NO EFFORT SPARED: BUILDING A NEW PROTOCOL TO THE BIOLOGICAL WEAPONS CONVENTION IN THE PANDEMIC AGE

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> *The States Parties to this Convention,*
> . . . .
> *Determined, for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons,*
> *Convinced that such use would be repugnant to the conscience of mankind and that no effort should be spared to minimize this risk,*
> *Have agreed as follows . . . .*[1]

I. Introduction

The United States recognized the ongoing threat of biological incidents, whether natural or manmade, in the 2018 *National Biodefense Strategy*: "Biological threats—whether naturally occurring, accidental, or deliberate in origin—are among the most serious threats facing the United States and the international community."[2] Written two years before the SARS-CoV-2 (COVID-19) global pandemic, these words were grimly prophetic. Of the

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[1] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, Apr. 10, 1972, 26 U.S.T. 583, 1015 U.N.T.S. 163 [hereinafter Biological Weapons Convention].

[2] WHITE HOUSE, NATIONAL BIODEFENSE STRATEGY, at i (2018).

349.64 million confirmed cases of COVID-19 reported between 30 December 2019 and 24 January 2022, 5.59 million people worldwide have died from the virus.[3] The United States has reported more cases and deaths than any other country.[4] The origins of COVID-19 remain unclear, controversial, and the subject of great international political debate.[5] The State Department released a statement at the end of former President Donald Trump's term that publicly raised the possibility that the virus outbreak could have been the result of an accident at the Wuhan Institute of Virology (WIV), stating, "The WIV has engaged in classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017."[6] This statement evokes the horrors of industrial biological warfare programs from the last century.

From the early 1900s to 1972, when the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BWC) entered into force, the most powerful states in the world had national programs dedicated to maximizing the destructive power of biological weapons.[7] Since 1972, BWC states parties have promised to cease offensive biological weapons research and either destroy their weapons and equipment stockpiles or divert them to peaceful purposes.[8] The BWC is nearly universal, with almost every state a party to the convention with the notable exception of Israel and a handful of smaller states, mostly in Africa.[9]

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[3] *WHO Coronavirus Disease (COVID-19) Dashboard*, WORLD HEALTH ORG., https://covid19.who.int (last visited Jan. 24, 2022).

[4] *Id.*

[5] Some posit that the virus may have originated from an animal before transference to humans, but the exact origins remain unknown. *See Basics of COVID-19*, CTS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/cdcresponse/about-COVID-19.html (Nov. 4, 2021); WORLD HEALTH ORG., REPORT OF THE WHO-CHINA JOINT MISSION ON CORONAVIRUS DISEASE 2019 (COVID-19) (2020).

[6] *Fact Sheet: Activity at the Wuhan Institute of Virology*, U.S. DEP'T OF STATE (Jan. 15, 2021), https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology/index.html.

[7] See W. SETH CARUS, NAT'L DEF. UNIV., A SHORT HISTORY OF BIOLOGICAL WARFARE: FROM PRE-HISTORY TO THE 21ST CENTURY 20–25 (2017), for an overview of state biological warfare programs in the twentieth century.

[8] Biological Weapons Convention, *supra* note 1.

[9] 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, *Report on Universalization Activities*, U.N. Doc. BWC/MSP/2019/3 (Oct. 8, 2019) [hereinafter *Universalization Report*].

Since the early 1990s, across multiple administrations, the U.S. view on the BWC has had two constant features: first, that the convention is not effective because it lacks a method to verify compliance, and second, that efforts to improve the convention would not make it more effective.[10] The ineffectiveness of the convention has become a common observation in both academic research and public discourse.[11] The states parties to the BWC formed an ad hoc group in the 1990s to create a system that would help solve the BWC's problem with compliance verification.[12] In 2001, the ad hoc group released its Protocol to the Convention on the Prohibition of the Development Production and Stockpiling of Bacteriological Biological and Toxin Weapons and on Their Destruction (Draft Protocol).[13] The United States rejected this protocol, arguing that it imposed excessive burdens on industry through inspections without advancing the goals of the BWC.[14] Since the failure of the Draft Protocol, biological research has increased and led to the development of new technologies that make genetically engineered or synthetic biological weapons more readily attainable.[15] In 2021, the State Department reported that North Korea and Russia had active offensive biological weapons programs and that it could not conclude that Iran and China have abandoned their programs.[16] These four states also

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[10] U.S. GEN. ACCT. OFF., NSIAD-93-113, ARMS CONTROL: U.S. AND INTERNATIONAL EFFORTS TO BAN BIOLOGICAL WEAPONS 18 (1992).

[11] *See generally* Jack M. Beard, *The Shortcomings of Indeterminacy in Arms Control Regimes: The Case of the Biological Weapons Convention*, 101 AM. J. INT'L L. 271 (2007) (discussing the weaknesses caused by a lack of precise definitions in the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BWC)); Jonathan B. Tucker, *Seeking Biosecurity Without Verification: The New U.S. Strategy on Biothreats*, ARMS CONTROL TODAY, https://www.armscontrol.org/act/2010-01/seeking-biosecurity-without-verification-new-us-strategy-biothreats (last visited Jan. 27, 2022) (discussing the Obama administration's decision not to support a new verification regime).

[12] U.S. GEN. ACCT. OFF., *supra* note 10, at 5.

[13] Biological Weapons Convention Ad Hoc Grp., Protocol to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, BWC/AD HOC GROUP/CRP.8 (May 30, 2001) [hereinafter Draft Protocol].

[14] *U.S. Rejection of Protocol to Biological Weapons Convention*, 95 AM. J. INT'L L. 899, 900 (2001).

[15] U.S. GOV'T ACCOUNTABILITY OFF., GAO-20-273, NATIONAL BIODEFENSE STRATEGY: ADDITIONAL EFFORTS WOULD ENHANCE LIKELIHOOD OF EFFECTIVE IMPLEMENTATION 5–6 (2020).

[16] U.S. DEP'T OF STATE, ADHERENCE TO AND COMPLIANCE WITH ARMS CONTROL, NONPROLIFERATION, AND DISARMAMENT AGREEMENTS AND COMMITMENTS 46–52 (2021).

happen to be the biggest challengers to U.S. national security interests and power.[17]

Despite the risk of biological incidents, strengthening the BWC through a verification system has not been a priority for the United States since 2001. This article argues that this is a mistake because the danger of biological outbreaks and attack is unacceptably high, the biggest state challengers to U.S. national interests may still possess biological weapons, and modest changes to the BWC to improve verification and enforcement could be an effective way to reduce the threat of biological attacks and incidents. It is in the United States' national security interests[18] to lead an international effort to strengthen the enforcement of the BWC at the next conference of states parties in 2022.[19] States parties should use the Draft Protocol as inspiration for a new U.S.-led international effort to strengthen the BWC by requiring states parties to declare the most dangerous biological agents and to allow inspection of their high-containment laboratories. This risk-based approach will encourage global awareness of the location of the world's deadliest biological agents, incentivize improved laboratory security, and increase the risk and cost of discovery for states choosing to conduct secret offensive bioweapons research.

The first part of this article briefly discusses pandemics in recorded history before reviewing the history of biological warfare with a focus on the first half of the twentieth century, which featured industrialized states applying the scientific method to create biological weapons. The second part examines the history of the BWC, its strengths and weaknesses, and the effort to improve it that led to the 2001 Draft Protocol. The third part reviews the goals and options for strengthening the BWC through verification. The fourth section offers a specific proposal for using the Draft Protocol as inspiration to create a simplified verification and transparency system to

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[17] WHITE HOUSE, NATIONAL SECURITY STRATEGY OF THE UNITED STATES OF AMERICA 25 (2017).

[18] The White House signaled a possible shift in policy and a willingness to strengthen the BWC in November 2021. Jake Sullivan, Nat'l Sec. Advisor, Statement on the U.S. Approach to Strengthening the Biological Weapons Convention (Nov. 19, 2021).

[19] The Ninth Review Conference was planned for 2021 but was delayed due to COVID-19. The preparatory committee met on 20 December 2021, and the parties agreed to hold the conference in Geneva, Switzerland, from 8 to 26 August 2022. Interim Rep. of the Preparatory Comm., 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, BWC/CONF.IX/PC/2 (Dec. 20, 2021) [hereinafter Interim Report of the Preparatory Committee].

strengthen the BWC. The final part discusses how a strengthened BWC supports U.S. national security in the era of strategic competition and includes a case study focusing on the origin of COVID-19 and the WIV.

