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**Addressing the Spectrum of Biological Risks:
A Policy Agenda for the United States**

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Testimony before the House Committee on Foreign Affairs,
Subcommittee on Terrorism, Nonproliferation, and Trade
*National Strategy for Countering Biological Threats:
Diplomacy and International Programs*
March 18, 2010

Chairman Sherman, Ranking Member Royce, and distinguished members of the Subcommittee, thank you for the invitation to appear before you today to discuss the effectiveness of current and planned U.S. international policies and programs to address biological threats, particularly bioterrorism.

Last November, the Obama Administration released a *National Strategy for Countering Biological Threats*, which provides a comprehensive roadmap for addressing the full range of biosecurity and infectious-disease challenges facing the United States. Although the strategy document sets out policy guidelines, it states that their implementation, including specific actions to be taken by Federal agencies, “will be directed separately.” Thus, the challenge facing the Administration and Congress in the months ahead will be to translate the broad guidelines in the National Strategy into a set of concrete policy initiatives, and to give them the political and budgetary support they will require for effective implementation.

In my testimony today, I will discuss ways to build on the strengths of the National Strategy and will make recommendations for translating the guidelines into action and for filling a number of gaps.

A Holistic, Preventive Approach to Biological Threats

The National Strategy takes a holistic approach to infectious-disease threats by viewing them as a spectrum that encompasses (1) natural emerging infections such as SARS and avian influenza, (2) the accidental release of pathogens from a research laboratory, and (3) the deliberate use of disease as a weapon by states and non-state actors such as criminals and terrorist organizations. In this way, the strategy document integrates public health and security concerns into a single paradigm. While it is true that certain attack scenarios involving exotic or bioengineered pathogens would be recognized almost immediately as bioterrorism, in other cases

it might not be clear for days or even weeks whether the cause of an outbreak was natural or deliberate. Fortunately, many of the same detection and response measures, such as disease-surveillance systems and the distribution of antibiotic drugs, are effective regardless of the source. Integrating the public health and security dimensions of the infectious-disease threat into a single paradigm therefore makes sense from a policy standpoint because it promotes efforts to reinforce the global public-health infrastructure in ways that bolster U.S. defenses against both natural epidemics and bioterrorist attacks.

The National Strategy also provides some needed balance to the nation's biosecurity posture by placing a greater emphasis on preventive measures to reduce the risks of biological weapons proliferation and terrorism. The Bush administration focused its biodefense efforts on strengthening domestic preparedness and response capabilities through programs such as BioShield and BioWatch, while tending to write off efforts on the prevention side of the equation—particularly those involving multilateral engagement—as too difficult. The Obama administration, to its credit, has recognized the importance of nipping biological threats in the bud before they can materialize fully.

Although terrorist organizations such as al-Qaeda continue to be interested in using standard biological agents such as the anthrax bacterium, which is relatively easy to obtain and weaponize, the National Strategy document emphasizes the dynamic nature of biological threats, including the potential risks associated with emerging biotechnologies. Synthetic genomics, for example, provides the technical capability to synthesize long DNA molecules from scratch and assemble them into a genome, the genetic blueprint of an organism. This feat has already been accomplished for several viral pathogens, including poliovirus, the 1918 pandemic strain of influenza virus, and the SARS virus, and it is only a matter of time before it becomes feasible for larger, more complex biological agents such as the smallpox virus. The ability to synthesize dangerous viral pathogens from scratch raises security concerns because it might enable sophisticated terrorist groups to circumvent stringent controls on “select agents” of bioterrorism concern, such as hemorrhagic fever viruses. Commercial gene-synthesis providers now exist in countries around the world, including China and Germany, so any effective biosecurity regime for synthetic genomics will have to be harmonized internationally, a task requiring outreach and coordination with foreign governments and companies.

