted by the United States, which are many and varied, are also undertaken for their own intrinsic value, whether to advance our understanding of the life sciences, promote developmental and humanitarian objectives, improve global health, or all of the above. Providing programs and initiatives through a broad range of institutions, stakeholders, and fora allows for the advancement of all of these objectives.

5. The breadth and scope of U.S. contributions and assistance precludes a comprehensive listing of every program in its entirety, but this report provides a selection of examples designed to illustrate the range and diversity of activities and demonstrate the full commitment of the United States to the letter and spirit of Article X.

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

(a) to facilitate the fullest possible exchange of information, equipment, and materials for peaceful purposes;

(b) to contribute to the advancement and application of the life sciences; and

(c) to implement the BWC in ways that avoid hampering the economic and technological development of States Parties.

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

7. When the BWC was negotiated, many scientists believed that antibiotics, vaccines, and other medical developments had led to the imminent demise of infectious disease; today, however, the numbers of outbreaks and of emerging and reemerging infectious diseases, many of which easily cross international borders, are on the rise. Strengthening global capabilities to prevent, detect, and treat naturally occurring infectious diseases is therefore a vitally important application of the life sciences.

8. Moreover, measures to limit vulnerability to infectious diseases, such as bolstering health care infrastructure, strengthening diagnostic capabilities, and developing new medical therapies, are beneficial not only in the event of a naturally occurring outbreak, but also in the case of a deliberate attack with a biological weapon. Improved disease surveillance can help public health officials to identify outbreaks that are caused deliberately, because unusual events can be more easily recognized if there is sufficient background data on the usual pattern of naturally occurring diseases. Thus, helping other States Parties strengthen their national capacities to prevent, detect, and respond to infectious disease outbreaks is a direct contribution to the object and purpose of the BWC, including Article X obligations.

9. The United States has provided a wide range of assistance to international partners, through bilateral, regional, and multilateral channels in both the public and private sectors, including, *inter alia*, improvements to global detection of disease; enhancements in capacities to investigate, diagnose, prevent, and respond to disease outbreaks; other improvements in global health; and cooperation on threat reduction and export controls.

Disease surveillance, detection, and response

10. In partnership with more than 60 other countries, international organizations, and public and private stakeholders, the United States is implementing *the Global Health Security Agenda (GHSA)*, with the intent to prevent and reduce the likelihood of disease outbreaks, detect infectious disease threats early to save lives, and rapidly respond to outbreaks with coordinated multi-sectoral engagement. The GHSA aims to ensure that participants are fully prepared to detect and respond to disease threats, as well as spur

progress on compliance with the IHR and other global health security frameworks, such as OIE standards and guidelines for veterinary services and animal health systems.

11. In July 2015, the United States Government announced its intent to invest more than $1 billion in resources to expand the GHSA and support partner countries in achieving its targets. Meeting these targets will expand our ability to prevent or mitigate the impact of naturally occurring outbreaks and intentional or accidental releases of dangerous pathogens; detect and report outbreaks when they occur; and respond and control outbreaks before they become epidemics. The United States has partnered with 32 international partners to undergo independent external assessments and establish a five-year roadmap to achieve and sustain the targets of the GHSA in each country. To do so, the United States Government, through the U.S. Agency for International Development (USAID), the Centers for Disease Control and Prevention (CDC), and other agencies of the Department of Health and Human Services, the Department of Defense, and the Department of Agriculture, is working with ministries of health, agriculture, environment and other key stakeholders in other countries to detect viruses with pandemic potential, improve laboratory capacity to support surveillance, strengthen national and local capacities to respond, and provide education on biosafety and biosecurity.

12. The CDC, as the nation's primary agency and worldwide leader for disease detection, has worked in partnership with countries to develop sustainable capacities to support disease surveillance and response activities. Through bilateral assistance and programs like the *Global Disease Detection (GDD) program*, CDC partners with host countries to identify new health threats and reduce the burden of infectious disease. GDD has established 10 regional centers to work directly with more than 59 ministries of health during outbreak responses to provide technical support and scientific collaboration. By enhancing laboratory systems, increasing preparedness and communication activities, and conducting public health research, among other activities, GDD works with partner countries to build and strengthen public health capacity. From 2006-2017, GDD Centers responded to over 2,250 disease outbreaks and other public health emergencies, with nearly two-thirds of responses initiated within 24 hours of receiving a request for assistance. GDD Centers have assisted in the detection and identification of 11 strains and pathogens never before discovered and 64 strains and pathogens new to a region. Another example of the CDC's support to other countries is its assistance to the Africa Centers for Disease Control and Prevention (Africa CDC), officially opened by the African Union in January 2017. Recognizing the value to global health security of an African-owned institution to prevent, detect, and respond to public health threats affecting African nations, the AU and the United States are working together to develop this new organization.

