

**BIOLOGICAL THREATS TO UNITED STATES
NATIONAL SECURITY**

HEARING
BEFORE THE
SUBCOMMITTEE ON
EMERGING THREATS AND CAPABILITIES
OF THE
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BIOLOGICAL THREATS TO UNITED STATES NATIONAL SECURITY

WEDNESDAY, NOVEMBER 20, 2019

U.S. SENATE,
SUBCOMMITTEE ON
EMERGING THREATS AND CAPABILITIES,
COMMITTEE ON ARMED SERVICES,
Washington, DC.

The subcommittee met, pursuant to notice, at 3:04 p.m. in Room SR-222, Russell Senate Office Building, Senator Joni Ernst (chairman of the subcommittee) presiding.

Subcommittee Members present: Senators Ernst, Fischer, Hawley, and Peters.

OPENING STATEMENT OF SENATOR JONI ERNST

Senator ERNST. Good afternoon, everyone. I want to thank you all for joining us today.

The Emerging Threats and Capabilities Subcommittee meets today to receive testimony from Dr. Julie Gerberding, Co-Chair of the Center for Strategic and International Studies' (CSIS) Commission on Strengthening America's Health Security; Dr. Thomas V. Inglesby, Director at the Center for Health Security at Johns Hopkins Bloomberg School of Public Health; and Dr. Tara J. O'Toole, Senior Fellow and Executive Vice President at In-Q-Tel.

Our focus today will be to gain a deeper understanding of the nature and severity of biological threats to our national security, as well as the preparedness of the United States to defend against and respond to these threats.

I thank our witnesses for being with us today.

The 2018 National Biodefense Strategy identified biological threats, whether naturally occurring, accidental, or deliberate in origin, as among the most serious threats facing the United States and the international community and capable of causing catastrophic harm to the United States.

Despite the severity of this threat, I note that a recent report by the Center for Strategic and International Studies' Commission on Strengthening America's Health Security states that the United States remains woefully ill-prepared to respond to global health security threats. I find this deeply concerning, given the potential devastation of a biological event, and look to our witnesses to provide their candid assessment of the U.S. posture and programs focused on dealing with this challenge.

Of particular interest is the role of the Department of Defense (DOD) in providing sufficient biodefense both abroad and at home.

DOD has had many biosecurity successes such as securing laboratories in allied countries, providing surveillance of especially dangerous pathogens, and developing lifesaving vaccines for our warfighters. While this subcommittee is principally focused on the Department of Defense's role in countering the threat, this does not stop at a vaccine. It requires constant research, investment, and planning across federal, State, and local governments.

While advancements in biotech research and development have provided innovative solutions for treating disease, developing alternative fuels, and promoting food security, they have also generated new security risks. For example, gene editing technology, new targeting methods, and vaccine-resistant disease could all be used for nefarious purposes by state and non-state actors alike.

Another particular area of concern for me in my home State of Iowa is the potential impact of a biological incident in the agricultural sector. A biological attack targeting specific types of crops or livestock could be devastating to Iowa farmers and have a severely negative impact on the Iowa economy. Such an event would not only impact Iowans. Indeed, folks across the country would potentially feel the effects of food shortages, and the American economy as a whole would suffer if our agricultural industry was to be the target of such an attack.

Again, I thank our distinguished witnesses for being with us, and I look forward to their testimony.

I will now turn it over to our ranking member, Senator Peters, for his opening statement.

STATEMENT OF SENATOR GARY PETERS

Senator PETERS. Well, thank you, Chairman Ernst for holding this very important hearing here today.

I want to thank each of our witnesses for taking time to come before us and present your thoughts, as well as answer our questions.

There is no question that the threats that we face in the area of biosecurity are vast, they are complex and evolving. Adversarial nation states still retain the capability to produce biological weapons in spite of the Biological Weapons Convention. Now even non-state terrorist groups like ISIS [Islamic State of Iraq and Syria] can recruit technically trained scientists to weaponize pathogens as instruments of terror.

We are in the midst of a technological revolution in gene editing with CRISPR [Clustered Regularly Interspaced Short Palindromic Repeats], which will give scientists an unprecedented ability to modify the genetic code.

Finally, we must safeguard against threats to our agriculture and food supply, such as the African swine fever that is spreading at a very rapid pace through Asia and Europe.

In recent years, Congress has worked to address these serious threats. The 2017 National Defense Authorization Act required the President to develop a comprehensive biosecurity to recognize the spectrum of threats that we face from natural occurring outbreak of Ebola to its use by ISIS.

Published in October of 2018, the Strategy is the first acknowledgement of the continuum of threats that we now face. Dangerous

pathogens know no international borders, and a public health biosecurity incident is just as dangerous as an attack by a bioweapon.

More importantly, the Strategy coordinates efforts across the Federal Government to better detect and prevent and, if necessary, respond to a biothreat.

While we have made significant progress in the area, we still face a number of gaps in our country's biological defenses. The bipartisan Commission on Biodefense identified numerous recommendations to strengthen those defenses and protect our country from the vast array of biological threats.

The Department of Defense plays a key role in supporting the biosecurity strategy, and I look forward to exploring the Department's contribution and hearing today about how we can improve those efforts.

Once again, thank you for your testimony here today. I look forward to it a great deal.

Senator ERNST. Now we will go ahead, and we will do our witness testimony. Dr. Inglesby, if you would go ahead and start. We will have about 5 minutes for your statement. Thank you.

STATEMENT OF DR. THOMAS V. INGLESBY, DIRECTOR, CENTER FOR HEALTH SECURITY, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

Dr. INGLESBY. Thank you. chairman Ernst, Ranking Member Peters, and members of the committee, thank you for the chance to speak with you today.