II. Pandemics and Biological Warfare in History

A. Pandemics

The threat of a pandemic, defined simply as a "contagious infectious disease that has spread to multiple geographic areas,"[20] has been a constant feature of human history, even though the biological causes of disease were poorly understood until recently. The Black Death plague outbreak in Europe killed an estimated 200 million people.[21] Despite recent advances in science and sanitation, the Spanish Flu killed around 50 million people, AIDS has killed around 35 million people, and the Swine Flu killed around 200 thousand people from 2009 to 2010.[22] Because many pandemic diseases start with animal to human transmission, and the process of mutation is continuous and dynamic, the threat of a pandemic is likely a permanent part of the human condition.[23]

The ability to understand disease and to genetically modify biological agents and toxins to make them more deadly is a new development. As technology advances, a virus could conceivably be created or modified to be as deadly as possible, unleashing a new type of global pandemic with devastating mortality.[24]

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[20] Silvio Daniel Pitlik, *COVID-19 Compared to Other Pandemic Diseases*, 11 RAMBAM MAIMONIDES MED. J. 1, 4 (2020).
[21] *Id.* at 11.
[22] *Id.*
[23] *Id.* at 3.
[24] See generally Nicole H. Kalupa, *Black Biology: Genetic Engineering, the Future of Bioterrorism, and the Need for Greater International and Community Regulation of Synthetic Biology*, 34 WIS. INT'L L.J. 952 (2017), for a detailed analysis of the threat of synthetic biology and engineered biological weapons.

B. Biological Warfare in History

1. Early History

The fear of plague and pestilence spreading from group to group is as old as recorded history. The biblical description of the plague of boils in the book of Exodus sounds vaguely like a biological attack:

> Then the Lord said to Moses and Aaron, "Take handfuls of soot from a furnace and have Moses toss it into the air in the presence of Pharaoh. It will become fine dust over the whole land of Egypt, and festering boils will break out on people and animals throughout the land."[25]

Some medical historians have argued that anthrax spores in the ash that Moses took from the furnace may have caused the plague of the boils.[26] A more recent infamous example of attempted biological warfare occurred in 1763, when European colonists gave Native Americans blankets from a smallpox hospital with the hope that they would become ill.[27]

Despite the widespread fear of disease in human history, the effective use of biological weapons prior to the twentieth century was rare because scientists did not understand that microorganisms cause disease until the 1860s.[28] This profound ignorance of basic biology for most of military history made biological warfare planning practically impossible until the 1900s. With the rise of modern industrial warfare came the development of state-sponsored biological warfare programs. Starting in World War I, Germany became the first industrial nation to develop and use biological agents.[29] Although the program was secret and its effectiveness uncertain, it is notable as the first state use of scientific principles for biological warfare, including coordination across several fronts, in both the United States and Europe.[30]

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[25] *Exodus* 9:8–9.

[26] Peter Gorner, *From Bible to Battlefield, Anthrax Has a Widespread Past*, CHI. TRIB. (Oct. 21, 2001), https://www.chicagotribune.com/news/ct-xpm-2001-10-21-0110210054-story.html.

[27] CARUS, *supra* note 7, at 7.

[28] *Id.*

[29] *Id.* at 12.

[30] *Id.* at 13. The Germans specifically cultivated diseases to sicken enemy pack animals in Europe, and even developed a secret lab in Silver Spring, Maryland, to make biological agents for attacks on U.S. ammunition factories. *Id.*

2. Industrial Biological Warfare

Germany's use of biological weapons and the widespread use of mustard gas in World War I led to the 1925 Geneva Protocol, which was the first international agreement to directly ban biological weapons in war.[31] Still in effect, and ratified by the United States in 1975, the protocol bans only the *use* of biological weapons in war amongst signatory states rather than the *possession* of biological weapons.[32] It was ultimately ineffective in preventing the use of biological weapons in war, especially since Japan did not sign the agreement and instead developed a large, state-sponsored biological weapons program beginning in the 1930s that would become the most comprehensive and notorious state program in history.[33]

Japan's biological warfare program in the 1930s and 1940s is notable for both its ambitious scope and its horrific abuses of prisoners of war and Chinese civilians.[34] Commonly referred to as "Unit 731," the program involved experiments on humans in an attempt to develop military applications of plague and other biological agents.[35] Operating from occupied Manchuria, Unit 731 attempted to poison Russian water supplies and dropped bombs containing plague-infested fleas on Chinese targets.[36] Detailed accounts of the program and casualties are difficult to find because the Imperial Japanese Army destroyed the program's buildings and records when the Soviet Army invaded northern China in 1945.[37] Despite the incredible cruelty of the human experimentation, including vivisection, the United States did not join the Soviet-led war crimes trial against Unit 731

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[31] Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, June 17, 1925, 26 U.S.T. 571 [hereinafter Geneva Protocol].
[32] *Id.*
[33] U.S. ARMY MED. RSCH. INST. OF INFECTIOUS DISEASES, USAMRIID'S MEDICAL MANAGEMENT OF BIOLOGICAL CASUALTIES HANDBOOK 3 (9th ed. 2020).
[34] Most of the information about Unit 731 comes from recorded testimony of Japanese soldiers and workers assigned to the unit and associated facilities. Records and facilities were destroyed at the end of World War II, and it appears that no prisoners or victims of biological experiments survived to bear witness. Despite the destruction of evidence, several authors have compiled testimonies of Japanese workers and soldiers who worked on the project. *See generally* HAL GOLD, JAPAN'S INFAMOUS UNIT 731: FIRSTHAND ACCOUNTS OF JAPAN'S WARTIME HUMAN EXPERIMENTATION PROGRAM (2019); DEREK PUA ET AL., UNIT 731: THE FORGOTTEN ASIAN AUSCHWITZ (2d ed. 2020).
[35] CARUS, *supra* note 7, at 15–19.
[36] U.S. ARMY MED. RSCH. INST. OF INFECTIOUS DISEASES, *supra* note 33, at 2–3.
[37] *Id.*

members.[38] The Soviets prosecuted a few former members, but the United States gave the scientists immunity from prosecution as war criminals in exchange for information about the weapons program and research.[39]

At the beginning of the Cold War, both the United States and the USSR developed large, state-run offensive biological weapons programs.[40] In 1969, President Richard Nixon announced that the United States would unilaterally abandon offensive biological weapons research;[41] the United States destroyed its supply of biological munitions between 1971 and 1972.[42] This announcement led the way for international talks leading up to the BWC.

Despite the success of the BWC, the Iraqis under Saddam Hussein reportedly experimented on live prisoners in the 1980s, exposing them to biological agents and recording the results, similar to the Unit 731 Japanese atrocities during WWII.[43] More recently, the anthrax letters in 2001 poisoned and killed several people across the United States, serving as a reminder that the threat of biological attacks from both state and non-state actors remains, despite improvements over time.[44] There is also a risk that terrorists or other non-state actors could acquire or develop biological weapons, like the Aum Shinrikyo cult's 1995 attempt to unleash anthrax and botulism in Japan.[45]

With the advent of computers and advancements in technology, future biological weapons threats may include not only naturally occurring substances, but also synthetic, lab-created organisms. A prospective bioterrorist could create a virus or bacteria that may be entirely novel or one that is a synthetically modified version of an existing anthrax or plague bacterium that is especially virulent or resistant to antibiotics.[46] Scientists may discover new ways to make deadly biological weapons, which places increased importance on reinforcing the BWC's international norm against all forms of offensive biological research.

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[38] CARUS, *supra* note 7, at 19.
[39] *Id.*
[40] *Id.* at 27.
[41] *Id.* at 39.
[42] U.S. ARMY MED. RSCH. INST. OF INFECTIOUS DISEASES, *supra* note 33, at 3–4.
[43] *Id.*
[44] *Id.*
[45] *Id.* at 6–7.
[46] *See* Kalupa, *supra* note 24.

II. The Biological Weapons Convention

A. Structure and Requirements

Entering into force on 26 March 1975, the BWC "was the first multilateral disarmament agreement banning an entire category of weapons of mass destruction."[47] Unlike the 1925 Geneva Protocol, the BWC bans offensive biological weapons at *any* time—not only in war. Article I sets up the key requirement of the treaty. Rather than an outright ban on specific biological agents and toxins, the agreement restricts the use of biological agents and equipment to peaceful purposes only:

> Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:
>
> (1) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for *prophylactic, protective or other peaceful purposes*;
>
> (2) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.[48]

Article II creates a complimentary obligation for each state party to "undertake[] to destroy, or to divert to peaceful purposes, as soon as possible but not later than nine months after the entry into force of the Convention, all agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention."[49]

Under Article VI, if a state party to the BWC believes a party has violated the convention, that state may lodge a complaint with the United Nations Security Council (UNSC).[50] The UNSC may initiate an investigation, solicit the cooperation of states parties, and share the results with the parties.[51] The BWC creates no independent body to investigate any such complaint. No state party has invoked Article VI to date.[52]

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[47] UNITED NATIONS OFF. OF DISARMAMENT AFFS., THE BIOLOGICAL WEAPONS CONVENTION: AN INTRODUCTION 1 (2017).
[48] Biological Weapons Convention, *supra* note 1, art. I (emphasis added).
[49] *Id.* art. II.
[50] *Id.* art. VI.
[51] *Id.*
[52] Eighth Review Conference of the States Parties to the Convention on the Prohibition Development, Production and Stockpiling of Bacteriological (Biological) and Toxin