13. USAID's *Emerging Pandemic Threats (EPT)* and *Global Health Security* programs seeks to aggressively preempt or combat emerging diseases that could spark future pandemics. The EPT and Global Health Security programs are composed of seven complementary projects (ONE HEALTH WORKFORCE, PREDICT, PREPAREDNESS & RESPONSE, Infectious Disease Detection and Surveillance (IDDS), and USAID's work with the Food and Agriculture Organization (FAO), World Health Organization (WHO), and International Federation of Red Cross and Red Crescent Societies (IFRC)). These programs operate in 32 countries (including 16 USG Phase I Global Health Security Agenda (GHSA) countries) in Africa, Asia, and the Middle East, in coordination with CDC and the Department of Defense (DoD). They focus on identifying zoonotic viruses at interfaces involving humans and livestock, domestic animals, or wildlife; characterizing and mitigating risk for disease transmission between animals and people; strengthening laboratory capacity to diagnose and report human and animal pathogens; providing workforce training to include strengthening outbreak response capacity; conducting community preparedness and engagement; and enhancing mechanisms and policies related to One Health and prevention, detection, and response for infectious disease in animals and

people. EPT and the Global Health Security programs work with governments, universities, and other key in-country, regional, and global partners to strengthen country-level capacities for routine infectious disease detection and outbreak response. EPT and the Global Health Security programs support the One Health concept by integrating multisectoral and multidisciplinary approaches in strategic planning and implementation.

14. The 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 disease and zoonotic agents that pose a threat to human health. ARS also actively collaborates with international partners worldwide on research projects dedicated to support 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 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.

15. The Armed Forces Health Surveillance Branch's *Global Emerging Infections Surveillance Section (AFHSB-GEIS)* enhances health protection of the armed forces through an integrated worldwide military laboratory network that conducts emerging infectious disease surveillance. GEIS provides direction, funding, and oversight to this laboratory network that 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. The GEIS program communicates information from its surveillance activities to support health protection decisions for forces assigned in the DoD Geographic Combatant Commands' regions of interest. Additionally, GEIS information is used to increase public awareness and understanding of global health security issues and inform public health decisions among the United States Government and international agencies. 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.

16. 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 main 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 gonorrhea*).

Capacity enhancement and global health security

17. In addition to the efforts above, the United States further supports the WHO's International Health Regulations (2005) (IHR), which, *inter alia*:

- Provide a framework for WHO alert and response activities that are implemented in collaboration with countries to control international outbreaks and other public health risks and emergencies;
- Allow the WHO to provide support for the implementation of national capacities for epidemic preparedness and response, including laboratory capacities and early warning alert and response systems; and

- Standardize approaches for readiness and response during a public health emergency of international concern, allowing the International Health Regulations Emergency Committee to issue travel and trade recommendations based on the best evidence available.
- The United States coordinates and works with multiple domestic and international partners to strengthen core public health capacities and capabilities globally in line with the IHR.

18. 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.

19. ASPR 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; the WHO serves 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, focused on risk management, communications, chemical events, radio-nuclear threats, pandemic influenza, and global laboratory cooperation.

Other improvements in global health

20. In addition to the programs and activities described above, the United States is a major contributor to the Global Fund to Fight AIDS, Tuberculosis, and Malaria, a multilateral organization aimed at fighting the three diseases worldwide. We also contribute significantly to several other multilateral health organizations, including UNAIDS, WHO, the International AIDS Vaccine Initiative (IAVI), and the GAVI Alliance, among others.

