

**United States Senate
Committee on Armed Services
Subcommittee on Emerging Threats and Capabilities**

Biological Threats to US National Security

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Chairman Ernst, Ranking Member Peters, and members of the Committee, thank you for the chance to speak with you today about Biological Threats to US National Security.

My name is Tom Inglesby. I am the Director of the Center for Health Security of the Johns Hopkins Bloomberg School of Public Health and a Professor of Public Health and jointly in Medicine at Johns Hopkins University. The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University.

Our Center's mission is to protect people's health from major epidemics and disasters and build resilience. We study the organizations, systems, and tools needed to prepare and respond.

I will provide comments on biological threats facing the country, major drivers of those threats, and key Department of Defense programs which are aimed at preparing for and responding to them. My testimony will also provide strategic recommendations about how the DOD, in concert with other departments and agencies should be considering and acting to prevent and prepare to respond to these threats.

Biological Threats to the US

The country faces a range of biological threats that can emerge without warning from nature, deliberate attack, or accidental release. We have had major influenza pandemics in the past and there is scientific agreement we will again experience a pandemic of influenza that sweeps the world, including the US. There will likely also be the emergence of new infectious diseases spread by respiratory route from person to person, such as the SARS or MERS viruses which emerged as surprises and had case fatality rates of 10% and 30%, respectively.

In terms of deliberate threats, we continue to face the prospect of biological weapons attacks, both from known very high consequence pathogens, such as the agents that cause anthrax and smallpox, as well as from unknown novel and engineered biological threats. Epidemics could also emanate from pathogens that are released from research labs accidentally, including from laboratories working on non-circulating viruses such as SARS or smallpox, or from research

work that has created novel epidemic strains of pathogens. We have seen biosafety breaches in our own DOD and CDC labs in the past, and accidents in other labs internationally. In the realm of animals and plants, we could also face high consequence natural, deliberate or accidental biological threats that could cause deadly large-scale animal outbreaks – epizootics – or the killing off of important crops. These kinds of natural, deliberate and accidental biological threats could pose serious challenges to US national security.

The global and US experience with Ebola in West Africa in 2014-2015, and then again in DRC in this last year, has given us a snapshot of what major epidemics can do. Ebola in West Africa sickened more than 28,000 and killed more than 11,000. Countries from around the region and different parts of the world stopped allowing travel to affected countries. National economies were badly damaged, and doctors and nurses were killed in high numbers. People lost confidence in government and police forces were used to create quarantines, which did not work. The epidemic there was only brought under control after enormous international collaboration with governments in the region and many billions of dollars spent.

In the US, we saw that only a few returning people with Ebola caused extraordinary public anxiety. Only a few cases generated intense national concern, leading to major response efforts by the Administration, as well as the attention of Congress and multiple governors and state governments. While this Ebola experience in the US did not in and of itself pose national security consequences, it is easy to extrapolate the enormous security and economic impact if there were hundreds or thousands of cases of Ebola in the US started via deliberate attack. Or, imagine if the disease at hand were easy to spread from person to person in the US (Ebola does not spread easily). There could be pressure to close borders, the potential for hospitals to collapse under pressure, scarcity of medicines or ventilators, impact on troop deployments, concern about safety of US personal overseas and much more.

We are now a year into an Ebola outbreak in DRC where approximately 2,000 people have been killed so far. No cases of Ebola have come to the US in this outbreak, and there are some hopeful signs that this DRC epidemic could be contained. But an important lesson is that diseases like Ebola can take hold in countries with poor public health infrastructure, and from these countries could have the capacity to spread regionally and beyond. This outbreak has teetered right on the edge of being out of control in this past year. If Ebola spread broadly outside of DRC, quite serious international security consequences would follow for the US and its partners, affecting travel, trade and security, and making it hard to operate safely in important regions of the world.