My name is Tom Inglesby. I am the Director of the Center for Health Security at Johns Hopkins and a professor of public health and medicine at Johns Hopkins University.

The country faces a range of biological threats that could emerge without warning, whether from nature, deliberate attack, or accident. These threats could include a global pandemic of avian influenza, lethal emerging infectious diseases spreading from person to person, bioweapons threats like smallpox or anthrax, or newly engineered biological threats. Epidemics could be caused by accidents from labs working with viruses like smallpox or SARS [Severe Acute Respiratory Syndrome] or MERS [Middle East Respiratory Syndrome], which are no longer circulating in the world, or from research aimed at creating novel potential pandemic strains of pathogens. The country also faces the potential for deadly large-scale animal outbreaks or plant epidemics that kill important crops.

In major human epidemics, there would likely be an urgent need for medicines and vaccines and ventilators, possible pressure to close borders, and the potential for hospitals to collapse under pressure. There could be serious impact on national security and to the Department of Defense with risks to health and life in the force and their families, a surge in need for medical supplies, big challenges to deployments, interruptions to logistics lines, and economic shocks, and other disruptions to the country.

The 2018 National Biodefense Strategy sets national priorities for addressing this range of biological threats, and this is forward progress. But now the challenge will be implementation across the

government. I have described a few of DOD's important biodefense programs in written testimony. A few brief words about them here.

The Joint Program Executive Office for Chem Bio Preparedness works to accelerate the development of new medical countermeasures. DARPA's [Defense Advanced Research Projects Agency] Bio Technologies Office runs programs seeking disruptive change in biotechnology, including new ways to manufacture critical molecules and building safety into the work of biological science. The Biological Threat Reduction program is helping build safe, secure labs in parts of the world where new outbreaks could emerge with efforts in 29 countries. I think all of these programs should be supported.

Here are my other recommendations to you. The DOD, together with HHS [United States Department of Health and Human Services] BARDA [Biomedical Advanced Research and Development Authority] should substantially increase efforts aimed at accelerating vaccine and medicine development for new threats. This will require strong programs in government working in close partnership with biopharma.

DOD planning assumptions for pandemics should anticipate great disruption to decision-making and operations. The recent Clade X and Event 201 exercises showed how pandemics could affect national decision-making around travel and trade, the use of medical and scientific assets overseas, troop deployments, civil liberties around quarantine, and the national and international allocation of scarce supplies of vaccine.

The U.S. Government should reestablish a biological threat assessment process, which used to be in place. It should include not only a focus on bioterrorism, but on state programs as well, as well as the possibility of omniscidal or apocalyptic groups seeking biological weapons.

The U.S. Government should plan for the possibility of global catastrophic biological risks. These are events that could lead to sudden widespread disaster beyond the capability of national governments and the private sector to control with potential for great loss of life and disruption of governments, economies, and global security.

I would urge you to strongly support the Biological Weapons Convention. It is a critical international norm against the development and use of biological weapons.

We should strengthen the U.S. agricultural biodefense planning and programs. The USDA [United States Department of Agriculture] has made substantial progress in recent years around strengthening its programs, but there are priorities that should be addressed, including stronger crop surveillance, animal wildlife surveillance, more support for animal vaccine development, and more funding for agriculture biodefense overall.

We should increase planning with the private sector on biothreat initiatives. The private sector is the maker of vaccines and medicines and diagnostics. It is also the key driver in maintaining travel and trade in major epidemics and in supply chain management, communication channels, and many more essential missions.

Finally, we should focus on strengthening the U.S. bioeconomy, which underlies a lot of this. That includes medicines and vaccines,

food production, energy production, and industrial processes. The success of the bioeconomy is important to national security just as in the way that U.S. manufacturing in Silicon Valley have been to U.S. national security as well.

In conclusion, there are a range of serious biological threats facing the country. It is critical that DOD continue to invest in and prepare for biological threats, particularly high consequence threats, even catastrophic ones, that could have major national security implications.

Thank you.

[The prepared statement of Dr. Inglesby follows:]

PREPARED STATEMENT BY TOM INGLESBY, MD

Chairman Ernst, Ranking Member Peters, and members of the Committee, thank you for the chance to speak with you today about Biological Threats to U.S. 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 United States

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 U.S. 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 percent and 30 percent, 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 U.S. national security.

The global and United States 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 U.S., 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 U.S. 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 U.S. started via deliberate attack. Or, imagine if the disease at hand were easy to spread from person to person in the U.S. (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 U.S. personnel 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 U.S. 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 U.S. 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.

United States preparedness and response programs

The 2018 National Biodefense strategy is the first U.S. 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 U.S. National Defense Strategy cites biotechnology as one of the top new technologies that affects the U.S. 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 percent 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 percent 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 Assistant Secretary for Defense NCB. The presidential budget for the CBD program in fiscal year 2020 was \$300 million for biodefense-related programs, while the budget for this program in fiscal year 2014 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 U.S. 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 U.S. that now has vaccine); a novel highly transmissible H5N1 bird flu that could infect humans with its current case fatality rate of 50 percent; 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 U.S. Agrodense 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 to 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 U.S. Bioeconomy

An important part of the U.S. 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 U.S. Bioeconomy is important to national security. Other governments have recognized the tremendous potential value of the bioeconomy and are making investments in U.S. companies, and the U.S. needs to have a strategy to grow and retain its biotech industries and workforce. The U.S. 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 U.S. 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 U.S. bioeconomy. If the U.S. 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 U.S. 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.