With 183 states parties,[53] the BWC has been the primary instrument for creating a strong international norm against the development of biological weapons. Almost every industrialized state in the world, with the notable exception of Israel, has signed the convention, with the remaining handful of non-signatory states concentrated in Africa.[54] States parties meet for a review conference every five years in Geneva, with the next conference expected in August 2022.[55] Despite the apparent success of the BWC in preventing biological attacks, the BWC has widely been criticized as ineffective, primarily on the ground that it has neither precise definitions nor a verification regime. Although there have been no major biological attacks by states parties since the treaty entered into force, there have been several flagrant violations of the BWC,[56] most notably Russia's revelation that in the 1990s it had violated the BWC by maintaining an offensive biological weapons capacity for years after the BWC entered into force.[57]

B. Shortcomings of the Biological Weapons Convention

1. Definitional Defects

The lack of precise definitions is a fundamental flaw in the BWC. The ban on biological weapons applies only to agents or toxins if they are "of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes."[58] The BWC offers no definitions or clarifying rules on the types of biological agents that have "no justification for prophylactic, protective or other peaceful purposes."[59]

The practical result is that the definition of "peaceful purposes" is left to each state to determine. Because the BWC lacks a verification regime, state definitions of "peaceful purposes" have not been subject to international scrutiny and the cost of compliance is low.

Weapons and on Their Destruction, *Final Document of the Eighth Review Conference*, at 14, U.N. Doc. BWC/CONF.VIII/4 (Jan. 11, 2017) [hereinafter *Eighth Review Conference Final Document*].

[53] *See Universalization Report*, *supra* note 9 (reviewing the current status of states parties, signatory states, and non-signatory states).

[54] *Id.*

[55] Interim Report of the Preparatory Committee, *supra* note 19.

[56] CARUS, *supra* note 7, at 28.

[57] U.S. ARMY MED. RSCH. INST. OF INFECTIOUS DISEASES, *supra* note 33, at 5.

[58] Biological Weapons Convention, *supra* note 1, art. I.

[59] *Id.*

2. Verification Void

States parties have long viewed this lack of verification[60] as a weakness in the BWC. Recognizing this, the states parties formed the ad hoc group in the 1990s to develop a draft protocol with a declaration and verification regime,[61] and the group released the text of the Draft Protocol in April 2001.[62] The Draft Protocol would have required annual declarations of biodefense facilities, and it would have implemented a system of random transparency visits to states parties.[63] It would have included a robust investigation mechanism and created an independent organization dedicated to enforcing the BWC and the Draft Protocol's new features.[64] Despite participating in years of negotiations and being heavily involved in shaping the text, the United States rejected the Draft Protocol the year it was released, leaving the BWC without a verification system to this day.[65]

The United States' negotiator summarized the U.S. position on the Draft Protocol, and these statements appear to reflect current U.S. policy:

> In short, after extensive analysis, we were forced to conclude that the mechanisms envisioned for the Protocol would not achieve their objectives, that no modification of them would allow them to achieve their objectives, and that trying to do more would simply raise the risk to legitimate United States activities.[66]

Although not explicitly stated by the U.S. negotiator, a primary reason for the change in U.S. position was the potential impact on the pharmaceutical industry.[67] The Draft Protocol defined "facility" broadly, including

> [*a*]*ll facilities* conducting research and development on pathogenicity, virulence, aerobiology or toxinology at any site at which *15 or more* technical and scientific person years of effort or 15 or more technical and scientific personnel were engaged on such research and development

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[60] As used in this article, "verification" means some combination of mandatory declarations and inspections which are common features of both the Chemical Weapons Convention and the Draft Protocol to the BWC.
[61] UNITED NATIONS OFF. OF DISARMAMENT AFFS., *supra* note 47, at 22.
[62] *See* Draft Protocol, *supra* note 13.
[63] *Id.* arts. 4, 6(B).
[64] *Id.* arts. 9, 16.
[65] Beard, *supra* note 11, at 284.
[66] *U.S. Rejection of Protocol to Biological Weapons Convention*, *supra* note 14.
[67] Beard, *supra* note 11, at 284.

> as part of the national biological defence programme(s) and/or activities.[68]

This could apply to thousands of sites, making management of inspections and U.S. treaty obligations overly cumbersome and requiring domestic resources to monitor.

Since the rejection of the Draft Protocol, BWC review conferences continue to emphasize confidence-building measures, encouraging cooperation and the sharing of technical information among states parties under the auspices of the Implementation Support Unit.[69] However, there has been no serious effort to reestablish a true verification regime or an independent organization to implement the BWC since 2001. Verification is still as necessary as it was twenty years ago. The State Department reported in 2021 that several near-peer states and regional state actors may still possess offensive biological weapons in violation of the BWC.[70] In particular, the State Department assessed that North Korea and Russia operate active offensive weapons programs and that it could not determine if China and Iran are complying with their Article I and Article II obligations.[71] As signatories to the BWC, these countries presumably believe the benefits of developing and stockpiling prohibited weapons outweigh the risk accountability for violating the BWC. When challenged, a state can either deny access to an installation or simply claim that its research is for peaceful purposes. Without a verification regime, the risk of being caught is low, and the international community has no way of knowing whether these (or any other) states parties are complying with their BWC obligations.

The Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction (CWC) is a useful comparison for analyzing the lack of verification in the BWC. The CWC requires the declaration[72] and destruction[73] of chemical weapons

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[68] *See* Draft Protocol, *supra* note 13, art. 4(C) (emphasis added).
[69] *See generally* Seventh Review Conference of the States Parties to the Convention on the Prohibition Development, Production and Stockpiling of Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, 14 BWC/CONF.VII/7 (Jan. 13, 2012) (reviewing confidence-building measures).
[70] U.S. DEP'T OF STATE, *supra* note 16, at 46–52.
[71] *Id.*
[72] *See* Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction art. I, Jan. 13, 1993, 1974 U.N.T.S. 45 [hereinafter Chemical Weapons Convention].
[73] *Id.* art. III.

stockpiles and production facilities, and it creates a tiered list of chemical schedules based on how likely they are to be used for non-military purposes.[74] The CWC also includes provisions for inspections to verify the destruction of weapons and facilities.[75] The CWC created the Organization for the Prohibition of Chemical Weapons as an independent international body to enforce the CWC's mandates.[76] Unlike the BWC, the CWC requires actual destruction of chemical weapons rather than just diversion to peaceful purposes.[77] States parties who violate the CWC face penalties and referral to the UNSC.[78]

This combination of mandatory declarations, robust inspections, and an independent organization tasked to implement inspections stands in stark contrast to the BWC's ambiguous language and its lack of both inspections and an independent enforcement body other than the UNSC. The Draft Protocol would have brought the BWC in closer alignment to the CWC, but the distinctions have become even more glaring since its failure in 2001.[79] The next session will analyze the specific structure and requirements of the Draft Protocol to see what almost came to fruition.

C. Trying to Be Better: The Draft Protocol

The Draft Protocol represents a twenty-year effort to enhance the BWC by adding "specific measures to improve its implementation and effectiveness."[80] At 162 pages, it is remarkably thorough because it was essentially ready to enter into force—that is, until the United States unexpectedly withdrew support. The two major features are declarations and random "transparency visits."[81] The Draft Protocol would have created the independent Organization for the Prohibition of Bacteriological (Biological)

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[74] *Id.* annex B.
[75] *Id.* arts. IV, V.
[76] *Id.* art. VIII.
[77] *Compare id.* art. 1, *with* Biological Weapons Convention, *supra* note 1.
[78] Chemical Weapons Convention, *supra* note 72, art. XII.
[79] This is not a claim that the CWC is without problems. Implementation can be cumbersome, and compliance relies on strong state party enforcement. Chemical weapons are still in use. In 2017, the Syrian government used chemical weapons on its own citizens, prompting international condemnation and a retaliatory strike by the United States. HUM. RTS. WATCH, DEATH BY CHEMICALS: THE SYRIAN GOVERNMENT'S WIDESPREAD AND SYSTEMATIC USE OF CHEMICAL WEAPONS 1–2 (2017).
[80] Draft Protocol, *supra* note 13, pmbl.
[81] *Id.* arts. 3, 6(B).

and Toxin Weapons "in order to strengthen the effectiveness and improve the implementation of the Convention and to ensure the implementation of this Protocol, and to provide a forum for consultation and co-operation among States Parties."[82] This body would have included an Executive Council and a Technical Secretariat to manage the new requirements, significantly expanding the size and scope of the administrative support to BWC implementation, which is currently limited to the modest Implementation Support Unit within the United Nations Office for Disarmament Affairs.[83]

Unlike the CWC, which divided chemical weapons into three categories based on potential for weaponization, the Draft Protocol focused on annual declarations of facilities.[84] Some scholars have argued that the Draft Protocol was not truly a verification regime in the same spirit as the CWC,[85] as the Draft Protocol referred to transparency rather than verification. Regardless of terminology, however, the Draft Protocol significantly increased the risk of non-compliance by allowing states parties to request investigations of suspected violators and affirmatively requiring states parties to declare certain biological research facilities.