National implementation of the BWC

21. The undertaking to facilitate exchange for peaceful purposes carries with it the responsibility to take appropriate steps to prevent misuse. Effective national implementation measures by States Parties are therefore a key means of achieving the aims of Article XI. Through range of assistance and cooperation activities, the United States works with other BWC States Parties to implement the Convention. In 2016, we worked with Canada, Chile, Ghana, and Mexico to review our respective means of national implementation and share best practices. Since then, we have worked not only with Ghana, but also with Morocco, to provide assistance on specific measures to enhance implementation.

22. A key area of BWC implementation is Article III, which obligates Parties not to transfer biological agents, toxins, weapons, related equipment, or delivery systems for non-peaceful purposes. The Department of State's Export Control and Related Border Security (EXBS) Program seeks to prevent the proliferation of weapons of mass destruction (WMD)

and destabilizing accumulations and irresponsible transfers of conventional weapons by helping to build 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, from executive exchanges to training workshops to the provision of detection equipment and specialized training for border control and enforcement agencies.

23. EXBS 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 their trade and border control systems, the program helps partner countries adhere to the guidelines of multilateral export control regimes and meet their obligations and commitments to important international initiatives, including Article III, UNSCR 1540, and the Proliferation Security Initiative.

Threat reduction

24. A related area is assistance and cooperation on efforts directly to reduce the threat that biological agents and toxins will be used for harm. The U.S. Department of State's *Biosecurity Engagement Program (BEP)* works in partnership with countries in the Middle East and North Africa, South Asia, Southeast Asia, sub-Saharan Africa, and Eastern Europe to promote safe, secure, and sustainable bioscience throughout the world. Specific activities planned for the coming year include conducting surveillance and laboratory diagnostic testing for emerging diseases in Southeast Asia; enhancing physical security of West African laboratories that house large numbers of Ebola samples; promoting One Health collaborations in East Africa; and supporting a biorisk management and genomics training center in the Middle East that serves as a regional training hub for biosecurity, biosafety, and molecular diagnostics.

25. The Department of State also leads U.S. interagency participation in the *G7 Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP)*, an initiative aimed at preventing terrorists from acquiring or developing weapons of mass destruction. The GP's Biosecurity Sub-Working Group has adopted five key "deliverables" to guide Partner's efforts to strengthen biosecurity and reduce threats, and serves as an important vehicle to coordinate efforts and build partnerships. The GP has regularly reported to the BWC on its collective efforts in furtherance of Article X and biosecurity.

26. The Department of Defense *Cooperative Biological Engagement Program* (CBEP) implements projects with the objectives of reducing threats posed by pathogens of security concern and related materials and expertise, as well as other emerging infectious disease risks. CBEP works to enhance partner-country and regional capabilities to: 1) identify, consolidate, and secure collections of pathogens and diseases of security concern in order to prevent the sale, theft, diversion, or accidental release of such pathogens; and 2) rapidly and accurately survey, detect, diagnose, and report outbreaks of security concern in accordance with international reporting requirements and in support of international nonproliferation agreements. CBEP also works to establish and enhance international research partnerships between U.S. and partner country scientists. CBEP programs are supported in partnership with countries throughout Africa, South and Southeast Asia, East and Central Europe, and the Middle East.

27. CBEP 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; enhancing emergency response skills; and fostering multi-sectoral cooperation between health and security forces to enhance response capacity to a deliberate biological attack. CBEP has also helped partner countries to implement specific projects. For example, the program provided diagnostic laboratory support in several West 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.

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

28. The United States is a world leader in life sciences research and development (R&D), accounting for more than a quarter of global investment. The United States Government provides support that enables scientists to participate in and foster the exchange of ideas that advance knowledge sharing in the life sciences. American universities, biotech companies, and individual biologists also drive both basic science and its application. The federal government no longer funds a majority of the basic research carried out in the United States. Data from the National Science Foundation (NSF) show that federal agencies provided 44% of the $86 billion spent on basic research in 2015 and reveal a slow but steady rise in spending on basic research by universities and private foundations, which reached a combined $22 billion in investment in 2015. The NSF data also indicated that U.S. pharmaceutical industry investment in basic research soared from $3 billion in 2008 to $8.1 billion in 2014.

International collaboration and exchange programs for scientific research

29. Programs that promote science education, train young scientists, and facilitate international researcher-to-researcher collaborations are further contributions to the fulfillment of U.S. Article X obligations. Such programs are beneficial for all participating countries and contribute to international scientific progress.