Senator ERNST. Thank you, Dr. Inglesby.
Dr. Gerberding, please.

STATEMENT OF DR. JULIE L. GERBERDING, CO-CHAIR, COMMISSION ON STRENGTHENING AMERICA'S HEALTH SECURITY, CENTER FOR STRATEGIC AND INTERNATIONAL STUDIES

Dr. GERBERDING. Good afternoon and thank you. Chairwoman Ernst, Ranking Member Peters, and all of the staff of the sub-

committee, thank you for paying attention to this really important national issue.

I am pleased to discuss with the subcommittee the recommendations of a report from the Center for Strategic and International Studies Commission on Strengthening America's Health Security. The full report was released today, and it is entitled "Ending the Cycle of Crisis and Complacency."

I co-chair this commission with former Senator Kelly Ayotte. Members of Congress who serve as commissioners include Senators Murray and Young and Representatives Bera, Brooks, Cole, and Eshoo. We also are served by several biosecurity experts from around the country, and their commission work is still ongoing.

We began our work with an indisputable premise, and that is that biological threats, whether from natural, intentional, or accidental causes, are occurring more often and have the potential to cause unprecedented harm to Americans and to people around the world.

The world we live in now is amazingly insecure, violent, and disordered, and it is exactly in these circumstances that these biologic threats emerge and spread. All we have to do is look at the DRC [Democratic Republic of the Congo] situation with Ebola to understand the complexity and the opportunity for emergence.

Not only is our disordered world more conducive to the emergence of biothreats, but we are also, of course, increasingly connected and interdependent. Globalization, international trade and travel all mean that an outbreak in one part of the world can very quickly be a threat to us here in the United States. In other words, a threat anywhere is a threat everywhere.

In that context, health security threats truly are national security threats, and that brings them right into the domain of the subcommittee.

Unfortunately, despite the fact that policymakers know to invest in threats when they emerge, all too often the recognition occurs only after a health crisis strikes. I certainly experienced exactly that in my government tenure with the anthrax, SARS, West Nile, avian influenza outbreaks. My successors at CDC [Centers for Disease Control and Prevention] have experienced the same thing with an influenza pandemic, MERS, Ebola, Zika, and so forth.

When biothreats are recognized, policymakers do allocate emergency resources, but critical time, sometimes weeks to months, passes before these resources are available, and in that time, lives are lost.

Once the crisis fades and public attention subsides, urgency morphs into complacency, investments dry up, attentions shift, and a false sense of security takes hold.

The commission asserts that the U.S. Government has to end this cycle of crisis and then complacency. We need to replace it with a doctrine that can guarantee continuous prevention, protection, and resilience.

In that spirit, we commend the release of the National Bio-defense Strategy last fall and the Global Health Security Strategy this year. These do provide a solid foundation, but we need action.

What the commission has presented in its report today is an agenda for specific actions that the Congress might undertake to

try and strengthen our ability to be prepared and respond to health security threats.

I do not have time to go into all of these. They are outlined in the summary report. But we do have a couple that we wanted to highlight because we think they would be especially germane to the subcommittee.

First and foremost, we think it is important that we clarify what leadership at the National Security Council is accountable for the overall government engagement in health security threats. Right now, it is unclear who would be in charge. Strong, coherent leadership at the National Security Council is essential to guaranteeing effective oversight long before crises emerge.

We also recommend actions to augment the important role that the Department of Defense plays in health security. One important area is DTRA [Defense Threat Reduction Agency], and we believe that DTRA should have extended authority to operate in all continents where health security threats exist.

Furthermore, the support for the military's infectious disease research laboratories should be strengthened. During my tenure, I had the opportunity I think to visit all of the Navy and Army laboratories around the world, and I saw firsthand how critical they were in the front line of influenza preparedness, but also the broad investment in developing and researching other infectious diseases that are not necessarily studied by other agencies or for which countermeasures would not be developed at all. I think these laboratories are a national treasure, a critical front line of our global surveillance and response, and we must continue to support them.

The last point I would like to comment on is the importance of our ability to rapidly respond to emerging threats and mitigate harm to affected people. The contingency fund levels for CDC and USAID [United States Agency for International Development] should be increased and sustained. In addition, we should establish a U.S. global health crisis response corps, which is based on existing CDC and USAID capabilities, but to have this team with the trained and exercised ability to deploy and work with local partners in health crisis settings, even when those settings are insecure.

In summary, the commission urges Congress to invest in bio-threat reduction as the national security imperative. We believe the long-term costs of strategic protection and prevention are but a tiny fraction of the astronomical costs of episodic and too often chaotic responses to emerging crises. These smart investments would draw support from all.

Thank you for the opportunity to testify. It is really my hope that we can end this cycle of crisis and complacency, and I request that the CSIS report on Ending the Cycle of Crisis and Complacency be submitted for the record. Thank you.

Senator ERNST. Without objection.

[The CSIS report on Ending the Cycle of Crisis and Complacency can be found in Appendix A.]

[The prepared statement of Dr. Gerberding follows:]

PREPARED STATEMENT BY DR. JULIE L. GERBERDING

Chairwoman Ernst, Ranking Member Peters, and other distinguished Members of the Subcommittee—I am truly grateful for the opportunity to appear before you today. The topic of biological threats to U.S. national security remains vitally important and is deserving of far greater consideration. Thank you for your leadership in this critical area.

The timing of today’s hearing is especially propitious, since it falls on the very day that we are releasing the full report of the Center for Strategic International Studies (CSIS) Commission on Strengthening America’s Health Security, entitled *Ending the Cycle of Crisis and Complacency*.