The Draft Protocol's facility declarations were complex. Article 4 required states parties conducting national biodefense programs to declare annually to the Technical Secretariat

> [a]ll facilities conducting research and development on pathogenicity, virulence, aerobiology or toxinology at any site at which *15 or more* technical and scientific person years of effort or *15 or more* technical and scientific personnel were engaged on such research and development as part of the national biological defence programme(s) and/or activities.[86]

The Draft Protocol also required declarations of high- and maximum-containment facilities, plant pathogen containment facilities, certain

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[82] *Id.* art 16.
[83] UNITED NATIONS OFF. OF DISARMAMENT AFFS., *supra* note 47, at 23.
[84] *See* Draft Protocol, *supra* note 13, art. 3.
[85] *See* Lynn C. Klotz, *The Biological Weapons Convention Protocol Should Be Revisited*, BULL. OF THE ATOMIC SCIENTISTS (Nov. 15, 2019), https://thebulletin.org/2019/11/the-biological-weapons-convention-protocol-should-be-revisited (arguing that verification is not the purpose of the Draft Protocol and that focusing on verification over transparency is bad policy).
[86] Draft Protocol, *supra* note 13, art. 4 (emphasis added).

production facilities, and any facility engaged in specified activities with the biological agents listed in Annex A of the Draft Protocol.[87]

Once states parties declared the above facilities, the Technical Secretariat was charged with conducting up to 120 random "transparency visits" per calendar year.[88] Each state party could receive no more than seven visits per calendar year, and no individual facility would be inspected more than three times in a five-year period.[89] The Technical Secretariat was required to provide fourteen days' notice prior to each inspection.[90] These transparency visits served three purposes:

> (a) Increasing confidence in the consistency of declarations with the activities of the facility and encouraging submission of complete and consistent declarations;
> (b) Enhancing transparency of facilities subject to the provisions of this section;
> (c) Helping the Technical Secretariat, subject to the provisions of this section, to acquire and retain a comprehensive and up-to-date understanding of the facilities and activities declared globally.[91]

States parties could also request from the Technical Secretariat a voluntary assistance visit, which would focus on technical assistance, information, and advice for complying with the BWC.[92]

Under Article 9, states parties had a right to request an investigation of non-compliance stemming from either a suspicious outbreak of a disease (i.e., a field investigation) or an investigation of a specific facility suspected of violating the BWC (i.e., a facility investigation).[93] Finally, Article 12 provided a mechanism for addressing non-compliance. The Executive Council could address violations by suspending the rights and privileges of the offending state party, recommending collective measures against the state party, or in particularly grave cases, referring the information to the United Nations General Assembly or the UNSC.[94]

When viewed as a whole, the Draft Protocol outlined a detailed, complex, and interlocking structure for improving the BWC. Most notably,

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[87] *Id.*
[88] *Id.* art. 6(A)5.
[89] *Id.* art. 6(A)7.
[90] *Id.* art. 6(B)22.
[91] *Id.* art. 6(B)15.
[92] *Id.* art. 6(C).
[93] *Id.* art. 9.
[94] *Id.* art. 12.

it created a mechanism to expose cheaters through inspections. By focusing primarily on facilities and capabilities rather than specific biological agents, the Draft Protocol relied more on detailed descriptions of facilities rather than bright-line rules based on the risk posed by specific activities or agents. In this sense, it differed from the tiered substance approach of the CWC, which the United States ultimately supported.

III. The Need for Verification Remains

Despite its faults, the Draft Protocol is an excellent starting point to inspire efforts to revitalize the BWC, which is vital considering that the threat of biological weapons remains prominent. The Draft Protocol represents almost two decades of work to improve the BWC. Rather than start anew with talks and discussions, the international community would be better served by using simplified and streamlined declarations and inspections focused on high-risk agents and toxins and on high-containment facilities as the baseline requirement for an improved BWC.

Any efforts to add a verification regime to the BWC should include a system that both imposes costs when states parties obscure offensive biological research and answers the following questions: (1) What are the most dangerous substances? (2) Where are they located? (3) What is the purpose of researching these substances?

The answers to each of these questions in the below subsections will demonstrate improvements to the BWC to ensure biological weapons and equipment are used for peaceful purposes. The Draft Protocol failed because its solution was too complex and burdensome, particularly to the United States. Ideally, a new protocol would develop the simplest effective solution that all states parties would accept. States parties should recognize the disadvantages of focusing on intricate definitions of facilities and attempt to simplify the language whenever possible while focusing on risk.

A. The Deadliest Biological Agents

If the fundamental flaw in the BWC is its lack of precise definitions, logical analysis begins with the terms of the agreement. Although the BWC bans the offensive use of any biological material, some microbes are much more dangerous than others. Recognizing this problem, the Draft Protocol included specific substances in Annex A for declaration and additional

scrutiny, including both human, animal, and plant pathogens.[95] The CWC also recognized this problem and created three tiers of chemicals to focus scrutiny on those that pose the greatest risk if weaponized.[96] However, instead of declaring specific substances, the Draft Protocol focused primarily on declaring facilities.[97] The U.S. Congress also recognizes that some biological agents are more dangerous than others, and it has passed several laws that require registration and impose strict regulations on agents and toxins that "have the potential to pose a severe threat to public health and safety."[98] The text of the BWC, however, makes no mention of specific substances, nor does it establish risk tiers. It applies broadly to "microbial or other biological agents, or toxins whatever their origin or means of production."[99] This broad language is useful in establishing a strong norm against the use of *any* biological material as a weapon of war, but it does not recognize that some biological materials are much more dangerous than others.[100]

In recognizing that some microbes are more dangerous than others, the Draft Protocol took an important step in tightening the regulatory power of the BWC. Listing specific substances puts states parties on notice that they must explain how their possession and research of these substances is peaceful. Publishing the most dangerous substances would make it more difficult for states to continually affirm that they are meeting their BWC obligations and impose higher costs if they were caught lying. It creates a consistent international consciousness of which agents are the most dangerous and puts the burden on states parties to explain the specific reasons for their use rather than simply affirm that their research is for defensive purposes.

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[95] *Id.* annex A.
[96] Chemical Weapons Convention, *supra* note 72, annex B.
[97] Draft Protocol, *supra* note 13, art. 4.
[98] CTRS. FOR DISEASE CONTROL & PREVENTION & NAT'L INSTS. OF HEALTH, BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES 416 (6th ed. 2020).
[99] Biological Weapons Convention, *supra* note 1, art. I.
[100] For example, the Ebola virus may have up to an 80% fatality rate, which is astronomical compared with other pathogens. U.S. ARMY MED. RSCH. INST. OF INFECTIOUS DISEASES, *supra* note 33, at 96.

B. High-Containment Facilities

Having identified which agents are the most dangerous, the next logical question to ask is where these agents are located. The exact definition and use of biological safety levels can vary by country, and there are no international biosafety standards.[101] With the progress in technology, many countries have built high-containment research facilities to reduce the threat of exposure or contamination of the most dangerous pathogens.

Recognizing the need to secure dangerous biological materials, the World Health Organization (WHO) hosted the first Consultative Meeting on High/Maximum Containment (BSL-4) Laboratories Networking in Lyon, France, in December 2017.[102] In the United States, BSL-4 protection is recommended "for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening diseases that are frequently fatal, agents for which there are no vaccines or treatments, or work with a related agent with unknown risk of transmission."[103] As of 2017, there were about fifty BSL-4 laboratories capable of working with the most dangerous biological agents, with several more planned or under construction worldwide.[104] All of these laboratories are located in BWC states parties.[105]

The BWC imposes no obligation on states parties to disclose where they conduct biological research, requiring only that states parties use such research for peaceful purposes. The Draft Protocol went further, proposing declaration requirements that would help to answer the question of where these materials are located. The Draft Protocol proposed an initial declaration of all biological warfare activity between 1946 and 1972, coupled with proof of diversion to peaceful purposes.[106] After this initial declaration, states parties would be required to file annual declarations of high-containment facilities and any facility with more than fifteen

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[101] Although there is not a universal standard or requirement for required features of a BSL-4 high-containment laboratory, both the World Health Organization and the U.S. Government have published standards requiring the laboratory to have a controlled air system with HEPA filtration. WORLD HEALTH ORG., LABORATORY BIOSAFETY MANUAL 62 (4th ed. 2020); CTRS. FOR DISEASE CONTROL & PREVENTION & NAT'L INSTS. OF HEALTH, *supra* note 98, at 50.