30. The 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.

31. 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.

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

(a) The National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases' *International Centers of Excellence in Research* program and multiple collaborative research initiatives with counterpart foreign institutions, which undertake research of mutual benefit in disease-endemic countries through partnerships that engage U.S. and foreign scientists who participate in scientific studies and training both in the U.S. and overseas;

(b) The *NIH Visiting Program*, which provides opportunities for foreign scientists to train and conduct collaborative research at the NIH;

(c) The *NIH/Fogarty International Center*, which supports promising research initiatives in the developing world through grants and fellowships and develops new partnerships between U.S. scientists and their counterparts abroad;

(d) The NIH/National Cancer Institute (NCI)'s *Short Term Scientist Exchange Program*, which facilitates scientific interactions between non-U.S. scientists and researchers at NCI, and the International Participants for the Cancer Prevention Fellowship Program's Summer Curriculum in "Principles and Practice in Cancer Prevention and Control";

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

(f) The Centers for Disease Control and Prevention's (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),* modeled after the domestic EIS training, works with other countries to develop and train their own workforce of field epidemiologists who detect, respond and contain emerging health threats wherever they occur. Over 70 countries have participated in FETP programs, with more than 10,000 graduates worldwide.

33. 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.

34. The United States Department of Agriculture (USDA) Foreign Agricultural Service (FAS) offers international trade and scientific exchange programs that help partner countries strengthen their capacities for agricultural productivity, food security and participation in international trade. These FAS programs link U.S. and foreign scientists and policymakers to address mutual priorities for prevention, surveillance, detection and diagnosis of plant and animal diseases, and food safety systems. For example, recent participants in the *USDA Norman E. Borlaug International Agricultural Science and Technology Fellowship Program* and *Cochran Fellowship Program* have worked on combating aflatoxin, African swine fever, anthrax, brucellosis, foot-and-mouth disease, highly pathogenic avian influenza, Rift Valley fever, tuberculosis, and additional diseases and pests of economic importance. FAS capacity-building programs also promote

international cooperation on other beneficial applications of life sciences, such as molecular genetic techniques for developing improved crop varieties.

35. 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. According to the 2016 annual survey conducted by the Council of Graduate Schools (CGS), in which four hundred U.S. institutions that offer master's and certificate and doctoral programs participated, about 92,500 first-time international graduate enrollments took place during the Fall 2016 admission cycle, a 5% rate of growth over the previous cycle. Today, the United States remains the country of choice for the largest number of international students, hosting about 1.21 million of the 4.6 million enrolled worldwide in 2017. About fifty percent of them were studying science, technology, engineering, and math (STEM) fields.

36. 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; for example, the Howard Hughes Medical Institute distributes International Student Research Fellowships, which are intended to facilitate the research training of outstanding international predoctoral students in the biomedical and related sciences. 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 and judged by doctoral-level scientists. Each year it enables more than 1,800 high school students from more than 75 countries, regions, and territories to showcase their independent 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. ASM also regularly hosts conferences focusing on specialized areas, including clinical virology, biodefense, and emerging infectious diseases.

Open access and online training courses

37. Many United States institutions support "open access" – the principle of making research results broadly available, free of charge. Open access databases promote collaboration and facilitate the spread of expertise throughout the globe, and reduce the costs associated with distributing scientific information and sharing results. 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.

38. In addition, many U.S. colleges and universities have adopted open access policies requiring researchers to make their publications available free of charge. In some cases, these policies may apply only to graduate theses or faculty members in specific fields, or may allow researchers to opt in; some, however, apply broadly to all the research conducted at that institution. A growing number of major U.S. institutions are also making undergraduate and even some graduate courses freely available online. Yale University, the Massachusetts Institute of Technology, Stanford University, and the Johns Hopkins

Bloomberg School of Public Health 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.

39. The *TrainingFinder 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 deliver, track, and share 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 doorway 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 the public health workforce.