I co-chair that Commission with former Senator Kelly Ayotte. CSIS launched the Commission in April 2017. It includes among its very active members Senators Patty Murray (D-WA) and Todd Young (R-IN), Representatives Ami Bera (D-CA), Susan Brooks (R-IN), Tom Cole (R-OK), and Anna Eshoo (D-CA), along with 12 other diverse leaders, including from the security world General Carter Ham, Admiral Jonathan Greenert, Christine Wormuth, and Rebecca Hersman.

We will make available the full Commission report for the Subcommittee.

Given the Subcommittee’s agenda, please allow me to lay out succinctly the central premises that guide our work, along with a summation of the Commission’s recommendations. My hope is that we can identify today several points of common purpose in the Commission’s work and the Subcommittee’s priorities.

We began the Commission’s work with a simple, powerful proposition: health security is national security, in a world that is increasingly dangerous and interdependent.

Biological threats—outbreaks from natural, intentional and accidental causes—are occurring with ever higher velocity, rapidity and costs.¹ At the same time, the world is increasingly insecure, violent and disordered, and it is exactly in danger zones where an increasing number of biological outbreaks occur.²

We need to adjust our thinking to account for this fundamental new reality. We need new approaches to operate effectively, on-the-ground, in difficult, insecure places.

Increasing levels of disorder and conflict around the world are resulting in the costly destruction of public health and clinical infrastructure. Population growth, urbanization, and the mass movement of populations are forcing more people into overcrowded and unsanitary living conditions, creating ideal conditions for the emergence and spread of infectious diseases. Globalization and the rise of international trade and travel mean that an outbreak in a disordered setting with a weak health system can quickly become a pandemic, threatening the United States and the rest of the world. Policymakers increasingly appreciate these threats can undermine the social, economic, and political security of nations.

The Commission also arrived at a stark, companion conclusion: U.S. health security policy is caught in a cycle of crisis and complacency, which leaves Americans very vulnerable.

When health crises strike—measles, MERS, Zika, dengue, Ebola, pandemic flu—the American people grow alarmed and U.S. policymakers spring into action, rushing to allocate resources in response. Yet all too often, when the crisis fades and public attention subsides, urgency morphs into complacency. Investments dry up, attention shifts, and a false sense of security takes hold.

That realization led us to our macro-conclusion: first and foremost, the U.S. Government needs to break the cycle of crisis and complacency and replace it with a doctrine that can guarantee continuous prevention, protection, and resilience.

We are convinced that we can break this cycle. Health security and biodefense are areas that historically enjoy strong bipartisan support in Congress, healthy and fruitful cooperation between Congress and the Administration, and strong, promising public-private partnerships.

Health security, luckily, is an oasis of sorts. In an era of acute political polarization, it is a policy zone where, across the political divide, we recognize our shared interests and can have informed discussions to chart a common path forward. We recognize that health security challenges are innately complex, and require all of us working together, across jurisdictions, agencies, and sectors, to create a much better

¹Katherine F. Smith et al., “Global rise in human infectious disease outbreaks,” *Journal of the Royal Society Interface* 11 (December 2014), <https://royalsocietypublishing.org/doi/full/10.1098/rsif.2014.0950>.

²Rebecca K. C. Hersman, *Meeting Security Challenges in a Disordered World* (Washington, DC: CSIS, May 2017), https://csis-prod.s3.amazonaws.com/s3fs-public/publication/170522_Hersman_MeetingSecurityChallenges_Web.pdf?UKD0LRcihyrV02wgy9AQQIqHGzhMidAcB.

line of defense. We should celebrate this good fortune and take full advantage of it.

The Commission also believes that the economic case to invest early in preparedness and biodefense is crystal clear—and powerful. There is much accumulated evidence from recent outbreaks proving the affordability of investing in preparedness, and the huge costs of not investing. The United States faces a choice: it must either pay now and gain protection and security, or wait for the next crisis and pay a much greater price in human and economic costs.

The long-term costs of strategic protection and prevention programs are but a tiny fraction of the astronomic costs of responding to sudden, emergent crises. The 2014–2016 West Africa Ebola outbreak is illustrative. Beyond the devastating loss of human lives, the outbreak had enormous social and economic costs, with global repercussions. The U.S. Government spent nearly \$2.4 billion in emergency funding to support the international Ebola response.³ The outbreak ultimately cost the global economy more than \$53 billion, an average of more than \$1.8 million per Ebola case.⁴ The cost of basic preparedness in low income countries is roughly \$1 per person per year.⁵

The Commission commends the recent advances in U.S. health security and biodefense policy, including the release of the National Biodefense Strategy last fall and the Global Health Security Strategy this year.⁶⁷ These are positive steps forward, which we should build upon.

What is urgently needed, in our opinion, is concrete, concerted action by Congress and the Administration.

The CSIS Commission on Strengthening America’s Health Security advocates for a package of strategic, affordable actions to advance U.S. health security. In combination, these actions constitute a doctrine that can guarantee continuous prevention, protection, and resilience.

First and foremost, we recommend that health security leadership at the White House National Security Council (NSC) be restored.

Today, it remains unclear who would be in charge at the White House in the event of a grave pandemic or cross-border biological crisis, whether natural, accidental, or deliberate. The lack of clarity is dangerous and should be rectified. Furthermore, strong, coherent leadership at the NSC is essential to guarantee effective oversight of global health security and biodefense policy and spending. With that leadership in place, it becomes possible to achieve higher efficiencies in the use of scarce resources, overcome fragmentation and redundancy of programs, and ensure greater rigor and accountability.