[102] WORLD HEALTH ORG., WHO CONSULTATIVE MEETING ON HIGH/MAXIMUM CONTAINMENT (BIOSAFETY LEVEL 4) LABORATORIES NETWORKING (2018).

[103] CTRS. FOR DISEASE CONTROL & PREVENTION & NAT'L INSTS. OF HEALTH, *supra* note 98, at 51.

[104] WORLD HEALTH ORG., *supra* note 102, at 46.

[105] *See Universalization Report*, *supra* note 9.

[106] Draft Protocol, *supra* note 13, art. 4(B)(3), annex A.

researchers engaged in biological research.[107] In rejecting the 2001 proposal, the United States rightly noted that this annual requirement was impossibly broad and could apply to thousands of pharmaceutical labs.[108] The United States also noted that the requirement to declare laboratories would not improve biosecurity but did not elaborate on this point.[109]

The principal reason underlying a requirement to declare laboratory locations is that such declarations would increase the cost of non-compliance, especially if a state chooses to maintain a secret biological weapons program. Because the locations of high-containment laboratories are well established, the most dangerous microbes are likely to be located in specific places. If there were an outbreak of disease in *another* location, that fact would constitute strong circumstantial evidence that a state was conducting unauthorized biological research. If those agents show up in other places within a state's territory, the state should have to explain why it is not honoring its commitments. In its current form, the BWC imposes almost no cost on non-complying states.

C. Peaceful Purposes

Having addressed the "what" and the "where," the most difficult question remains: what is the *purpose* of biological research? The simple answer of the BWC is that it must be "peaceful," but the text fails to define that term. Peaceful research is the only acceptable purpose of biological research under the BWC, but a state can simply declare that its research is peaceful without further inquiry. The Draft Protocol does not define "peaceful purpose," but it does give examples such as "peaceful uses of genetic engineering, the prevention, diagnosis and treatment of diseases caused by microbial and other biological agents or toxins, in particular infectious diseases, and for other relevant fields of biosciences and biotechnology for peaceful purposes."[110] This presents a low bar for states parties; to show compliance, a state must simply declare that their research is for peaceful purposes, whatever that means.

The most well-known example of a transition to biological research for peaceful purposes occurred after the United States abandoned its offensive

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[107] *Id.* art. 4(C).
[108] *U.S. Rejection of Protocol to Biological Weapons Convention*, *supra* note 14, at 900.
[109] *Id.* at 901.
[110] Draft Protocol, *supra* note 13, art. 14(4)(G).

biological weapons program in 1969.[111] The United States converted from offensive to defensive research to develop vaccines and expertise in biological response.[112] This research continues today at the United States Army Medical Research Institute of Infectious Diseases, the mission of which is to "[p]rovide leading edge medical capabilities to deter and defend against current and emerging biological threat agents."[113] There are also examples of states, most notably Russia, failing to convert offensive programs to peaceful purposes.[114]

It may not be possible to properly define "peaceful" or imagine every type of research that could be applied to "peaceful purposes." There is a distinct possibility that a state could turn its research for "peaceful purposes to research for improper purposes. This "dual-use" problem should be seen as a barrier to overcome rather than an excuse to refrain from any attempt to improve the BWC. The need for a verification regime remains, and the most practical way to achieve useful results is to create a new protocol requiring the declaration of the most dangerous substances and inspections of high-containment facilities.

Some scholars have argued that the ad hoc group intended the Draft Protocol not to serve as a verification regime that would ensure compliance through inspections, but rather as a good-faith effort to increase transparency.[115] Increasing transparency is a valid aim, but if transparency increases while states maintain active biological warfare programs, the ultimate goal of the BWC will not be realized. The Draft Protocol would have implemented random laboratory transparency visits (not inspections) with fourteen days' notice and created an independent body to investigate and respond to allegations of BWC violations.[116] Although these were termed "transparency visits" rather than "verification inspections," they have the practical effect of verifying whether a facility's activity mirrors its declarations. However, as in the original BWC, the Draft Protocol's

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[111] Statement on Chemical and Biological Defense Policies and Programs, PUB. PAPERS 968 (Nov. 25, 1969).
[112] *Id.*
[113] ABOUT USAMRIID, U.S. ARMY MED. RSCH. INST. OF INFECTIOUS DISEASES, https://www.usamriid.army.mil/aboutpage.htm (Nov. 19, 2018).
[114] *See generally Assessing the Biological Weapons Threat: Russia and Beyond: Hearing Before the Subcomm. on Eur., Eurasia, & Emerging Threats of the H. Comm. on Foreign Affs.*, 113th Cong. (2014).
[115] *See* Klotz, *supra* note 85.
[116] Draft Protocol, *supra* note 13, art. 4.

enforcement body remained the UNSC, referral of a matter to which is the most drastic enforcement option.[117]

With the Draft Protocol's shortcomings and benefits in mind, the next section argues for specific changes to the BWC to require declarations, inspect certain laboratories, and increase the cost of non-compliance.

IV. Declarations, Inspections, and Implementation

A. Declarations

Almost twenty years after the Draft Protocol failed, the BWC continues to drift aimlessly. Every time the parties meet, they declare solemnly to abide by a treaty that demands little from them in terms of transparency or changed behavior. In the pandemic age where global travel and commerce allow disease to spread freely across borders, it is time for a change: parties must declare the location of the most dangerous biological materials and allow inspections of high-containment laboratories.

The United States Department of Health and Human Services and the United States Department of Agriculture have jointly produced the "Select Agents and Toxins List," which provides a convenient and well-established list of biological materials that states parties could declare.[118] United States law already regulates these sixty-eight agents, requiring those in possession to register in a national database.[119] Agents and toxins are placed on the list specifically because they pose a threat to human or animal health.[120] Of the listed agents and toxins, fourteen are designated "Tier 1," meaning that they "present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety."[121] Because these Tier 1 agents pose the greatest risk to humankind, the BWC should require their declaration. In addition to these Tier 1 agents, the BWC signatories should declare any coronavirus research, such as the research

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[117] *Id.* art. 12.

[118] *Select Agents and Toxins List*, FED. SELECT AGENT PROGRAM, https://www.selectagents.gov/sat/list.htm (Apr. 26, 2021).

[119] CTRS. FOR DISEASE CONTROL & PREVENTION & NAT'L INSTS. OF HEALTH, *supra* note 98, at 45.

[120] *Select Agents and Toxins List*, *supra* note 118.

[121] *Biosafety/Biocontainment Plan Guidance*, FED. SELECT AGENT PROGRAM (Sept. 9, 2020), https://www.selectagents.gov/compliance/guidance/biosafety/definitions.htm.

conducted at the WIV. The rationale is that though coronaviruses are not Tier 1 agents, the worldwide COVID-19 pandemic has shown that they can cause massive harm, especially when a new strain emerges.[122]

The Draft Protocol required annual declarations of specific types of facilities and their capabilities, in addition to all labs that work with the substances listed in Annex A.[123] Although this requirement was comprehensive and provided a great deal of transparency about biological research in states parties, it also imposed high costs of implementation by requiring careful monitoring and technical expertise to verify capabilities and activities.

A new requirement to declare research with Tier 1 agents and toxins could be much simpler than the proposed Draft Protocol regime. States would annually certify whether they possess any of the listed substances, where those substances are located, and an explanation of the peaceful research involved. For example, a hypothetical declaration of COVID-19 related research would read, "SARS-associated coronavirus, Center of Disease Control, Atlanta, Georgia, vaccine research." States would also declare the location and purpose of their high-containment laboratories, to include the type of research performed at these facilities.

While the Draft Protocol declaration language[124] is a start, it is ineffective. Using that language as a guide, this article proposes the following required substance declaration:[125]

> **ANNUAL DECLARATIONS**
> ***National biological activities involving Tier 1 bacteriological (biological) and toxins conducted during the previous year***
> **Each State Party shall declare:**
> **(a) Whether private or government facilities conducted research or other activities using Tier 1 agents and toxins and/or Coronaviruses;**
> **(b) The peaceful purpose of the research in section (a) above and the location of the research; and**
> **(c) All BSL-4 facilities, both animal and human focused, and a list of the research activities conducted at these facilities. BSL-4 facilities are those designed for**

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[122] *See WHO Coronavirus Disease (COVID-19) Dashboard*, *supra* note 3.
[123] Draft Protocol, *supra* note 13, art. 4.
[124] *Id.*
[125] This article's recommended legislative changes appear in bold typeface.

> **maximum containment of biological material and include features such as handling units, breathing air systems for suit laboratories, supply and exhaust high-efficiency particulate air (HEPA) filters, material transport docks (dunk tanks, pass-through chamber, autoclaves), shower barriers, effluent treatment systems, and built-in redundancy for critical systems.**[126]

By focusing declarations on the most harmful substances and the highest-containment laboratories, states parties would be required to determine where the most dangerous biological materials are located within their borders, if they are not already aware. This is a powerful incentive to comply with the treaty, and it encourages both internal biosecurity and greater transparency about where the most dangerous substances are located. The United States' compliance would be comparatively straightforward because domestic law already requires registration and a national database of Tier 1 agents. Domestic law reinforces compliance from the U.S. perspective, increases the chances of U.S. cooperation, and lowers the cost of sharing information and best practices. This also aligns with previous national security strategies. Focusing on substances recognizes the difficulty of monitoring research activities in a large, industrial nation and incentivizes compliance by focusing on the shared goal of safety.

