House Armed Services Committee
Subcommittee on Intelligence, Emerging Threats, and Capabilities

Hearing on Biodefense:
Worldwide Threats and Countermeasure Efforts for the Department of Defense

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Since the beginning of time man has co-opted nature's sources of poison and disease for weaponry. Ancient warriors dipped their arrows in poison; fouled water supplies with feces and dead animals; bombarded enemies with containers filled with snakes, disease-bearing rodents, and scorpions; and hurled human plague cadavers over the walls of besieged cities. These rudimentary forms of biowarfare gave way to more advanced weapons in the World War I era, when governments put scientists into the equation, asking them to figure out how to wage germ warfare more effectively. At that time, advocates of biological weapons lauded their cheapness in comparison to other weapons, their ability to offset an opponent's conventional military advantage, their deep psychological impact on an opponent if used, the difficulty of pinpointing a biological attacker, and the self-perpetuating nature of a strike involving contagious diseases. Finally, proponents noted that, biological weapons leave infrastructure standing, allowing the victor to take over the defeated nation's intact industrial and other capacities.

Not so long ago, a group of countries known as the "dirty dozen" were thought to be harboring offensive biological weapons programs. Today, the number of suspected proliferators is down to a handful as concerns have faded about possible programs in Cuba, Libya, Iraq, and Egypt. A great many nations, including China, India, Pakistan, and Taiwan, have pharmaceutical and biotechnology industries and the scientific know-how to pursue biological weapons, but little public evidence exists to sustain suspicions of anything other than that they may be "leaning" offensively behind the guise of their biodefense programs.

The "usual suspects," however, have apparently not forsaken germ warfare. According to U.S., South Korean, and Russian intelligence estimates, North Korea is strongly suspected of having an offensive bioweapons program that dates to the 1960s. At universities, medical, and specialized institutes North Korea reportedly continues military-applied research on anthrax, botulinum toxin, cholera, plague, and perhaps smallpox. Some assessments state that North Korea is engaged in research but is poised to weaponize a range of pathogens, while others assert that Pyongyang has stockpiled biowarfare agents. When considering this spectrum of possibilities, it is useful to keep in mind that scientists in this isolated dictatorship may lack the state-of-the-art skills and equipment necessary for advanced biological weaponry. North Korea belongs to the treaty that prohibits the development, production, and stockpiling of biological weapons, the Biological and Toxin Weapons Convention (BWC).

* Affiliation provided for identification purposes, only. The James Martin Center for Nonproliferation Studies does not take institutional positions on public policy issues.

Syria, which has been embroiled for more than two years in an ongoing civil war that has taken over 100,000 lives, is also strongly suspected of having a germ weapons program. In July 2012, Syrian Foreign Minister Jihad Makdissi stated that Syria would never use chemical or biological weapons and that the Syrian military controls all such stockpiles and sites, though he later attempted to walk back his perhaps unintentional confirmation of Syria's unconventional weapons capabilities. A United Nations investigative report released on September 16th contained overwhelming evidence that the regime of Bashir al Assad committed the August 21st poison gas attacks on the suburbs of Damascus. Assad has since joined the Chemical Weapons Convention, and inspectors have taken modest initial steps to begin overseeing the dismantlement of Syria's chemical weapons capability. Syria has signed, but not ratified, the BWC. In March 2013 testimony before the Senate Select Committee on Intelligence, Director of National Intelligence James Clapper gave the U.S. government's assessment: Syria has stockpiles of biological warfare agents.

Three other states are suspected of bioweapons activity. Over the past two decades, intelligence agencies have voiced concerns about an offensive Iranian biological weapons program, but publicly available information is largely inconclusive on the matter. Iran has a well-developed biotechnology and pharmaceutical industry that could mask and support a significant program, and Tehran's attempts to acquire dual-use equipment and materials are documented. Israel also has a robust biotechnology sector and is believed to have conducted extensive biodefense research. The work done in this program is of course relevant offensive research, but few experts appear to believe that Israel has stockpiled biowarfare agents. Israel has neither signed nor ratified the BWC, but Iran is a BWC member state.