Another worrisome development not mentioned in the National Strategy document is the rise of the “open-source biology” and “do-it-yourself-biology” movements, which seek to make sophisticated biotechnologies such as genetic engineering and synthetic biology readily available to amateurs and hobbyists, including those without formal scientific training. Some of these enthusiasts may have benign intent but may not be fully aware of the potential hazards and security risks associated with the new genetic technologies, while others may be aspiring “biohackers” who are either reckless or malicious. Because microbes are alive and self-replicating, the inadvertent or deliberate release of an engineered microorganism could have serious consequences for the environment and public health. To manage these risks, the U.S. government should undertake a number of measures. In addition to promoting a “culture of responsibility in the life sciences,” it will be necessary to introduce effective oversight measures, biosafety and biosecurity training programs, and voluntary or mandatory guidelines to ensure that powerful biotechnologies such as synthetic biology are employed in a safe and secure manner. It should be possible to devise prudent measures to prevent misuse without impeding legitimate research or curtailing beneficial applications.

Revitalizing the Biological Weapons Convention

The Biological Weapons Convention (BWC) bans the development, production, stockpiling, and transfer of biological and toxin warfare agents, as well as delivery systems specifically designed for their dispersal, and thus complements the 1925 Geneva Protocol banning the use of such weapons in war. At present, 163 countries are parties to the BWC, and 13 have signed but not ratified it; an additional 19 states have neither signed nor ratified. Since it entered into force 35 years ago, the BWC has embodied the norm against the use of disease as a weapon. Yet because it was negotiated at the height of the Cold War, when the Soviet Union rejected on-site inspections as tantamount to espionage, the Convention lacks any formal verification measures. As a result, it is widely viewed as a weak instrument whose lack of teeth has enabled countries such as the Soviet Union and Saddam Hussein's Iraq to violate their treaty commitments without being held to account.

Unfortunately, the task of verifying the BWC is exceedingly difficult for a number of reasons. First, the fact that biological pathogens and production equipment are "dual-use," meaning that they can be used for either peaceful or hostile purposes, greatly complicates the task of distinguishing legitimate from prohibited activities. Second, although the BWC allows the development of defensive measures, the line between defensive and offensive work can be hard to define and often depends on an assessment of intent. Third, tens of thousands of civilian vaccine plants, industrial fermentation facilities, and legitimate biodefense centers around the world are potentially capable of producing significant quantities of biowarfare agents, making it extremely challenging to ferret out the small fraction of sites that are actually engaged in illicit activity. Finally, the highly intrusive inspections of commercial biotechnology plants that would be required to detect violations of the BWC could put at risk valuable proprietary information, such as genetically engineered microbes used to produce certain drugs and vaccines.

These considerations helped to persuade the Bush administration in July 2001 to reject a draft protocol, negotiated over the previous six and a half years, that was designed to bolster the BWC with a system of mandatory declarations and on-site inspections. Also to blame for the failure of the talks were efforts by some states to exploit the protocol negotiations to weaken the Convention itself. Russia, for example, insisted that key terms in the BWC be defined narrowly in an apparent bid to create "safe harbors" for illicit biological weapons development, while Iran, Pakistan, and a few other developing countries sought to dismantle national export controls (harmonized by the Australia Group) on dual-use materials and equipment relevant to biological weapons, on the grounds that such controls "discriminated" against developing countries. Thus, although the U.S. rejection of the draft BWC protocol precipitated the collapse of the negotiations, other states shared responsibility for creating the impasse that ultimately doomed the talks.

The Obama administration, after weighing the costs and benefits of reviving the BWC protocol, announced last December that it had decided against doing so. Nevertheless, the administration's current assessment that BWC verification is not feasible in practical terms is no excuse for inaction or complacency. To move beyond the legacy of the failed protocol negotiations, the United States must think seriously about alternative ways of revitalizing the BWC and building confidence in compliance. According to the State Department's most recent arms control compliance report, published in 2005, the U.S. intelligence community suspects four BWC member states (China, Iran, North Korea, and Russia) of violating their treaty

commitments. Yet the sole measure mentioned in the National Strategy for addressing compliance concerns—bilateral consultations through confidential diplomatic channels—appears unlikely to make much of a difference.

Bolder, more innovative measures will be required to build confidence in BWC compliance and deter violations. For example, the United States could propose a mechanism for “consultative visits” under Article V of the Convention to address compliance concerns at specific facilities. Such visits would be initiated at the request of a member state and carried out by national experts on a bilateral or multilateral basis; the visits would not be designed to meet the rigorous standards of verification but would seek instead to increase transparency and build confidence. Because the conduct of a consultative visit would require the voluntary cooperation of the host country, BWC member states wishing to resolve concerns and ambiguities about their compliance would presumably cooperate with a visit request, while those countries with something to hide would probably refuse—although they would pay a political price by doing so.