This proposal would abandon entirely the Draft Protocol requirements to declare specific activities, equipment, and small laboratories. These requirements discourage compliance by requiring additional investment to measure compliance. This approach maximizes the spirit of transparency of the Draft Protocol without the burdensome requirements of monitoring small laboratories. Importantly, this approach complements U.S. domestic law, which will increase the chances of U.S. support and add legitimacy to the process.

B. Inspections

Rather than the Draft Protocol's random transparency visits, states parties should agree to regular international inspections of BSL-4 laboratories. The random transparency visits would have covered a huge

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[126] This language incorporates the World Health Organization's recommended design features. *See* WORLD HEALTH ORG., *supra* note 102, at 5.

variety of facilities, with limited utility depending on the facility visited. A much better use of time and resources is to focus on safety and research activities of BSL-4 laboratories. This is a not a novel concept. In fact, the United States and Russia already submit to regular WHO inspections of CDC and VECTOR[127] laboratories, the only two known locations of the variola (smallpox) virus.[128] The WHO produces a report with the findings after the biennial inspections.[129] There are few BSL-4 laboratories worldwide, and most are already subject to rigorous regulation and inspections under domestic law.[130] Annual or semi-annual inspections of BSL-4 laboratories would impose much less of a burden on states parties than the Draft Protocol's transparency visits, which could have subjected hundreds of private labs in the United States to random visits with only fourteen days' notice. Most BSL-4 labs are state-run, and the inconvenience to the few private labs is well worth the benefit of increased safety and transparency.

The Draft Protocol established a new Organization for the Prohibition of Bacteriological (Biological) and Toxin Weapons with a Technical Secretariat, which it charged with implementing random transparency visits to covered biological facilities. This was one of the more ambitious changes recommended in the Draft Protocol. The Technical Secretariat monitored and coordinated the inspections of a potentially huge list of facilities worldwide. The approach above intends to reduce the administrative burden of inspections by focusing on BSL-4 facilities, which are relatively few in number worldwide. Instead of focusing on inspecting just a few facilities at random, the goal should be to inspect all BSL-4 facilities in each five-year period between BWC review conferences. This would create an expectation of regular inspections and would be fair because all states parties would know that they would be inspected. At each BWC conference, the states parties could agree to an international inspection team and a schedule, with inspections beginning after the 2022 conference and enduring over the following five years.

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[127] VECTOR is the common name for Russia's state-run BSL-4 laboratory.

[128] *Variola Virus Repository Safety Inspections*, WORLD HEALTH ORG., https://www.who.int/activities/variola-virus-repository-safety-inspections (last visited Jan. 28, 2022).

[129] *Id.*

[130] The United States Army Medical Research Institute of Infectious Diseases, for example. *See Biological Safety at USAMRIID*, U.S. ARMY MED. RSCH. INST. OF INFECTIOUS DISEASES https://www.usamriid.army.mil/biosafety/index.htm (Apr. 21, 2017).

The sample language could look as follows:

> **INSPECTIONS**
>
> **Each state party shall agree to allow an international inspection team access to its BSL-4 facilities once every five years. This team will inspect safety procedures and verify that research is for peaceful purposes and declared activities and agents match actual research conducted and declared.**

In developing the inspection team, states parties could look to the WHO to provide expertise on laboratory best practices and to find international experts with the experience and qualifications to conduct inspections. The likely source for these experts would be BSL-4 facilities worldwide. The experts already meet periodically, as evidence by the WHO meeting.[131] Choosing these experts will be critical to establishing the credentials and credibility of the inspection team. The states parties should identify experts within their own bioresearch facilities and select those who have the most knowledge of BSL-4 operations and could have the most impact. To promote legitimacy, it is important that no single country dominate the inspection team.[132] Each team should have a cross section of global experts who can inspect the labs free from governmental or national influence.

C. Implementation

The Draft Protocol recommended a robust investigation system within the proposed Organization for the Prohibition of Bacteriological (Biological) and Toxin Weapons.[133] This investigation mechanism would allow states parties to self-regulate, but the Executive Council could ultimately refer the most serious cases to the UNSC.[134] This outcome is similar to the current procedure in Article VI of the BWC.[135]

This article recommends establishing an independent implementation body similar the Draft Protocol's proposed Organization for the Prohibition of Bacteriological (Biological) and Toxin Weapons. This independent body

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[131] WORLD HEALTH ORG., *supra* note 102.

[132] For example, a team of majority Chinese experts inspecting the WIV would not serve the purpose of open and unbiased reporters, nor would a team of majority American experts inspecting the CDC.

[133] Draft Protocol, *supra* note 13, art. 16.

[134] *Id.*

[135] Biological Weapons Convention, *supra* note 1, art. VI.

is necessary to implement the facility inspections recommended above and to provide technical and administrative assistance to states parties. However, this body should not have a mandate to investigate violations and should instead focus its limited time and resources on inspections and technical assistance. The burden of fact-finding and building a case against an offending state party will fall largely on individual states, which can present that information to the UNSC through existing BWC processes. The goal of the recommendations is to begin to increase the independence and strength of the BWC. The modest, limited declarations and inspections recommended above could provide a basis for more dramatic changes in the future, including eventual investigations of violations by an independent body. For now, however, the independent body should function more like the Technical Secretariat proposed by the Draft Protocol, focusing on technical assistance and facility inspections.

D. Why Bother?

1. Recognize the Threat

The limited declare-and-inspect approach recommended above is notably less ambitious than the Draft Protocol recommendations. The agents and facilities covered are limited in scope, and it does not recommend an investigation mechanism other than the one already contained in the BWC. It is intended to be an initial step towards strengthening the BWC rather than the comprehensive reworking the Draft Protocol envisioned. But if the threat of cheating remains, why bother reforming the BWC at all? The simplest answer is that despite all its weaknesses, the BWC is the best way to coordinate international biosecurity efforts in an increasingly globalized world that relies on the free movement of goods, people, and information.

Even with increased disclosures and regular inspections, a state could still conduct offensive biological weapons research in secret. That does not mean that regulating biological weapons is hopeless, however. Because the BWC has never included an independent inspection or enforcement body, critics and cynics will be quick to note the unique challenges of enforcing the BWC while downplaying its benefits. This problem is particularly acute because the current cost of compliance with the BWC is almost non-existent, other than declaring that a state party's biological programs are for peaceful use.

Because the United States rejected the Draft Protocol, the proposal for new declarations and inspections is aligned with current U.S. national strategic priorities. It is also designed to be modest because there will likely be some warranted skepticism, and perhaps even bitterness, towards U.S. efforts in this area, given the last-minute decision to reject the Draft Protocol in 2001. While modest, it will accomplish two basic goals. First, it will create an enforceable standard and common awareness of which biological agents and toxins are the most dangerous; second, it will reinforce safety in the highest-containment laboratories worldwide. Creating an independent body tasked with technical implementation and inspections will establish an international center of expertise for biological threats.

By creating a common understanding of the select agents and toxins that are most dangerous to human and animal health, the declarations would raise the cost of compliance and discourage cheating. A state party could intentionally fail to make proper declarations, but any outbreak of disease from one of the listed agents would be met with increased scrutiny. This will also force states to take an accounting of the types of agents that are currently within their borders (assuming they have not done so already). It may have the additional benefit of identifying gaps in tracking these materials and allow closer regulation and scrutiny at a national level than before. Most importantly, it would solve the problem of the meaningless conference declarations that simply restate the international norm "condemn[ing] any use of biological agents or toxins other than for peaceful purposes at any time."[136] Although it has succeeded in creating and reinforcing the international norm against the use of biological agents and toxins in war, the BWC has not demanded concrete action from states parties. By focusing on the most dangerous substances, the proposed declarations would provide an incentive for state cooperation (i.e., internal security) and thus promote international cooperation in reducing the danger from the most toxic substances.