We advocate for the right mix of quality investments of resources.

We need to invest directly and consistently over the next decade in the capacities of low-income countries. Such a long-term, predictable approach is essential, if basic preparedness is to be created.

The best approach to protect the American people is to stop outbreaks at the source. The Global Health Security Agenda, or GHSA, established in 2014, is designed to do just that.⁸ GHSA has a proven track record in building health systems and health security preparedness in low- and middle-income countries, financed through a \$1 billion Ebola emergency supplemental funding.⁹ We should sustain that record of success, not disrupt or curtail it.

³“West Africa—Ebola Outbreak, Fact Sheet #6, FY 2016,” USAID, January 21, 2016, https://www.usaid.gov/sites/default/files/documents/1866/west_africa_fs07_01-21-2016.pdf.

⁴Caroline Huber, Lyn Finelli, and Warren Stevens, “The Economic and Social Burden of the 2014 Ebola Outbreak in West Africa,” *The Journal of Infectious Diseases* 218, suppl. no. 5 (December 15, 2018): S698–S704, <https://doi.org/10.1093/infdis/jiy213>.

⁵The International Working Group on Financing Preparedness (IWG) estimates \$0.50–\$1 per person per year would be needed, although there is variation in cost estimates by country. The range of \$0.50–\$1.50 captures most reasonable estimates. See: International Working Group on Financing Preparedness, *From Panic and Neglect to Investing in Health Security*.

⁶White House, National Biodefense Strategy (Washington, DC: September 2018), <https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf>.

⁷White House, *United States Government Global Health Security Strategy* (Washington, DC: 2019), <https://www.whitehouse.gov/wp-content/uploads/2019/05/GHSS.pdf>.

⁸The GHSA is coordinated by a multilateral steering group comprised of 10 countries, including the United States, and is advised by several international organizations including the WHO, Food and Agriculture Organization (FAO), the World Organization for Animal Health (OIE), the World Bank, and Interpol. See: “Membership,” Global Health Security Agenda, updated March 26, 2019, <https://www.ghsagenda.org/members>.

⁹“Implementing the Global Health Security Agenda: 2017 Progress and Impact from U.S. Investment,” GHSA, February 2018, <https://www.ghsagenda.org/docs/default-source/default-document-library/global-health-security-agenda-2017-progress-and-impact-from-u-s-investments.pdf?sfvrsn=4>.

The DOD contributes to this and other U.S. health security efforts through a number of programs that are aimed at countering biological threats from all sources.¹⁰ The DOD operates a worldwide public health, infectious disease research, and disease surveillance network to protect U.S. and allied forces against infectious diseases and other biological hazards. Critical programs include the DOD Defense Threat Reduction Agency's (DTRA) Cooperative Threat Reduction (CTR) Biological Threat Reduction Program (BTRP) and the DOD Global Emerging Infections Surveillance and Response (GEIS) Program.^{11 12} These programs benefit both the military and the general public. They should be protected and strengthened.

Specifically, we recommend that the U.S. Government expand DTRA's geographic authorities to operate in all continents where health security threats exist, including South America. Furthermore, support for military overseas infectious research laboratories should be sustained. DOD biological research and development programs often focus on diseases not studied in other venues and result in medical countermeasures that would otherwise be delayed or not developed at all.

We need to exercise multilateral leadership to persuade partner countries to invest more of their own resources in preparedness.

The financing gap in preparedness is, arguably, the most glaring problem we face in global health security. In the poorest and most fragile countries, where many needs are pressing and resources are constrained, leaders often face difficult trade-offs between investing in preparedness versus more tangible efforts like building roads or schools. Congress should press

for U.S. leadership to launch a five-year challenge initiative at the World Bank that would incentivize long-term investment by fragile and conflict-affected countries in their own basic health security capacities. The United States would, under this plan, shoulder 20 percent of the donor costs over the five-year period, using its influence to leverage other donors to cover the remaining 80 percent. The goal is that low-income countries eventually assume higher and higher responsibility for their preparedness. Such ownership is the only sustainable solution to the finance gap.

We need far better confidence that we can access adequate, quick-disbursing resources when a health or biosecurity crisis strikes.

We simply cannot afford costly delays while scrambling to assemble resources. During moments of crisis, swift and early action is most essential. The Commission recommends that Congress increase contingency funding levels for the CDC and USAID, and that the U.S. Government make annual contributions to the WHO's Contingency Fund for Emergencies.

The Commission argues that we need to launch initiatives that will allow us to operate far more effectively in insecure settings.

The disordered world spans chronic and emerging conflicts, humanitarian crises, fragile states, and mal-governed and stateless spaces. The world is becoming more dangerous and insecure, and it is those very places where dangerous outbreaks are often occurring: witnessing what is unfolding in the Democratic Republic of the Congo, Syria, Yemen, Afghanistan, Pakistan, and Venezuela.

In the meantime, however, access by U.S. civilian outbreak response experts into these insecure settings has become highly problematic. Across several cases, we see seasoned U.S. experts—the “cerebral cortex” to lead the international response—confined to the sidelines.

The Commission advocates for the establishment of a U.S. Global Health Crises Response Corps, which will build upon and integrate existing CDC and USAID capabilities, to work with local partners to respond early to outbreaks and biosecurity incidents in disordered and insecure settings. This is a civilian capacity, which would have a DOD advisor. It would receive specialized training and exercises in building teams and would be provided with special support in terms of communications, intelligence, entry and exit protocols, and language and local mediation skills. It would also be equipped to strengthen local capacities to deliver services.