I will now discuss a number of other measures that could help to reinforce the norms embodied in the BWC and enhance global biosecurity.

Strengthening Global Disease Surveillance

A perennial source of North-South tensions in BWC-related forums is Article X of the Convention, which requires states parties to cooperate in the peaceful applications of biotechnology and to facilitate trade and technology transfer for this purpose. Several BWC member states, led by Iran, have argued that Article X requires the removal of export controls on dual-use biotechnology equipment, yet the Australia Group countries have rejected this claim on the grounds that the BWC obligates them not to aid or abet biological weapons proliferation. One way for the United States and its allies to respond to demands from developing countries for technical assistance without weakening the dual-use export control regime would be to expand global networks for infectious disease surveillance and response under the auspices of the World Health Organization (WHO). Not only would such measures help to meet U.S. obligations under Article X, but they would also directly enhance U.S. national security.

Congress has long tended to view U.S. assistance to the WHO and individual developing countries in combating infectious diseases as a form of foreign aid, divorced from critical U.S. national security concerns. In today’s globalized world, however, that perception is increasingly myopic. National borders and oceans no longer pose a barrier to the spread of epidemics: an individual in Africa or Asia incubating a serious viral disease can travel by air to the United States within 24 hours and start transmitting it to others. Indeed, pandemic infections such as SARS and the H1N1 strain of influenza have circled the globe in a matter of months. Although the current flu pandemic has fortunately proved to be less virulent than was initially feared, we may not be as lucky the next time.

Given these facts, the United States can no longer afford to treat epidemics in developing countries as “out of sight, out of mind.” As the globe continues to shrink, an outbreak of serious epidemic disease anywhere in the world poses potential risks to Americans here at home. Accordingly, global networks for infectious disease surveillance and response provide an “extended defense perimeter” for the United States by making it possible to detect and snuff out epidemics—whether natural or human-caused—before they reach U.S. shores. Existing disease surveillance networks still contain many gaps in coverage, however, preventing the timely detection and containment of outbreaks close to the source.

The new realities of public health in a globalized world are finally beginning to sink in. In May 2005, the 192 member countries of the WHO unanimously approved a major revision of the International Health Regulations (IHR), which provide the international legal framework for prevention and response to the cross-border spread of epidemics and other public health emergencies. The updated regulations set new standards for transparency and cooperation, including the timely reporting to the WHO of all “public health emergencies of international concern” that could potentially affect more than one country. Significantly, such incidents could include deliberate releases of biological, chemical, or radiological materials. The revised IHR also require all WHO member states to establish national surveillance and response capabilities for the prompt detection, reporting, and control of public health emergencies of international concern, and expand the WHO Secretariat’s powers to monitor and respond to public health emergencies regardless of origin.

The revised IHR are a major step toward global public health preparedness against the full range of biological threats, from natural emerging infections to bioterrorism. Nevertheless, because many developing countries lack the technical and financial resources to fulfill the IHR mandate that they establish effective national surveillance and response capabilities, the United States and other advanced countries must be prepared to help out. For example, Title III, Subtitle B of the Weapons of Mass Destruction Prevention and Preparedness Act (S. 1649), introduced last year by Senators Joe Lieberman (I-Conn.) and Susan Collins (R-Maine), calls for expanding U.S. assistance for this purpose. Although channeling the bulk of U.S. technical and financial assistance through the WHO rather than bilaterally would entail some loss of control, it would give the effort much greater international credibility.

Another major gap in current global disease surveillance systems arises from the fact that many infectious diseases are “zoonotic,” meaning that they infect both animals and people. In the case of natural viral infections, such as West Nile encephalitis and avian influenza, wild birds are “sentinel species” that typically become infected before humans and thus provide early warning of an impending epidemic. Similar sentinel species exist for diseases that pose bioterrorism concerns, such as anthrax, tularemia, and plague, yet disease-surveillance systems for animals are significantly less developed than those for humans. It is therefore vital for international health and security to expand the monitoring of zoonotic infections in animals and to integrate them with human disease surveillance networks.