Russia, which inherited a Soviet germ weapons program of unparalleled scale and sophistication, also remains on the list of suspects. Insider accounts of former Soviet bioweaponeers and the distinctive features of many weapons institutes that outsiders have observed demonstrate that the USSR's investment in bioweapons rivaled its nuclear weapons program. After inaugurating the BWC in 1975 as a depository nation, Moscow accelerated its bioweapons program with a work force of over sixty thousand scientists and technicians, including ten thousand who developed and tested anti-crop and anti-livestock agents. The Soviets went far past the classic agents like anthrax, pioneering the militarization of hemorrhagic fever viruses by successfully weaponizing Marburg, developing two different strains of plague to resist five known antibiotics apiece, and also making strains of anthrax, tularemia, and glanders resistant to known antibiotics and vaccines. With genetic engineering, the Soviets attempted to create entirely novel virulent strains, including ones that produced toxins. Other Soviet bioweaponeers conducted research with bioregulators and neuro-modulating peptides, which are incapacitating agents that can affect individual behavior, for instance by stimulating insomnia and increasing aggressiveness. The capstone of this massive covert weapons program was stockpiles of hundreds of tons of anthrax and dozens of tons of plague and smallpox, mainly for use against U.S. and other Western non-battlefield targets.

In the spring of 1992, Russian President Boris Yeltsin stated the bioweapons program would be closed, but thereafter Moscow quickly began denying that the program ever amounted to anything and to this day maintains a stony silence about the Soviet bioweapons program. In

its 1992 voluntary declaration under the auspices of the BWC, Russia stated that the USSR did not amass biological weapons and claimed that inadequate methodology, equipment, and materials meant that Soviet bioweaponeers failed to achieve anything militarily significant. Governments and former top Soviet bioweapons scientists have publicly voiced suspicions that Russia continues to conduct offensive research and development. Russia still denies outsiders any access to key military biological facilities that were critical components of the Soviet germ weapons program, including the Center for Military-Technical Problems of Anti-Bacteriological Defense at Ekaterinburg, formerly Sverdlovsk; the Scientific Research Institute of Military Medicine in St. Petersburg; the Scientific Research Institute of Microbiology at Vyatka; and the Virology Center of the Scientific Research Institute of Microbiology at Sergeev-Posad. For these and other reasons, the 2013 U.S. arms control compliance report states that it remains "unclear if Russia has fulfilled its obligations under . . . . the BWC."

The BWC contains no on-site verification measures to ascertain treaty compliance, so the onus for estimating the number, scale, and sophistication of state-level bioweapons programs falls to the intelligence community. This situation is problematic because from the outside looking in, the intelligence "signatures" of biological weapons programs are far less discernible than nuclear or chemical weapons programs. Even the telltale signs, such as the presence of high-level biosafety containment, that do exist are not always reliable. Prior to the 1991 Gulf War, U.S intelligence did not identify Iraq's principal bioweapons production facility, Al Hakem, even though this site had a layout very similar to Iraq's main chemical weapons production site, Al Muthanna. Without biosafety containment equipment, Iraq produced anthrax and botulinum toxin at Al Hakem. In the late 1980s, Iraq powered up its germ weapons program with huge purchases of the nutrients needed to grow biowarfare agents. Before that, under the guise of legitimate research Iraqi scientists ordered the seed cultures for anthrax, botulinum toxin, and other agents from culture collections in the United States and France. U.S. intelligence apparently did not detect these activities, although in the mid-1990s Israeli intelligence did pick up indications of Iraq's growth media purchases. In 2005, the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction stated that the U.S. intelligence community "substantially underestimated the scale and maturity of Iraq's" bioweapons program prior to the 1991 Gulf War and that the US intelligence assessment about the threat of Iraq's rejuvenated biological and chemical weapons programs, notably its alleged mobile bioweapons production trailers, prior to the 2003 Gulf War was "simply wrong."

Finding signs of terrorist interest and activity in biological weapons arena is even more difficult. In the past couple of decades, sub-national actors also have occasionally turned to germ warfare. Aum Shinrikyo, the Japanese cult best known for its mid-March 1995 attack with the nerve agent sarin in Tokyo subway system, also tried to master biological weaponry. However, the cult's scientists failed utterly at two essential steps. First, they did not acquire virulent strains of the disease-causing agents they tried several times to disseminate from 1990 to 1995. Second, Aum was unable to develop and test effective dispersal systems for biowarfare agents. U.S. intelligence agencies admitted in 1996 testimony before the Senate Committee on Government Affairs that they were not aware of the cult's unconventional weapons programs until after the subway attack.