2. Reinforce Safety

There is no international standard for the features of a BSL-4 laboratory, nor is there a global organization that certifies high-containment laboratories.[137] Although there is consensus that certain substances should

[136] *Eighth Review Conference Final Document*, *supra* note 52.
[137] WORLD HEALTH ORG., *supra* note 102, at 4.

be contained in secure laboratories, states vary in defining high-containment facilities, with some distinguishing between animal and human containment levels. Even without specific agreement, the WHO has published guidelines, as has the United States, for its own laboratories.[138] Despite regional variations, there are some common features in BSL-4 laboratories:

> On a simplified level, all forms of maximum-containment laboratories have many commonalities. Design features include air handling units, breathing air systems for suit laboratories, supply and exhaust high-efficiency particulate air (HEPA) filters, material transport docks (dunk tanks, pass-through chamber, autoclaves), shower barriers, effluent treatment systems and built-in redundancy for critical systems.[139]

The recommended language above uses this language for inspections of all state party BSL-4 laboratories, with the goal of inspecting every laboratory every five years. These regular inspections will serve to ensure safety protocols and to discourage cheating and secret weapons development. This will have the additional benefit of reinforcing common safety standards and best practices across states parties because each of the approximately fifty known BSL-4 laboratories exist in BWC states, including three in China and one in Russia.[140]

V. The BWC and U.S. National Security

A. National Biosecurity

Despite its rejection of the Draft Protocol, the last twenty years have seen U.S. policymakers increasingly recognize the threat of both deliberate biological attacks from state and non-state actors and the threat of naturally occurring or accidental outbreaks of disease. One example is President George W. Bush's publication of a presidential directive on biodefense in 2004.[141] After the anthrax attacks in the early 2000s, Federal regulation of

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[138] *Id.*; CTRS. FOR DISEASE CONTROL & PREVENTION & NAT'L INSTS. OF HEALTH, *supra* note 98, at 51.
[139] WORLD HEALTH ORG., *supra* note 102, at 5.
[140] *Id.*
[141] WHITE HOUSE, HOMELAND SECURITY PRESIDENTIAL DIRECTIVE—10: DEFENSE FOR THE 21ST CENTURY (2004), *reprinted in* STAFF OF H. COMM. ON HOMELAND SEC., 110TH CONG.,

biological threats shifted in focus, more explicitly linking national security to both biological weapons and the threat posed by pandemic diseases.[142]

In 2009, the National Security Council under President Barack Obama published the *National Strategy for Countering Biological Threats*. The strategy introduced three lines of effort:

> (1) improving global access to the life sciences to combat infectious disease regardless of its cause;
> (2) establishing and reinforcing norms against the misuse of the life sciences; and
> (3) instituting a suite of coordinated activities that collectively will help influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences.[143]

The Obama strategy was guided by the assumption that "[t]he rapid detection and containment of, and response to, serious infectious disease outbreaks—whether of natural, accidental, or deliberate origin—advances both the health of populations and the security interests of States."[144] It also reaffirmed the United States' commitment to the BWC and explicitly mentioned "revitalizing" the convention, although it made no mention of the Draft Protocol.[145] Finally, it noted that

> [t]here are a relatively small number of high-risk pathogens and toxins that have properties which enable them to be used in a deliberate attack. . . . [I]t is reasonable to seek to reduce the risk by limiting ready access to known virulent strains of high-risk pathogens and toxins. In addition, the use of proper safety controls and practices is a key contributor to risk management.[146]

The tiered approach to declaring substances recommended above reflects the logic of President Obama's biosecurity strategy. Despite the Obama administration's commitment to the BWC, it explicitly rejected pursuing a BWC verification protocol in December 2009, with the Under

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COMPILATION OF HOMELAND SECURITY PRESIDENTIAL DIRECTIVES (HSPD) 57 (Comm. Print 2008).

[142] *See* Laura K. Donohue, *Pandemic Disease, Biological Weapons, and War*, *in* LAW AND WAR 84 (Austin Sarat et al. eds., 2014) (analyzing the constitutional problems with using the U.S. military to enforce public health measures).

[143] NAT'L SEC. COUNCIL, NATIONAL STRATEGY FOR COUNTERING BIOLOGICAL THREATS 3 (2009).

[144] *Id.* at 4.

[145] *Id.* at 19.

[146] *Id.* at 13.

Secretary for Arms Control and International Security stating, "The Obama administration will not seek to revive negotiations on a verification protocol to the Convention. We have carefully reviewed previous efforts to develop a verification protocol and have determined that a legally binding protocol would not achieve meaningful verification or greater security."[147]

In President Trump's 2018 *National Biodefense Strategy*, the trend of reframing natural and accidental disease outbreaks as a national security threat continued: "Enhancing the national biodefense enterprise will help protect the United States and its partners abroad from biological incidents, whether deliberate, naturally occurring, or accidental in origin."[148] The 2018 strategy also highlighted the risk of poorly secured biological agents and poor biocontainment that "could lead to an outbreak through a laboratory acquired infection or if a pathogen is accidentally released into the environment."[149] In a break with the general tone of President Trump's foreign policy, this document also recognizes the international scope of biological threats and commits to multilateralism, stating that the United States "will work with multilateral organizations, partner nations, private donors, and civil society to control disease outbreaks at their source by supporting the development and implementation of biodefense and health security capabilities, policies, and standards."[150] While this language is clearly at odds with the stance the Trump administration took regarding the WHO after the COVID-19 pandemic began, it shows that the United States recognized the international nature of the problem.[151]

In keeping with the previous national documents, the 2018 strategy notes that "[p]reventing acquisition of dangerous pathogens, equipment, and expertise for nefarious purposes, and maintaining the capability to rapidly control outbreaks in the event of a biological attack, are strategic interests of the United States."[152] Unlike the Obama-era strategy, however, the 2018 strategy makes little mention of the BWC, other than to note its existence

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[147] Ellen Tauscher, Under Sec'y for Arms Control & Int'l Sec., Address to the Annual Meeting of the States Parties to the Biological Weapons Convention (Dec. 9, 2009).
[148] WHITE HOUSE, *supra* note 2, at 1.
[149] *Id.* at 2.
[150] *Id.* at 3.
[151] *See* Christina Morales, *Biden Restores Ties with the World Health Organization That Were Cut by Trump*, N.Y TIMES (Jan. 20, 2021), https://www.nytimes.com/2021/01/20/world/biden-restores-who-ties.html (discussing differences in approach to the World Health Organization between the Trump and Biden administrations).
[152] WHITE HOUSE, *supra* note 2, at 2.

and obligations.[153] The trend in both documents is a focus more on domestic biodefense than on international partnership. This is a mistake because a stronger BWC offers many benefits to the United States and the international community. The Biden administration has already declared that the United States will "revitalize and expand global health and health security initiatives for all nations to reduce the risk of future biological catastrophes, whether naturally occurring, accidental, or deliberate."[154] More recently, the National Security Advisor released a statement ahead of the Ninth Review Conference signaling a shift toward collective action:

> [T]he United States will also be proposing immediate action at the Review Conference on a number of practical measures that will build capacity to counter biological threats and benefit BWC members. The United States is committed to working with all States Parties to strengthen the BWC, and with all responsible nations to end the development of biological weapons and the threat they pose.[155]

Those practical measures should include some form of declarations and lab inspections and a willingness to reengage with the spirit of the Draft Protocol, rather than continuing to reject it.

The threat of intentionally developed biological weapons remains real for the United States, as does the risk of natural or accidental biological incidents. China, Russia, Iran, and North Korea likely have some level of biological weapons capability that could threaten the United States,[156] and all four happen to be among the greatest threats to U.S. national security.[157] On 15 January 2021, the State Department explicitly accused China of violating the BWC in Wuhan, declaring that, "[d]espite the WIV presenting itself as a civilian institution, the United States has determined that the WIV has collaborated on publications and secret projects with China's military. The WIV has engaged in classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017."[158]

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[153] *Id.* at 14.
[154] WHITE HOUSE, INTERIM NATIONAL SECURITY STRATEGIC GUIDANCE 12 (2021).
[155] Statement by Jake Sullivan, *supra* note 18.
[156] U.S. DEP'T OF STATE, *supra* note 16, at 56.
[157] WHITE HOUSE, *supra* note 17.
[158] *Fact Sheet: Activity at the Wuhan Institute of Virology*, *supra* note 6.

B. The BWC Supports U.S. National Security Goals

Just as U.S. policymakers have come to see both natural and intentional biological incidents as threats to national security, the BWC can be viewed as more than just an arms treaty. Although it focuses primarily on banning biological weapons, it also functions as a forum for discussing biosecurity. As stated by the United Nations Office for Disarmament Affairs:

> Besides addressing disarmament and security issues, the BWC also supports the promotion of the peaceful uses of biological science and technology and thereby helps to prevent the global spread of diseases. Article X of the BWC requires States Parties to "facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information" for the use of biological agents and toxins for peaceful purposes.
>
> . . . .
>
> The BWC also helps to build capacity to respond to disease outbreaks and provides a multilateral framework in which States Parties can meet regularly to advise and assist each other in developing their national capacities in such areas as disease surveillance, detection and diagnosis; biosafety and biosecurity; education, training and awareness-raising; emergency response; and legal, regulatory and administrative measures.[159]

The goals of the 2018 *National Biodefense Strategy* align with the functions of the BWC. It is the exact type of multilateral instrument with which the United States pledges to work to combat biological threats, yet the document refers to the BWC only in appendices.[160] This is a missed opportunity to connect the ends of U.S. policy to an obvious means to achieve them.