Increasing the Transparency of Biodefense Research

A critical element of building confidence in BWC compliance is to increase the transparency of biodefense research programs, which have expanded dramatically in the United States and other countries since the terrorist attacks of 2001 and could theoretically serve as a cover for offensive bioweapons development. Enhanced transparency is in the U.S. interest for two reasons: (1) it offers greater insight into the BWC-related activities of other countries, thereby providing greater confidence that they are complying with their treaty obligations, and (2) it helps to mitigate international suspicions about U.S. biodefense programs that might drive other nations to pursue questionable research. Past transparency exercises have also provided some intelligence windfalls. During the early 1990s, for example, visits by Soviet officials to Fort Detrick, Dugway Proving Ground, and other U.S. biodefense sites under the U.S.-UK-Russian Trilateral Agreement exposed as false the Soviet claim that the United States had

secretly maintained an offensive bioweapons program, and led directly to the defection of Kanatjan Alibekov (aka Ken Alibek), a top Soviet bioweapioneer, in the fall of 1992.

At present, the BWC Confidence-Building Measures (CBM) process is the only formal international mechanism for increasing the transparency of national biodefense activities. Under this process, BWC member states are politically but not legally bound to submit specific data about treaty-relevant facilities and activities on an annual basis, including maximum-containment laboratories and unusual outbreaks of infectious disease. Unfortunately, less than half of BWC states parties participate in the CBM process, and many of the submissions are incomplete or inaccurate. In addition, the CBM declaration forms were last revised in 1991, yet rapid scientific and technological advances have rendered them increasingly obsolete. To address these problems, the United States should work with other nations to conduct a thorough review and updating of the CBM mechanism. Activities that might be covered by the updated declarations include studies involving the aerosolization of pathogens and research that could enhance the military potential of biological agents.

Another urgent requirement is for improved oversight of national biodefense programs. Although the BWC allows states parties to conduct defensive research, a lack of transparency about whether or not certain research activities are treaty-compliant can generate corrosive suspicions on the part of other countries. A particularly controversial area of the U.S. biodefense program, for example, involves classified “science-based threat characterization” research at the Department of Homeland Security’s National Biodefense Analysis and Countermeasures Center (NBACC) at Fort Detrick in Maryland. Such research seeks to fill “knowledge gaps” about certain pathogens and toxins of biowarfare or bioterrorism concern, including genetically modified agents, in order to guide the development of medical countermeasures. Some observers contend, however, that these efforts blur the line between permitted and prohibited activities under the BWC.

The Departments of Defense and Homeland Security and the Office of the Director of National Intelligence have all established oversight mechanisms to ensure that the biodefense research projects that they conduct or sponsor comply with the BWC. Nevertheless, guidelines and review procedures vary from agency to agency, and there is no established process for high-level, interagency oversight of activities that raise significant BWC compliance concerns. Despite the shortcomings of the U.S. treaty compliance review mechanism, it is still superior to that of other countries with large biodefense programs, such as Russia and China, whose intentions and activities in this field remain largely opaque. Actions by the United States to increase the oversight and transparency of its own biodefense programs would put the U.S. government in a stronger position to demand similar openness from others.

Expanding U.S. Biological Engagement Programs

Biological engagement programs can also reinforce the goals of the BWC. The Defense Department’s Biological Threat Reduction Program (BTRP) and the State Department’s Global Threat Reduction Program (GTRP) have long provided financial and technical assistance to improve biosafety and biosecurity at facilities in the countries of the former Soviet Union. In recent years, however, the BTRP and other threat-reduction programs have largely disengaged from Russia because of bureaucratic and political difficulties in dealing with the Russian government, which has refused requests for greater transparency at former biological weapons facilities, particularly those controlled by the Ministry of Defense. As the U.S. National Research

Council has pointed out, however, “There are considerable risks entailed in not participating in research engagement activities but instead simply remaining on the sidelines and speculating as to what may be taking place.” Accordingly, the United States should seek to reengage with the Russian biodefense institutes by offering to conduct collaborative research in areas of mutual interest.