Drivers of the Biological Threat

There are a number of trends that make naturally emerging epidemics and pandemics more likely. Many of the emerging diseases that affect people have jumped from animals, and people in large numbers are living close to animals and encroaching on previously wild ecosystems. More and more people live in megacities where public health and health care is not strong, and where disease can move quickly. Once a disease gets started, it can move around the world by plane in 24 hrs. The climate is changing -- animals are moving into new places, vectors like mosquitoes have broader range, and pathogens will have new, more conducive climates to thrive. And there is growing global resistance to antimicrobials that we have relied upon.

In the realm of deliberate threats, there is continued global dispersion of biotechnology, which is a powerful force for economic growth. Genome sequencing and synthesis get continually faster and cheaper. In 2013, there had been several thousand human genomes sequenced; in 2019, there are now well over 1 million. Every government with any life science capability can now sequence and synthesize whatever it would like to. Genomes can be engineered to give them new, potentially dangerous characteristics, transforming pathogens that are now benign into pathogens that have the ability to spread or the ability to be lethal.

In addition to engineered pathogens themselves being a serious concern, a related concern is the availability of the information needed to make them publicly online. If potential novel pandemic pathogen strains are created and the process for creating them is put on-line, the recipes for the creation of those novel pandemic pathogens will be permanently retrievable by anyone with access to the web. This category of problem has been called “information hazard.”

A key problem with biosecurity against new biological threats as it exists now is that new threats can emerge or be developed far more quickly than defenses against those threats can be made. Continuing to push forward with the ability to rapidly make countermeasures against novel threats will be pivotal. Two high-profile assassinations in Malaysia and the United Kingdom using chemical weapons have underscored the importance of ensuring capability to respond to weapons and tactics that use unconventional weapons.

US preparedness and response programs

The 2018 National Biodefense strategy is the first US biodefense strategy that takes on natural, deliberate and accidental biological threats. The strategy addresses nation-state and terrorist threats, and both international and domestic biological threats. It also includes a focus on human, animal and plant biological threats in one overall approach. This approach to addressing the full spectrum of biological threats is a potential strength and a way to enumerate all priorities in one place. The potential downside of a strategy with this breadth is that it will be challenging to assess where we stand with respect to all priorities articulated, and to measure progress over time for activities that span across government. It will be important to make sure agencies and offices understand their responsibilities, timelines and budgets for addressing the priorities in the strategy.

Valuable DOD efforts around Biosecurity

At a high level, it is noteworthy that the US National Defense Strategy cites biotechnology as one of the top new technologies that affects the US national security environment. That strategy document also identifies defense against biological weapons as a continued priority, and recognizes that bioengineering is “increasing the potential, variety, and ease of access to biological weapons.” Despite preparedness for biological threats being a priority in that strategy, our own Center’s analysis shows the funding for DOD biodefense programs has steadily been decreasing over the last 5 years. What follows are a few valuable DOD biosecurity related programs that are worth specifically calling out.

Joint Program Executive Office Chem Bio defense program (JPEO CB)

The mission of this program is to “manage the nation’s investments in chemical and biological equipment,” including medical countermeasures. There is good, new potential within this program. They have capabilities to characterize new biological threats, and they are working to create capabilities to develop countermeasures for new threats. They work closely with the development and surge manufacturing company Ology, and they have established clinical trials networks overseas to get new medicines into the field quickly. About 90% of the time they are working on day to day research and development for medical countermeasures to biological threats that are already known (e.g. plague), but 10% of the effort is dedicated to creating and testing capabilities (i.e. working with major cell lines for the range of known medicines and vaccines) that would be needed to deal with surprises or unknowns. The JPEO-CB program is establishing a new way of trying to accelerate MCM development for DOD, so it is too soon to know whether it will succeed as planned. But the combinations of science, technology, clinical trials, and manufacturing seems to have promise and worth supporting. The budget for this program has been cut in half over the last 5 years, and that seems like a mistake to me. At a higher DOD level, JPEO is the implementer for the DoD-wide Chemical and Biological Defense Program (CBD) for the Asst Sec for Defense NCB. The presidential budget for the CBD program in FY2020 was \$300 million for biodefense-related programs, while the budget for this program in FY2014 was almost twice that at \$560 million. We haven’t reduced the number of biological threats facing the force (or the country) since that time. So it is illogical that the program has been cut nearly in half.