¹⁰For more detail on how the DOD supports U.S. global health security efforts, refer to Thomas R. Cullison and J. Stephen Morrison, *United States Department of Defense Role in Health Security* (Washington, DC: CSIS, June 27, 2019), <https://healthsecurity.csis.org/articles/the-us-department-of-defense-s-role-in-health-security-current-capabilities-and-recommendations-for-the-future/>.

¹¹“Cooperative Biological Engagement Program,” Defense Threat Reduction Agency, <http://www.dtra.mil/Missions/Partnering/CTR-Biological-Threat-Reduction/>.

¹²See James B. Peake et al., *The Defense Department's Enduring Contributions to Global Health: The Future of the U.S. Army and Navy Overseas Medical Research Laboratories* (Washington, DC: CSIS, 2011), <https://www.csis.org/analysis/defense-department's-enduring-contributions-global-health>.

The Commission also advocates that the U.S. Government strengthen and adapt programs and capacities to deliver health services in fragile settings that meet the special needs of acutely vulnerable populations, especially women and children. This means ensuring the continuity of immunization programs, the protection against and response to, gender-based violence (GBV), and strengthening the delivery of maternal and reproductive health and family planning assistance.¹³

The last area of priority concern to the Commission is the revolution underway in the life sciences, driven by technological transformations that pose both opportunities and risks.

There is a race underway to develop new vaccines, therapeutics, and diagnostics in light of the mounting risks of emerging infectious diseases and growing resistance. It is essential to plan strategically, with strong private-sector partners, to support targeted investments that will accelerate the development of new technologies for epidemic preparedness and response. We argue that the U.S. Government should directly invest in the Coalition for Epidemic Preparedness Innovations, or CEPI, an international alliance that finances and coordinates the development of new vaccines to prevent and contain epidemics. The U.S. Government should also redouble its efforts to develop a universal flu vaccine and new antibiotics.

We are also facing an unforeseen communications crisis in public health, fueled in part by the rapid spread of misinformation and disinformation online through weaponized social media. When misinformation crowds out facts, confidence in public health and medicine can erode precipitously, causing outbreaks of preventable diseases such as measles and polio. Congress should press for the U.S. Government to expand its efforts to better understand and address this complex phenomenon, effectively communicate accurate science to the American people, restore trust and confidence, and reclaim social media as a force for good in public and global health.

Again, thank you for the opportunity to address you today, and I look forward to hearing your perspective. It is my sincere hope that we can work closely together to advance the U.S. health security agenda.

Senator ERNST. Dr. O'Toole, thank you.

STATEMENT OF DR. TARA J. O'TOOLE, SENIOR FELLOW AND EXECUTIVE VICE PRESIDENT, IN-Q-TEL

Dr. O'TOOLE. Thank you, Madam Chairman, ranking member, for the invitation to talk about this very important and——

Senator ERNST. Do you have your mic on?

Dr. O'TOOLE. Thank you for having me here today and for holding this hearing on this very important, complex, and I think relatively neglected topic.

As my two eminent colleagues have described, these biotreats are various, and all of them are quite terrifying. But I would like to suggest a hierarchy of biotreats that is a little different.

First of all, we do live in an age of epidemics, and this is not going to change. It is a consequence of trade and travel patterns and the rise of urbanization in situations where people live in conditions of poor sanitation, nutrition, et cetera.

Secondly, we have the deliberate bio-attack threats. Bioweapons have been with us a long time, but because of the revolution in biology that is going on, we have the capacity to make new, more powerful bioweapons that could evade all of our capacity to diagnose them and to treat them. It is very unlikely, given the difficulty of gathering intel on these programs, that we will have advanced tactical knowledge of what weapon we might be facing or even where it might come from because I think, as the ranking member said, more and more people are going to have access to

¹³Fleischman, Janet, How Can We Better Reach Women and Girls in Crises? (Washington, DC: CSIS, October 2019) <https://healthsecurity.csis.org/articles/how-can-we-better-reach-women-and-girls-in-crises/>.

this technology as it becomes a foundational technology of the 21st Century economy.

The third threat and in my mind in some ways worse than the first two is that we will fail to win the economic competition for the biorevolution. There is no question that we are in a geopolitical competition to wield these new technologies which I believe are going to undergird much of the 21st Century economy. I want to spend most of my time talking about that.

We are in the situation today with regard to bioweapons and the threat of bioterror because of the advances that have been made in the life sciences in the past 40 years and the convergence of those advances in biology and biotechnology with digitalization.

What we now understand is that biology is programmable. Life runs on code. It is not 1's and 0's. It is nucleic acids that make up the code, but we are beginning—we are past beginning—we are now able to read, write, and edit that code. Our ability to do so is improving exponentially, faster than Moore's Law.

This is going to be phenomenally beneficial. It is going to impact multiple different industries, not just biomed, not just agriculture. That is because one of the industries that is rising is that of synthetic biology. Organisms are becoming programmable manufacturing systems, and we are already using organisms to make flavors, fragrances, new fabrics, materials with totally previously unknown properties, et cetera. Biology is likely to become the fundamental manufacturing platform of the future.

We in the United States are the innovation engine of this new technology, and it is really several families of technologies. But China has said repeatedly and very forcefully—and they are backing up their words with actions—that they intend to own the biorevolution. They are building the infrastructure, the talent pipeline, the regulatory system, and the financial system they need to do that. That is before we even talk about the secrets and the information and the intellectual property they are stealing from us, which is a small trickle of the contributions that they are building for their own economy.