Biological threat-reduction programs should also be expanded globally. In recent years, the State Department’s Biosecurity Engagement Program has initiated pilot programs outside the former Soviet Union, with an emphasis on countries such as Indonesia, Pakistan, and the Philippines, that harbor collections of dangerous pathogens and have active Islamist insurgencies that have both the intent and the capability to acquire biological weapons. Nevertheless, the State Department lacks sufficient resources to assess biological threats in other parts of the world, such as sub-Saharan Africa. The effectiveness and sustainability of U.S. bioengagement programs has also suffered from a gap between U.S. biosecurity goals and the needs and priorities of the recipient states, which are usually more concerned with natural infectious disease threats than with the prevention of bioterrorism. While securing collections of dangerous pathogens to keep them out of the hands of terrorists is important, the United States also needs to develop an appreciation for how combating natural epidemics is relevant to U.S. national security. Accordingly, Congress should increase funding for biological engagement in countries around the world that face biosecurity threats, while transitioning from U.S.-directed assistance programs to true partnerships that focus on areas of interest to both sides.

Strengthening the UN Mechanism to Investigate Alleged Use

The Chemical Weapons Convention, which entered into force in 1997, includes a set of multilateral procedures for investigating allegations of chemical weapons use. In the biological weapons area, however, the failure to conclude the BWC protocol, which would have included field-investigation measures, means that the only option for investigating the alleged use of biological weapons is a long-standing mechanism under the auspices of the United Nations Secretary-General. During the early 1980s, a series of resolutions in the UN General Assembly and the Security Council gave the Secretary-General the authority to launch field investigations of the alleged use of biological or chemical weapons in violation of the 1925 Geneva Protocol. Such an investigation can be launched either on the Secretary-General’s own initiative or at the request of a UN member state. About a dozen UN field investigations took place during the 1980s and early 1990s in Southeast Asia, Iran, Iraq, Mozambique, and Azerbaijan, but since then the mechanism has been inactive.

In 2006, the UN General Assembly urged the Secretary-General to update the nearly 20-year-old roster of experts and reference laboratories that can be made available on short notice and to revise the technical guidelines for conducting investigations of alleged use. Although the UN updated the roster of experts in 2008, it made little progress in revising the investigation procedures because of objections from some countries, notably China. Another problem is that the UN lacks the resources to rapidly field a team of suitably trained and equipped investigators. Instead, the Secretary-General must hastily assemble a team from the experts provided by member states on an *ad hoc* basis. Such individuals have varying degrees of expertise and training and no previous experience of working together, reducing their effectiveness.

In order to remedy these problems, the United States should take the lead in updating and strengthening the Secretary-General’s field investigation mechanism. To that end, the State

Department should work closely with the UN Secretariat, other member states, and the International Criminal Police Organization (Interpol) to train a multinational cadre of experts capable of investigating complaints of biological weapons use, create logistical arrangements for conducting short-notice field investigations anywhere in the world, and adopt validated methods for the collection, chain-of-custody, and analysis of environmental and biomedical samples. The United States should also offer scientific and technical support to UN investigation teams, including expertise in microbial forensics and other advanced investigative techniques. Creating an effective UN mechanism for investigations of alleged use would have an important deterrent effect by making it more likely that a covert biological attack will be attributed to the perpetrator, be it a state or a non-state actor.

One drawback of the Secretary-General's mechanism is that it focuses exclusively on investigations of biological weapons *use* in violation of the Geneva Protocol and does not address the earlier phases of the weapons acquisition process prohibited by the BWC. Accordingly, when political conditions permit, it would be desirable for UN member states to broaden the Secretary-General's mechanism to authorize investigations of alleged breaches of the BWC, including the illicit production of biological warfare agents.

Preparing for the Seventh BWC Review Conference

A critical event for advancing U.S. biosecurity objectives will be the Seventh Review Conference of the BWC, which will convene in late 2011 in Geneva, Switzerland. This comprehensive review of the treaty's implementation will be a "make-or-break" political opportunity for the United States.

Ever since the collapse of the BWC protocol negotiations in 2001, the treaty regime has suffered from a lack of U.S. leadership and a sense of stasis, even as new threats gather on the horizon. In late 2002, BWC member states agreed to hold annual meetings devoted to exchanges of information on national measures to enhance biosecurity and prevent bioterrorism. This "intersessional work program," which has now gone on for seven years, has addressed such topics as penal legislation, pathogen security measures, infectious disease surveillance, and scientific codes of conduct, and this year's meetings will discuss investigations of alleged use. The intersessional process has been modestly successful by keeping BWC member states focused on biosecurity issues, engaging a variety of civil-society organizations, and smoothing ruffled feathers caused by the undiplomatic way the Bush administration rejected the BWC protocol in 2001. Nevertheless, it is clear that the current work program is approaching the end of its useful life and must be replaced in 2011 with a new and more ambitious process.