In America, another cult, the Rajneesh, tested a plot in 1984 to keep voters away from the polls in a Wasco County, Oregon, election by sprinkling *Salmonella typhimurium* on salad bars and elsewhere, sickening 751. Public health authorities, not law enforcement and intelligence officials, connected this surge in gastrointestinal illness to deliberate acts. According to the Federal Bureau of Investigation, Dr. Bruce Ivins, a 26-year veteran of the U.S. Army Military Research Institute for Infectious Diseases (USAMRIID) sent five letters with freeze-dried anthrax to U.S. senators and media outlets in the fall of 2001. The FBI originally turned to Ivins to help them investigate the attacks, only fingering him as the culprit in 2008. Evidence indicates that Ivins may have prepared the anthrax used in the 2001 attacks inside his Ft. Detrick laboratory. The 2001 anthrax attacks inspired a wave of bioterrorism hoaxes and plots and a handful of genuine events. For example, in 2003 an unknown person or group tried to blackmail the U.S. government not to implement new trucking regulations by sending a chain of letters with containers of powdered ricin and threats to make Washington, DC, "a ghost town." Ricin-laced letters reappeared in 2013; two U.S. citizens have been charged with mailing ricin to prominent politicians, a judge, and a gun control advocacy group.

Despite increase indications of terrorist interest in and intent to commit acts of bioterrorism, sub-national actors are still much more likely to attack with traditional tools (e.g., bombs, guns) rather than disease. Nonetheless, experts and policy makers alike consider a major bioterrorist attack to be a when-not-if matter, predicting such an attack in the near- to mid-term future. Economist Martin Shubik argues not just the inevitability, but the "high probability" of mass casualty biological attacks because "[b]iological weapons, with their easy accessibility, lack of effective international controls, and disproportionately large effectiveness, offer a singularly attractive mix to radical groups."

The history of biological weapons activities to date has few concrete patterns save one: bioweapons proliferators shroud their activities in utmost secrecy. Beyond that, biowarfare programs come in all sizes and types, from grandiose, resource rich, high-tech ones to small, almost primitive, efforts funded on a shoestring. Some state-level proliferators aimed for incapacitating diseases, others only weaponized the anti-personnel diseases for which vaccinations and medical treatments were available, and yet others turned untreatable and even entirely novel diseases into weapons. Some bioweapons possessors used their arms against humans and animals, others amassed but did not use their germ arsenals. Terrorists have shown little, if any interest in anti-agricultural agents, but some nations devoted considerable resources to anti-agricultural agents. These variances complicate the efforts of security and intelligence analysts to identify or anticipate the nature of current and future offensive bioweapons programs, of U.S. scientists to improve defenses against biological weapons, and of policy makers to formulate steps to prevent and punish proliferation.

Research with pathogens is essential to decode the inner workings of diseases and to develop diagnostics, therapeutics, and vaccines to combat infectious disease. This research forms the core of U.S. biodefense and is also necessary to safeguard the public from natural eruptions of disease. In the wake of the 2001 anthrax attacks, the U.S. budget for biodefense has increased manifold, from $414 million in FY 2001 to $5.54 billion in FY2013. Likewise, the number of U.S. high containment, biosafety-level 4 laboratories, which increase the safety of research with highly lethal and contagious diseases, jumped from five to fifteen.

The U.S. boom in biodefense has caused some at home and abroad to question whether the United States may have resumed the offensive bioweapons activity that U.S. President Richard M. Nixon shut down on November 25, 1969, with the observation that "mankind already carries in its own hands too many of the seeds of its own destruction." U.S. scientists have spoken of their apprehensions about the type of research performed at the some of the new BL-4 facilities and lack of access to those sites, and representatives of other countries have expressed concerns about possible U.S. noncompliance with the BWC. Therefore, it is worth keeping in mind that the more transparency the Defense and Homeland Security Departments provide into this programming, the more likely such worries will be allayed and the less likely it will be that U.S. biodefense programming will unintentionally launch an arms race in germ weapons by other countries that miscalculate U.S. intentions and activities.

U.S. biodefense programs already have and will continue to benefit from the new techniques, equipment, and knowledge that are propelling life sciences developments at a breakneck pace. The life sciences revolution will also boost environmental remediation, energy generation, agricultural productivity, and other discoveries in medicine. Cutting-edge life sciences techniques, knowledge, materials, and equipment may, however, be deliberately or inadvertently misapplied. The field of life sciences is so dynamic that do-it-yourselfers, known as biohackers, are being drawn to it. Along with countless others, those in DIY bio are availing themselves of the advantages of advanced automated equipment that "de-skills" complex life sciences techniques and processes.

One of the new life sciences disciplines that has raised security concerns is synthetic biology, the ability to generate microorganisms *de novo* from base pairs of nucleic acids. Already, among other pathogens, scientists have artificially created the polio and 1918 influenza viruses that killed and crippled tens of millions worldwide in the twentieth century. With each passing year, scientists can assemble more complex microorganisms from scratch in shorter amounts of time. Base pairs for synthetic assembly can be purchased for just a few dollars, so synthetic biology opens the way for governments and sub-national actors alike to put together rare and tightly controlled pathogens as well as eradicated diseases. Moreover, before long proliferators will be able to print whatever DNA sequences they wish. Several companies are developing desktop DNA printers.