They have good reasons to go after the biorevolution. They have a huge population. They have the highest incidence of cancer on earth. Their population is aging. They are going to need to deal with challenges like Alzheimer's, just as we are, and they have to find an affordable way to deliver health care to their rising middle class.

But I do want to note that the United States has not done a good job at translating biology into products. Our translational infrastructure for biology is mostly coming from small startup companies in the private sector, which is where In-Q-Tel does its business. Those are the innovation engines for biology and much else.

We need to think about how we would build a more robust infrastructure particularly to manage epidemics, whether they are deliberate or natural. For example, we need to have the capacity, once an epidemic is noted, to immediately create diagnostics that could be used like pregnancy tests by the people themselves to determine who is sick and who is not. That would be strategically invaluable in managing the epidemic. We need to be able, as Dr. Inglesby suggested, to rapidly develop a new vaccine in response to an epi-

demic. We are within reach of technologies that can do that. We need to get much more ambitious as a country in how we are going to prepare for bioattacks and for natural epidemics. But we also need to tend to building infrastructure for securing and promoting the bioeconomy.

Thank you.

[The prepared statement of Dr. O'Toole follows:]

PREPARED STATEMENT BY TARA O'TOOLE, MD, MPH

Good afternoon, Chairman Ernst, Ranking Member Peters, and distinguished members of the Subcommittee. Thank you for the opportunity to appear before you today to discuss how the Department of Defense can help counter the potential biological threats facing Americans.

I have worked as a practicing physician, but much of my career has been spent in academia and government. I was a program manager at the Congressional Office of Technology Assessment, served as Assistant Secretary of Energy, and founded and led the Johns Hopkins and University of Pittsburgh biodefense centers from 1999–2009. I served five years as Under Secretary of Homeland Security for Science and Technology, where I oversaw the National Biodefense Analysis and Countermeasures Center and supported the creation of a new National Bio and Agro-Defense Facility. In 2014, I became executive vice president and senior fellow at In-Q-Tel (IQT), a non-profit investor for nine United States national security agencies, accelerating and shaping commercial startup technologies to advance the national interest.

I appreciate the opportunity to come before you today and commend the Subcommittee for addressing this vital and neglected aspect of national security. I would like to emphasize four points.

First, rapid advances in the life sciences, biotechnology, and artificial intelligence, plus what we know about our adversaries' programs, require a fundamental shift in United States biodefense strategy. New and evolving technologies have enabled a more dangerous and dynamic biothreat landscape than is contemplated in current biodefense policy and programs.

The past decades of biological science have brought us an array of powerful technologies such as DNA sequencing, gene editing, and synthetic biology. These and other advances have caused a revolution in our understanding of, and ability to alter, living organisms. We have learned that biology is essentially programmable: life runs on code. The knowledge and technologies needed to read, write, and edit this code are improving exponentially—faster than Moore's Law. In other words, the code of life, which consists of four different base pairs instead of ones and zeros, is being digitized, and this information is being stored in huge genomic data banks.

These capabilities have and will continue to generate great benefits across a range of industries, such as new approaches to cancer treatment, and extremely efficient ways to produce complex chemicals and new materials. But these capabilities can also be exploited for evil purposes.

All powerful technologies can be dual-use, and this is particularly true of modern biotechnologies. The same methods that enable the repair of genes which cause disease, allow us to genetically engineer bacteria to produce insulin, or alter a virus to create a vaccine, can be employed to create pathogens not seen in nature. Such pathogens, which could affect humans, animals, or plants, could be constructed to be particularly virulent, evade conventional diagnostic tests, or to resist available drugs and vaccines.

As bioengineering methods advance, and especially as artificial intelligence methods are applied to DNA sequencing, synthesis, and editing, the deliberate creation of new pathogens will be within reach of many more actors. In addition, because techniques such as genomics and gene engineering are so useful in so many industries, and will be so central to the blossoming bioeconomy, more and more people around the world will have access to these technologies and know how to use them.

The United States had a powerful, secret offensive biological weapons program during the Cold War, which lasted until 1969. Most people today, even in the military, do not understand how effective and advanced these programs were. The bioweapons we built then were intended to be strategic weapons, like nuclear weapons. The country tested these bioweapons in all conditions short of actual conflict and demonstrated them to have the large area coverage and lethality of nuclear weapons. And this was accomplished using 1960s technologies.

Given the unavoidable expansion of these dual-use biotechnologies; the absence of any enforceable national treaties controlling bioweapons production and use; and the rise of competitive peer state adversaries; the United States must urgently consider how it will defend itself against what could be an existential threat to civilian populations, our agricultural assets, and warfighters.

In addition to these man-made biological threats, we live in an age of epidemics. Naturally-occurring outbreaks of infectious disease have increased in frequency and impact over the past two decades. They are the consequence of modern trade and travel patterns, human intrusion into once remote ecosystems, and global urbanization with its attendant problems of poverty and poor sanitation. As has been seen with human outbreaks of SARS, MERS, Ebola, and Zika, and the ongoing epidemic of African Swine Fever in Asia which has resulted in the deaths of over 300 million pigs, these outbreaks impose tragic costs in terms of death, suffering, economic losses, and social upheaval.

Second, the United States should aggressively develop and apply new and emerging technologies to create new capabilities needed for a robust bio-defense against natural and man-made biothreats. Such a strategy would have the additional benefit of strengthening United States competitiveness in the global economy.