At next year's Seventh BWC Review Conference, the United States will have a unique opportunity to give new vitality and direction to the Convention. At the same time, the U.S. delegation will have to navigate some potentially treacherous political shoals. It is likely that several BWC member states, including Iran, Pakistan, India, and Russia, will seek to revive the BWC protocol negotiations in order to pursue their negative agenda of attempting to weaken the Convention itself. Other states, including some U.S. allies, have better intentions and are eager to return to the protocol talks as a way of moving forward after a long period of political drift. Accordingly, if the United States wants to make sure that proponents of the protocol do not hijack the review conference, it will have to offer an alternative package of bold and compelling measures to strengthen the BWC. Such a package might include credible measures to increase the transparency of national biodefense programs and to address BWC compliance concerns,

along with a set of cooperative, multilateral approaches for combating the full spectrum of biological threats.

Because developing and vetting an ambitious package of policy initiatives within the U.S. government will be a long and arduous process, now is the time for the State Department, the lead agency for the Seventh Review Conference, to get the ball rolling. It will also be necessary to coordinate with close allies to generate international political support for U.S. proposals. At present, however, the State Department is embroiled in an internal reorganization of its arms control and nonproliferation bureaus, creating a temporary leadership vacuum. Given the high stakes involved in the review conference, it is imperative that the department resolve the internal dispute over which bureau is responsible for the BWC and begin preparing for 2011 as soon as possible.

Another important task for the Seventh Review Conference will be to address the “institutional deficit” of the BWC. Whereas the Chemical Weapons Convention has a highly effective implementing body in the Organization for the Prohibition of Chemical Weapons (OPCW) in The Hague, the BWC lacks even a small professional secretariat. The last BWC review conference in 2006 established an Implementation Support Unit (ISU) consisting of three people at the UN Office in Geneva, but this entity has limited authority and a temporary mandate that must be renewed by the member states in 2011. The bipartisan Commission on the Prevention of WMD Proliferation and Terrorism recommended in 2008 that the United States “support an appropriate increase in the size and stature” of the ISU so that it can serve as “as an effective facilitator and coordinator for an expanded set of BWC activities and initiatives.” The Obama administration should accept this advice and push to make the ISU permanent, while expanding its staff and responsibilities.

Finally, although BWC verification measures are currently off the table, the United States should be open to exploring how advanced biotechnologies might be applied in the future to address the task of biological verification. To this end, the Seventh Review Conference could mandate the creation of an expert scientific body to examine the strengths and limitations of advanced biotechnologies such as biosensors, microbial forensics, and bioinformatics for verification purposes. A previous effort to evaluate possible biological verification measures from a scientific and technical standpoint, known as VEREX, took place from 1992 to 1994. Because this effort involved experts provided by BWC member governments, however, it proved to be overly politicized. To avoid this pitfall, any technical assessment of possible biological verification technologies should be conducted by an objective, non-political entity, such as a consortium of national academies of science. The evaluation process must also include the active participation of representatives from the biotechnology and pharmaceutical industries to ensure that commercial proprietary information can be adequately protected.

Conclusions

The Obama administration’s *National Strategy to Counter Biological Threats* describes the full spectrum of biological threats facing the nation and suggests a comprehensive approach for combating them. Nevertheless, the real test of the administration’s seriousness in addressing these threats will be its ability to convert the broad policy guidelines in the strategy document into a set of concrete initiatives. Much as President Obama’s Prague speech of April 5, 2009 provided the overall vision and political impetus for the administration’s ambitious nuclear disarmament and nonproliferation agenda, a “Prague II” speech devoted to biosecurity,

infectious disease, and public health would demonstrate that the White House is prepared to allocate political energy and budgetary resources to this set of issues. The administration might also consider hosting an international Biological Security Summit, modeled after next month's Nuclear Security Summit, to help build a global consensus behind the U.S. proposals. In any event, implementing the *National Strategy to Counter Biological Threats* effectively will require President Obama to give the same level of political attention to biosecurity that he has devoted to crafting and promoting his nuclear weapons agenda over the past year.