DARPA Biological Technologies Office (BTO)

The mission of BTO is to “foster, demonstrate, and transition breakthrough fundamental research, discoveries, and applications that integrate biology, engineering, computer science, mathematics, and the physical sciences.” BTO has about 10 programs with talented program managers from a range of scientific disciplines. They run programs on in issues including: engineering to develop new functional systems and products; developing new platform technologies for miniaturizing biological samples; creating systems that help support operations in extreme environments; protecting against emerging threats to food, water and agriculture; and, developing new systems to prevent and respond to infectious diseases. They are seeking big disruptive changes. For example, I have been particularly impressed with the Living Foundries program which “aims to enable ...on-demand production of molecules by programming the fundamental metabolic processes of biological systems to generate a vast number of complex molecules that are not otherwise accessible.” This program’s success has led to the DOD intention to establish a new Manufacturing Innovation Institute dedicated to Synthetic Biology which, while not associated with US Biodefense, will seek to use synthetic biology to manufacture new products more cleanly, more sustainably and/or cheaply than current industrial processes. Equally impressive is the Safe Genes program which works to prevent “accidental or intentional misuse of genome editing technologies” by building in intrinsic biosafety systems within the science itself. I think the approach to biosafety in this program should really be a model for other BTO work and for USG funded work around bioengineering of pathogens. BTO overall has an approach to life sciences research and development that is unique in the government and really should be supported. The proposed 2020 Administration BTO budget for this was 1/3rd of its budget from the year before and that kind of cut would be a mistake.

Biological Threat Reduction Program (BTRP) of the Cooperative Threat Reduction Program (CTR) in the Defense Threat Reduction Agency (DTRA)

The mission of BTRP is “enhance disease detection, diagnosis, surveillance, and reporting capabilities; develop human resource expertise in public and animal health; promote safe and secure laboratory working environments; and consolidate pathogens of security concern into a minimal number of safe and secure facilities in a sustainable manner.” (cf program website) For example, they have helped to build labs in Uganda and in Liberia where early warning on disease outbreaks can help mobilize response more quickly. Their labs have helped in the Ebola response in the West Africa Ebola response. They provide biosafety and biosecurity programs around the world, including recently in North Africa where there is concern about violent extremist organizations. Through efforts of the BTRP program, national experts from Algeria, Egypt, Libya and Tunisia were trained and returned home better skilled to teach biosafety and biosecurity around their countries. They are doing this work in 29 countries and have developed strong working partnerships in these places.

Strategic recommendations with relevance to DOD and broader USG

Support key USG programs to accelerate MCM development process

In addition to the DOD programs aimed at R&D for MCM development, there are key MCM related efforts at NIH, BARDA, FDA and CDC. For example, BARDA has developed 52 licensed products for biodefense, runs the *Bioshield* program for MCM procurement, and has a large pandemic flu effort. But it has not been funded to develop a strong program on new vaccines for Emerging Infectious Diseases and unknown novel threats. BARDA has done advanced development work on Ebola and Zika in crises, but then when the crisis passes it does not have the funding to create a full-scale organization dedicated to rapidly creating MCMs for novel biological threats that could emerge from nature or deliberate weapons use. I think these efforts to build capabilities for EIDs and unknown threats (in addition to the JPEO CB efforts around development and manufacturing) should be strongly supported with new funding.

A recent bio-exercise our Center held, *Clade X*, shed light on how crucial medical countermeasures would be in the event of a severe pandemic, and how current timelines for production are too slow to be meaningful. *Clade X* also showed how biological crises could affect national decision making around travel and trade, the use of medical and scientific assets overseas in a crisis, troop deployments, civil liberties around quarantine, and the national allocation of scarce supplies of vaccine.

Given how crucial the availability of MCMs will be to any biological crisis in the future, we need to keep pushing these programs and technologies forward, trying different models, different technologies, and explore new arrangements with industry. There should be substantial investment into platform technologies and broad-spectrum antivirals. There should be a major program in the USG (BARDA and DOD) focused on developing MCMs for unknown or novel threats. It’s also critical for the USG to work more effectively with the biopharma industry to make products we will need in a crisis. The USG cannot make products effectively without industry, but it has been a sometimes fickle partner that encourages industry to do substantial amounts of work but then has sometimes dropped the ball quickly when a crisis starts to resolve.