Other important new technologies at the forefront of the life sciences revolution, like RNA interference and nanobiotechnology, are also vulnerable to abuse. Malicious actors could combine sophisticated targeted-delivery technologies with bioregulators, which can be directed to manipulate the human immune, nervous, and endocrine systems. In June 2000, geneticist and molecular biologist Matthew Meselson observed: "A world in which these capabilities are widely employed for hostile purposes would be a world in which the very nature of conflict has radically changed. Therein could lie unprecedented opportunities for violence, coercion, repression, or subjugation." These worrisome possibilities simultaneously underscore the need for biodefense programs and the need to consider how the architecture that governs life sciences research can be strengthened to reduce the chances that the governments and sub-national actors will exploit the dark side of the life sciences.

Conceptually, institutional peer review boards are the watchdogs that help ensure that life sciences research is performed responsibly and safely. In the United States and many other countries, peer governance of scientific research is not exercised comprehensively or evenly. Evidence also indicates that where such committees exist they do not always function effectively. Not only are these committees an unfunded mandate, the self-regulatory approach is innately handicapped because scientists are sometimes reluctant to restrict the work of other scientists. As the debate about various governance approaches for the life scientists has unfolded, plenty of its practitioners have grumbled about oversight of their work, resisting constraints that might serve the interests of security. The flood of advances in the life sciences has underscored the need to update oversight mechanisms, and esteemed scientific advisory panels proposed upgrades to existing oversight procedures.

Much of the debate has revolved around biosecurity, which consists of measures that are intended to foil the theft or diversion of high-risk pathogens. U.S. biosecurity procedures, known as the Select Agent Rules, took shape after a 1995 incident when a lieutenant in the Aryan Nations, Larry Wayne Harris, used false pretenses to buy three vials of bubonic plague from a U.S. pathogen repository. Though the ruse was spotted before Harris could attempt foul play, the incident sparked the maiden U.S. biosecurity regulations to control the transfer of and access to select pathogens. Known euphemistically as the "guns, guards, and gates" approach because physical security is one of its core components, biosecurity can also encompass licensing of facilities to work with pathogens; procedures to ensure the accountability of pathogens and to ascertain personnel reliability; pre-transport approval of transfers of pathogens and appropriate security during transport; oversight of scientific, commercial, and defense work with pathogens; and appropriate security for information related to processes and techniques useful in weaponizing an agent.

Poorly designed regulations do not ameliorate a problem, they exacerbate it. Current select agent regulations, it is important to recognize, would not have stopped anthrax letter attacker Ivins. In its indictment of Ivins, the FBI released information that shows that Ivins was mentally unstable and that he was abusing alcohol and drugs. Employees hired through a personnel screening process that concentrates on criminal, financial, and professional background checks but superficially addresses mental health, substance abuse, and lifestyle issues means that laboratory workers could be high or inebriated on the job, emotionally disturbed, or extorted to reveal private matters (e.g., nudist club membership). U.S. biosecurity procedures do not require substance abuse screening and address mental health matters tangentially. In 2009, the U.S. National Advisory Board on Biosecurity declined to recommend full-scope screening for researchers working with high-risk pathogens, citing worries that more intrusive initial and ongoing personnel screening could cause scientists to abandon this specialized area of research.

A 2009 inventory of USAMRIID's culture collection revealed yet another shortcoming of the Select Agent Rules approach. This inventory turned up 9,220 vials not listed in the facility's computerized inventory, including vials of botulinum neurotoxins and the Ebola, Junin, Rift valley fever, and Venezuelan and Western equine encephalitis viruses. USAMRIID officials chalked this jumble up to errors made when the facility computerized its pathogen inventory in 2005 and samples that departing workers left behind in the facility's 335 freezers and

refrigerators. Unable to rule out foul play, including the possibility that someone smuggled out vials, USAMRIID officials pointed to deterrent measures that they have since added, such as video cameras in the laboratories, exit checks of personnel, stepped up personnel screening and pathogen cataloging and auditing procedures, and random internal inspections. If USAMRIID's 2009 inventory saga illustrates anything, it is just how misapplied the paradigm of nuclear controls is in the life sciences world.