Oversight of dual-use research of concern

40. The dual-use nature of much research in the life sciences requires particular responsibility on the part of those using dangerous pathogens and toxins. Given the leading role played by the United States Government in funding important public health research, it has worked with other stakeholders in this realm to produce guidance to help ensure such responsibility. In 2012, the United States issued its "Policy for Oversight of Life Sciences Dual Use Research of Concern," which established a regular review of United States Government-funded or -conducted research with certain high-consequence pathogens and toxins to identify dual-use research of concern (DURC) and implement risk mitigation measures where applicable. In 2014, a complementary policy, the "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern," was issued to address institutional oversight of DURC. These policies aim to preserve the benefits of life sciences research, while minimizing the risk of misuse.

41. In 2017, the United States Department of Health and Human Services (HHS) issued the "Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens" (HHS P3CO Framework), which is responsive to and in accordance with the "Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight" previously issued by the White House Office of Science and Technology Policy. The HHS P3CO Framework, provides a multidisciplinary, department-level pre-funding review and evaluation of proposed research that is reasonably anticipated to create, transfer, or use enhanced potential pandemic pathogens (PPPs),[1] and seeks to preserve the benefits of life sciences research involving enhanced PPPs, while minimizing potential biosafety and biosecurity risks. We seek to engage other BWC Parties in a dialogue on such oversight measures, both in BWC meetings and bilaterally, as we have done with France.

[1] A PPP is a pathogen that satisfies both of the following: 1) it is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations; and it is likely highly virulent and likely to cause significant morbidity and/or mortality in humans.

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

International trade

42. The United States is the largest economy in the world and the second-largest exporter of goods and services. In 2017, U.S. businesses exported $1.5 trillion of goods. Specifically in the life sciences sector, the United States is a leader in the healthcare, pharmaceutical, and medical devices markets. In 2010, the United States launched the National Export Initiative (NEI), which sought to improve the private sector's ability to export goods and services; in May 2014, the U.S. Department of Commerce launched the second phase of the NEI program, NEI/NEXT, which aims to streamline the export/import process and negotiate new access, enforce existing agreements, and build the capacity of developing countries. Such measures, along with others to enhance the international trade system, promote investment, trade, and economic growth and to help firms work with our international partners abroad, illustrate U.S. efforts to avoid hampering economic or technological development or international cooperation in the life sciences for peaceful purposes.

43. The United States Government's export licensing system is designed to be fast, transparent, and effective in fulfilling Article III and United Nations Security Council Resolution (UNSCR) 1540 obligations to guard against the risks of proliferation and terrorism. 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 items with chiefly commercial uses that can also be used in conventional arms, weapons of mass destruction, terrorist activities, or human rights abuses.

44. In 2009, President Barack Obama directed the agencies involved in administering the U.S. export control system to conduct a broad-based review of export controls in order to enhance national security. This review led to the Export Control Reform (ECR) initiative. This three-phase plan will eventually consolidate the current system into a single control list, a single licensing agency, a single primary enforcement coordinating agency, and a single information technology system. As of 2018, Phase I is finished and Phase II is nearly complete. The ECR effort will make the process of export licensing easier, cheaper, and faster, while protecting U.S. interests in national and international security.

45. BIS administers and enforces controls on the export of items through the Export Administration Regulations (EAR). In the most recent period from October 1, 2017 to June 30, 2018, BIS approved 22,977 license applications valued at $190.8 billion. Of these, 1,170 licenses, valued at $87.0 million, were approved for the export of biological materials and handling equipment controlled by Australia Group. In contrast, BIS rejected only nine license applications for exports of such items, a mere 0.7% of the total. Moreover, many U.S. exports are under our no-license-required provisions, and of the $48.6 billion in U.S. exports of biological and life science items, only 0.6% ($314.9 million) even required a Commerce license. These facts demonstrate that, consistent with our obligations under Article X of the BWC, these regulations have a minimal impact on overall U.S. trade in relevant items.

Overcoming impediments to ongoing exchanges and international cooperation

46. 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 countries receiving assistance in order to further promote the fullest possible exchange of equipment, materials, and information.

47. Recognized, 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.

48. Comprehensive and uniform regulations support long-term research and development collaborations. Unfortunately, regulatory agencies in many States 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.

49. High tariffs, taxes, and other fees also present significant market access barriers. These markups often increase the end-user price of medicine 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

50. International cooperation and exchange in the life sciences and in combating disease 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 programs for 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.