Approach risk assessment strategically and safely

The process of risk assessment involves understanding science, intelligence, vulnerability. It also needs to incorporate the possibility of surprise, and the chance that the USG may receive no intelligence or scientific warning regarding new biological threats. DHS used to have a biological threat assessment process that was one practical tool for trying to understand the range of biological threats facing the nation. DHS stopped preparing its biological threat assessment in the last couple years for unclear reasons, and now there is no overall USG risk assessment process for biological threats. A process should be re-established for prioritizing biological risks in the USG.

Biological risk assessment in the years since 9/11 has been focused predominantly on terrorism risks. Inclusion of bioterrorism has its logic given that biological expertise is widely distributed in the world, and small groups of talented people could do great damage with biology if they had training, time and resources. However, there has been insufficient attention in risk assessment efforts concerning threats posed by other countries. State actor programs should be specifically included in bio risk assessment. The USG bio risk assessment in the past also did not take into account the potential for omnicidal terrorist groups, movements or cults that have apocalyptic, population reduction, or other catastrophic goals. That should change now.

While establishing a rigorous bio risk assessment is valuable and necessary, it is very important that it does not prompt the creation or lab or field testing of novel pathogen strains with epidemic or pandemic potential. Neither the USG nor other governments should be creating highly dangerous new strains of epidemic pathogens for the purpose of demonstrating that such strains could be created by our adversaries. Not only could such strains inadvertently escape a laboratory, they could also be deliberately removed from a lab and used to do great harm. Science now has the potential to create strains of pathogens that could self-propagate in society beyond our ability to respond to them and initiate new epidemics. The USG should not support work in this realm unless there is an extraordinary justification, with very high benefits that would warrant the risks and which could be achieved in no other way.

Risk assessment should include a focus on the possibility of catastrophic biological risks

The USG risk assessment process for biological threats should include within its scope the possibility of global catastrophic biological risks. These would be events, whether naturally emerging or reemerging, deliberately created and released, or laboratory engineered and escape, that could lead to sudden, extraordinary, widespread disaster beyond the capability of national and international governments and the private sector to control. If unchecked, these kinds of events could lead to not only loss of life but also sustained damage to the USG, other governments, economies, societal stability, or global security. Examples of this kind of event could include smallpox for many parts of the world (though less so for the US that now has vaccine); a novel highly transmissible H5N1 bird flu that could infect humans with its current case fatality rate of 50%; and bioengineered viruses that threaten either the food supply broadly, or that target specific populations. Even if USG decision makers deem the probability of these threats taking place to be low, the consequences of them should they occur are enormous enough to warrant specific attention from USG policy and programs, including the above mentioned programs for rapidly responding to unknown threats with MCM development, scale up and surge manufacturing.

Support the BWC and ways to increase international assurance

National security decision makers in the USG – the NSC DOD, DOS, Congress, etc – should strongly support bio non-proliferation efforts, particularly those related to the strengthening of the Biological Weapons Convention (BWC). The BWC has established a very important norm in the world against the development and use of biological weapons. While various public assessments have concluded that some countries secretly pursue biological weapons, no country openly admits to creating or developing biological weapons. Because there is a strong taboo against them, there is no open biological arms race. The USG should continue to do what it can to bolster that deeply valuable norm, and to build mechanisms between countries that can offer assurance that countries are not pursuing biological weapons programs.

Strengthen US Agricultural biodefense

In recent years, I have been very happy to see an increase in attention by USDA to Agricultural biological threats, whether they come from natural or deliberate cause. There are many important elements of US Agrodefense including the coming opening of NBAF for research, and the intramural research that ARS and extramural work that NIFA support on these issues. The USDA has a number of surveillance systems in place, and it has a laboratory network for diagnosing animal diseases and plant diseases. There is a National Veterinary Stockpile for countermeasures to serious animal diseases. There are USDA offices in every county in the country. And USDA was a key partner in the development of the National Biodefense Strategy.