The BWC presents several benefits to advance U.S. security. First, it is already well established and has a history of debate and cooperation spanning decades. Second, it promotes steady engagement on a critical issue through regular meetings. Finally, it is currently somewhat integrated with the WHO and the United Nations, which means efforts to improve the BWC

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[159] UNITED NATIONS OFF. OF DISARMAMENT AFFS., *supra* note 47, at 11.
[160] *See generally* WHITE HOUSE, *supra* note 2.

can influence other organizations working with biological security.[161] Rather than seeing the BWC as a footnote to unilateral efforts, the United States can advance its national security interests by recognizing the BWC for what it is: the only well-established international forum dedicated to eliminating biological weapons and promoting biosecurity, which could be a key part of improving U.S. biosecurity through international cooperation.

C. Wuhan Hypothetical

The ongoing COVID-19 pandemic provides an apt example of how regular inspections and declarations could increase biosecurity and improve public health, both domestically and internationally. The WIV is a Chinese BSL-4 laboratory located near the suspected outbreak site. After SARS outbreaks in the early 2000s, the Chinese government began to expand the laboratory in 2005, intending for it to "become the prevention & control research and development center for China's emerging infectious diseases, virus culture collection centers and WHO reference laboratory, which shall play a basic and technical role in China's emerging infectious diseases prevention and control, and biosafety."[162]

As the outbreak gained global attention and concern in February 2020, the WHO created a "joint mission" involving experts from multiple countries, including the United States and China. The goal of the mission was "to rapidly inform national (China) and international planning on next steps in the response to the ongoing outbreak of the novel coronavirus disease (COVID-19) and on next steps in readiness and preparedness for geographic areas not yet affected."[163] The joint mission identified some basic assertions that are now widely known, even if disputed, such as that COVID likely transferred to humans from an animal source and that large-scale precautions like social distancing and wearing masks could slow the spread of the virus.[164]

In January 2021, the WHO sent a team to investigate the origins of the virus amidst an environment of widespread distrust and speculation.[165] In

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[161] UNITED NATIONS OFF. OF DISARMAMENT AFFS., *supra* note 47, at 12.

[162] *About WIV*, WUHAN INST. OF VIROLOGY, http://english.whiov.cas.cn/About_Us2016/Brief_Introduction2016 (last visited Jan. 28, 2022).

[163] WORLD HEALTH ORG., *supra* note 5, at 3 (citation omitted).

[164] *Id.*

[165] The final report was completed on 30 March 2021. WORLD HEALTH ORG., WHO-CONVENED GLOBAL STUDY OF ORIGINS OF SARS-COV-2: CHINA PART (2021). Some of this

the final week of President Trump's presidency, the State Department issued a strong statement condemning the Chinese government's secrecy surrounding the outbreak.[166] The statement mentioned longstanding doubts about China's compliance with the BWC and the fact that China had ruled out the possibility that the outbreak could have originated with a laboratory outbreak at the WIV.[167] By March 2021, with the preliminary report pending, the WHO joint study team came under heavy criticism for perceived bias towards the Chinese animal origin theory and the lack of transparency about is procedures—many of the same concerns raised by the State Department in January.[168]

A group of international medical experts was so concerned that it issued an open letter to the international community, in which they claimed that the study could not be trusted because it was not equipped with the proper expertise, data, or resources to reach an unbiased conclusion of the pandemic's origins.[169] The letter cited concerns that the animal origin theory had been accepted without any real data to confirm it and that the lab accident hypothesis had not been seriously considered.[170] Soon after, the WHO team abandoned its plan to release an interim report; when the report was finally released in March 2021, it was inconclusive about the origins of the virus.[171] The report has been tainted by the intense distrust rampant in the international community and by the nagging doubt that the team was not properly resourced, unbiased, and permitted to access pertinent information. Even the United States intelligence community is divided on the likely origins of the virus, and the true cause of the virus will likely remain unknown.[172] This political tension has come at great cost to efforts to

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distrust has been fueled by the United States' accusations against China, longstanding suspicions that China has not abandoned its biological weapons program, and China's refusing access and denying any culpability in the origins of the disease. *See* John Sudworth, *Covid: Wuhan Scientist Would 'Welcome' Visit Probing Lab Leak Theory*, BBC (Dec. 21, 2020), https://www.bbc.com/news/world-asia-china-55364445.

[166] *Fact Sheet: Activity at the Wuhan Institute of Virology*, *supra* note 6.

[167] *Id.*

[168] Betsy McKay et al., *WHO Investigators to Scrap Plans for Interim Report on Probe of Covid-19 Origins*, WALL ST. J. (Mar. 5, 2021), https://www.wsj.com/articles/who-investigators-to-scrap-interim-report-on-probe-of-covid-19-origins-11614865067.

[169] Colon D. Butler et al., *Open Letter: Call for a Full and Unrestricted International Forensic Investigation into the Origins of COVID-19* (Mar. 4, 2021), https://int.nyt.com/data/documenttools/covid-origins-letter/5c9743168205f926/full.pdf.

[170] *Id.*

[171] WORLD HEALTH ORG., *supra* note 165, at 6–10.

[172] OFF. OF THE DIR. OF NAT'L INTEL., UPDATED ASSESSMENT ON COVID-19 ORIGINS (2021).

understand the origin of the disease and prevent a future pandemic: the lab's considerable expertise and experience with coronaviruses has become a source of great suspicion rather than a potential asset to be leveraged in the global fight against the virus.

Imagine that the proposed changes to the BWC had been in effect when COVID-19 emerged in late 2019. If international teams agreed upon by China and the other states parties had been allowed to inspect the WIV, there would be a baseline of knowledge and trust about what occurred there. Because the WIV is a BSL-4 laboratory working with coronaviruses, China would have been required to declare the nature of the research done at the facility, specifically its coronavirus research. There would already be a baseline of public international disclosure for analysis and comparison. There would also be a set of facts on the ground, resistant to political spin and manipulation. Perhaps this record would encourage the Chinese government to be more forthcoming about the origins of the virus and make it more difficult for political leaders in the United States to make claims about the origins of the disease for geopolitical reasons. Rather than peeling back layers of mistrust and suspicion to get to the truth, the international community could benefit from a shared understanding of a threat and act accordingly. An international body perceived as independent could ease tensions and act as a neutral arbiter for the benefit of all.

The inspections proposed in this article would not eliminate tension and distrust between the United States and China, but they could go a long way toward creating a shared understanding of biological threats and capabilities. Since its inception, the BWC has allowed states to make low-cost claims of compliance, with little chance of being exposed or held accountable for abuses. If the WIV had been subject to annual international inspections, there would be a history and an understanding that could build mutual trust and confidence. There would be a factual basis and record against which to assess the conspiracy theories and claims of governments. Inspection reports could serve as a guarantee against rampant speculation and finger pointing in the international community, especially if inspection teams contained multi-national, well-respected experts who the world perceived as unbiased public health officials. This type of international cooperation among peers is not some unattainable, utopian ideal—it already happens between Russia and the United States in smallpox laboratories. Even among competitors and state rivals, cooperation to stop a global pandemic can occur, and the changes to the BWC would facilitate that.

VI. Conclusion

States parties will meet at the ninth BWC review conference that is planned for summer 2022.[173] This will be the first meeting since the outbreak of COVID, with the full awareness of the massive economic and social costs of a global pandemic. Rather than the usual norm-reinforcing declarations against offensive biological weapons programs, the United States should lead an effort for a new verification protocol to increase transparency and accountability for biological research. The recent interim *National Security Strategic Guidance* recognizes both the need for American leadership and that the global nature of biological threats requires international cooperation:

> Recent events show all too clearly that *many of the biggest threats we face respect no borders or walls, and must be met with collective action*. Pandemics and other biological risks, the escalating climate crisis, cyber and digital threats, international economic disruptions, protracted humanitarian crises, violent extremism and terrorism, and the proliferation of nuclear weapons and other weapons of mass destruction all pose profound and, in some cases, existential dangers. None can be effectively addressed by one nation acting alone. And none can be effectively addressed with the United States on the sidelines.[174]

Given the complexity of the Draft Protocol and the limited organizational resources of the BWC secretariat, the best way ahead is to draw inspiration from the spirit of the Draft Protocol, focusing on limited declarations of the most dangerous biological agents and toxins and on limited inspections of high-containment facilities. The BWC has succeeded in upholding a strong norm against the use of biological weapons in war for almost fifty years, but in the age of the global pandemic, the world needs more. The states parties, led by the United States and sobered by the toll of COVID-19, should come to the ninth review conference in August 2022 with a renewed dedication to spare no effort to minimize the risk of biological weapons.

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[173] UNITED NATIONS OFF. OF DISARMAMENT AFFS., *supra* note 47.
[174] WHITE HOUSE, *supra* note 154, at 7.