The protection, control, and accountability of nuclear materials can be exercised because of the ability to detect, weigh, and confirm quantities of nuclear materials. In contrast, scientists consider a precise inventory of culture collections to be somewhat futile first because microorganisms can be isolated from nature. Laboratory pathogens can also be replicated and stored in deliberately mislabeled containers without drawing undue attention. Moreover, as synthetic biologists worldwide sharpen the techniques to create pathogens artificially, the concepts of restricting access to pathogens and taking precise inventories will become less relevant to preventing villainy. For these reasons, life scientists regard "locking up" pathogens as a costly hindrance with dubious security gains.

The concept and practice of biosecurity is in serious need of an overhaul, but the Executive Branch seems inclined to live with the devil it knows, the Select Agent Rules, despite evidence that those regulations may have important opportunity costs for U.S. biodefense. Some top scientists and laboratories have apparently opted out of work with high-risk pathogens. Therefore, Congress should require the Executive Branch to prepare a cost-benefit study on the Select Agent Rules and alternative approaches to biosecurity.

Common sense indicates that the emphasis in biosecurity should be placed on personnel reliability rather than guns, guards, and gates. The time has come for life scientists to accept that working with certain materials, equipment, and technology is a responsibility, not a right because their mistakes could have severe consequences for the public at large. Several professions with a significant bearing on public safety−law enforcement officers, airline pilots, those working in the U.S. nuclear weapons program−have mandatory full-scope personnel screening to help short-circuit accidents and other employee misdeeds. Similarly, scientists in high-biosafety containment laboratories should be screened initially and periodically after hiring for problems (e.g., depression, substance abuse, susceptibility to coercion) that could negatively influence their reliability, trustworthiness, and reasoning. Accordingly, reconfigured regulations for high-biosafety level laboratory work should step up personnel screening requirements, streamline and reduce inventory control requirements, and establish procedures to create a "culture of responsibility" in life sciences laboratories.

Far, far too often, a scientist's knowledge of important biosafety, biosecurity, and research oversight procedures depends on the inclinations and practices of their laboratory supervisor. No time should be wasted in correcting this ad hoc situation; Congress should consider how mandatory education and competency demonstration requirements could be instituted. All colleges and universities granting undergraduate and graduate life sciences degrees should be required to include instruction on the ethical aspects of life sciences research, the BWC's prohibitions, and the fundamentals of biosafety, biosecurity, and research oversight in their curricula. All institutions working with high-risk pathogens should be obligated to

provide regular refresher training on these matters. All scientists handling high-risk pathogens should have to demonstrate competency in biosafety, biosecurity, and research oversight procedures that is commensurate with their job responsibilities.

For the time being, the most severe biological threats that America faces will be from natural disease outbreaks and state-level bioweapons programs. As noted, the ability of intelligence to find and characterize covert bioweapons programs is lacking, so the United States needs to go back to the drawing board on data collection strategies, tactics, and tools that can be used to monitor biological facilities. The U.S. government appears to have done little to learn from the invaluable experience of the United Nations Special Commission's biological inspections, and this oversight merits correction. With ordinary inspection tools−observation, document tracking, interviews−and old-fashioned gum-shoe detective work, the inspectors collected considerable evidence that Iraq was hiding a bioweapons program behind a façade of civilian activity. The United Nations Special Commission reported Iraq's development, production, and weaponization of biowarfare agents to the Security Council, compelling Iraq to admit culpability. Thus, the experience of the United Nations Special Commission stands as a direct challenge to the conventional wisdom that the BWC is "inherently unverifiable."

Since the effectiveness of U.S. biodefense depends in no small part on the quality of U.S. biological threat assessments, Congress should require a study evaluating the limitations and prospective contributions of intelligence and inspections to the standing need to detect and deter bioweapons proliferation. The study should address the utility of these tools in isolation of each other as well as the potential synergy between intelligence, increasingly powerful sampling and analysis capabilities, analysis of import/export data, and other on-site inspection tools. This study should include an assessment of how the global institutionalization of cross-cutting biosafety, biosecurity, and research oversight standards might benefit detection of covert bioweapons activity. Such standards would generate a voluminous data that can be perused to aid efforts to separate legitimate peaceful biological work from illicit biowarfare activities. This appraisal could find that inspections can be expected to detect certain biowarfare activities reliably, such as the stockpiling of biological weapons and bulk agent production, but not necessarily to catch offensive research and development of biological weapons. Whatever the study's conclusions, the analytical process entailed would be a springboard to identify alternatives to give U.S. policy makers more data of a more reliable quality about suspected bioweapons activities, which would in turn inform U.S. biodefense programs.