Despite many positive elements of Ag defense and recent positive trends, there are things that need to be strengthened. There should be some kind of overall risk assessment process for Agricultural biological threats, or at least one by class of animal and plant. The Agricultural Research and Development Authority (AGARDA) was authorized in 2018 for up to \$50M but is not yet funded. Plant surveillance for the most serious diseases is weak compared to livestock animal surveillance efforts. Wildlife surveillance for emergence of new diseases, too, should be strengthened. The Veterinary Stockpile budget is small about 100 times smaller than the human SNS. And overall the budget for USDA programs on Ag defense is not enough for the programs that are needed.

Recognize the role of the private sector in preparing for, responding to biological threats

The country relies on the private sector to make the vaccines, medicines, diagnostics and medical equipment etc that we need to respond. It is less well recognized that the private sector will also be responsible for making travel and trade systems continue to function in a pandemic. The private sector will need to keep supply chains open, run communication channels for the public and carry out many other critical functions. Together with the Bill and Melinda Gates foundation and the World Economic Forum, our Center ran an international pandemic exercise in NY last month called *EVENT 201*. This exercise showed how dependent national governments and international organizations would be on many domains of the private sector in a pandemic crisis. We would need systems to keep planes flying and ships moving despite infectious disease risks. International partnerships with the private sector would be needed to make decisions about distribution and allocation of vaccines – if they are made in country X, will other countries in the world be able to access them? Should there be central stockpiles at the World Health Organization for new pandemic diseases? And the private sector will be central to financial

response in a pandemic-- not just funding for the direct public health and medical response to a pandemic, but how to keep finance systems functioning, make sure there are not banks or companies too big to fail in ways that could start to unravel international finance systems.

Promote and Ensure the US Bioeconomy

An important part of the US economy is built on biotechnology, including in the realms of new medicine and vaccine development, food production, energy, and industrial processes. The success of the US Bioeconomy is important to national security. Other governments have recognized the tremendous potential value of the bioeconomy and are making investments in US companies, and the US needs to have a strategy to grow and retain its biotech industries and workforce. The US government should move toward contracting mechanisms that recognize many of the in-kind benefits of biotechnology. Fuels, specialty chemicals, and other products made using biological processes may be expensive in comparison to products made through more traditional approaches, but the higher cost does not include the potential benefits of biologically processed products, including sustainability, reduced logistics costs if the biologically produced products can be produced closer to where they are needed, opportunities to alleviate supply chain constraints or avoid disruptions, and avoidance of environmental contamination and damage.

The USG should also identify ways to recruit and retain talent needed to run innovative biotechnology R&D programs. It should initiate the tracking of data around the biotech workforce and company formation as these data compared to other countries. Data on the US brain drain in science and technology is available from the academic perspective through the National Science Foundation, but there is limited data from the industry perspective. The USG should consider strategic use of non-dilutive capital, matched by VC investments, to help drive the creation of key biotech companies that would be important to the US bioeconomy. If the US government were more explicit about what kinds of biotechnology-derived products it may need, the biotechnology industry could be more valuable to the government. There are direct applications of synthetic biology beyond medical countermeasures that offer value to the US economy and defense. Products such as biologically made concrete, cloth, caffeine production, food, and rare earth mining are just a few biotechnologies that may be valuable to the government or to defense. In addition, there are medical benefits, including regenerative manufacturing of organs or human tissue, that may benefit injured warfighters.

Conclusion

In summary, there are a range of natural, deliberate and accidental high consequence biological threats facing the country. The Dept of Defense has responsibilities, programs, science and assets that are critical in efforts to prevent, detect and respond to those biological threats. The DOD's efforts are part of a larger USG national biodefense strategy and set of programs that are key to preparing the country for major biological events. It is critical that DOD continue to invest in and prepare for biological threats, particularly for high consequence, even catastrophic biological events, that could have national security implications, either through direct serious health and life risks to troops, challenges to deployments, interruptions to logistics, illness in family members, major damage to the economy, or other major shocks and disruptions to the country.