The 2018 National Biodefense Strategy (NBS), many years in the making, is a detailed and coherent declaration of the broad capabilities needed to prevent, detect, contain, and recover from naturally-occurring epidemic disease. The NBS does not, however, recognize the urgency or potential challenges of protecting the nation from deliberate and covert bioweapons attacks, which could be far more devastating than even the most serious natural outbreak. The NBS also lacks a mechanism for continuous monitoring of the capabilities inherent in rapidly evolving biotechnologies. Nor does the document assign priorities, confer authorities commensurate with stated responsibilities, or provide new resources. Critically, in my view, it lacks a viable, appropriately ambitious, strategic plan for biodefense technology development.

The biothreats posed by new biotechnologies, the potential for large-scale outbreaks in this age of epidemics, the rise of powerful nation state adversaries, and the feasibility of non-state actors wielding bioweapons, requires that the United States immediately commit to significant investments in developing and deploying the technologies needed for biodefense.

To start, the national security community needs to develop a more realistic understanding of biothreats and their underlying dynamics. This will require competence in genomics, proteomics, computer science, and artificial intelligence—skills in short supply across the government. Also needed is a much more ambitious, strategic approach to the technologies needed for biodefense—that is, for detecting, managing, and quenching epidemics, including epidemics caused by pathogens not previously seen in nature, and possibly designed by humans.

Relying on traditional, slow, and costly methods of drug and vaccine development and hoping that what we need will be available in expensive (and inevitably inadequate) stockpiles of medical countermeasures will not suffice. What is needed is a national commitment to the develop technologies that, for example, would enable rapid design and manufacture of medical countermeasures (diagnostic tests, vaccines, and therapeutics) at scales and in timeframes that could impact management of a large, lethal, and fast-moving epidemic. Also needed—and in use commercially today—are technologies that provide situational awareness during outbreaks. This requires the collection, wrangling, and analysis of essential data needed to make informed decisions about epidemic management. Such technologies, if deployed, should provide a defense against both engineered bioweapons and newly emergent natural diseases.

Third, Department of Defense (DOD) leadership is critical to United States biodefense, but talent and resources are currently quite limited.

DOD has historically played a critical role in response to disease outbreaks overseas. The key diagnostic test, vaccine, and therapy that were deployed to contain the 2014 West African outbreak of Ebola virus would not have been available but for DOD investments in R&D. DOD's long experience with technological development could make significant contributions to protecting warfighters and civilians against natural and man-made biothreats. The Department is not, at present, optimally organized nor stocked with the sufficient trained staff to execute this mission.

For several years, DOD's Defense Advanced Research Projects Agency (DARPA) has executed important projects in biotechnology, including in projects designed to better understand biothreats, and has recently expanded its Biological Technologies Office (BTO) staff and budget. The quality of DARPA's work is excellent, and their staff is highly expert. But BTO is less than 50 people. The Joint Program Executive

Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) also has a number of excellent people working on important aspects of biotechnology, focused on providing warfighters protection from CBRN threats. But JPEO-CBRND's mission and budget could benefit from being considered a higher priority within DOD.

The Committee might consider a review of current DOD biodefense programs with the aims of increasing coordination, encouraging risk-taking, and placing an emphasis on capabilities for rapid medical countermeasure development, while providing sufficient resources to allow DOD officials to make meaningful contributions. Contract and budget mechanisms to effectively partner with innovative small companies, which populate most of the biotech landscape, will be essential, as will programs to recruit and retain talented scientists and engineers.

Fourth, China has urgent and compelling reasons to aggressively pursue advancements in biomedicine and biotechnology. But China's geopolitical strategy to dominate the bioeconomy—and indeed to “own the biorevolution”—represents as great a threat to United States national security as their bid to assert dominance in artificial intelligence, quantum computing, and space.

China is planning, organizing, and financing efforts to become the world leader in biotechnology. The Chinese government rightly seeks ways to feed billions in the face of a changing climate, to bring medicines to a population with the world's highest cancer incidence and 100 million diabetics, and to help its aging population stay healthy. Many nations share these goals, and we should find ways to cooperate to advance biology's humanitarian contributions.

Yet it is also true that China sees biology as a route to expand its global power. China is using all the means available to an authoritarian state to reach its 5-year R&D plan to make the biotechnology sector 5% of its GDP by 2020. China is investing heavily in research, building new facilities, recruiting talent from abroad, reforming its regulations for drug approvals, establishing financial rules that favor Chinese companies, and linking its giant internet firms like Tencent and Alibaba to biotech development. Having watched the UK lead the industrial revolution and the United States lead the information revolution, China aims to capture the revolution in biotechnology.

The United States should not cede this ground. The United States and its international partners must plan, organize, and invest to advance key aspects of biotechnology and then harness the vitality of our entrepreneurs to turn discovery into product. The first step is a national biotechnology strategy, one that can incorporate the vital contributions of the biodefense strategy but also transcend it, recognizing that biology will reshape world leadership as much as our quality of life on this planet.

CONCLUSION

The challenge of preparing for bioattacks and epidemics, natural or engineered, is integrally linked to broader imperative of maintaining America's leadership in biotechnology. Within the national security community there has been much focus on artificial intelligence, which clearly has enormous implications for our economy and our defense establishment, and already shapes our shopping habits, provides big data analyses, and operates robots. Biology will prove equally transformative—Americans just do not see it yet. This is a problem because biotechnology is both a humanitarian and geopolitical necessity.

Biotechnology will dramatically and literally reshape our lives and our world. It will also become a significant source of national power—economic, and in all likelihood military—as it creates entirely new possibilities, materials, and products. The question is whether our government can best position the United States to capitalize on this promise.

Thank you.

Senator ERNST. Thank you, Dr. O'Toole. Thank you to our witnesses.

We will begin with 5-minute sessions of questioning, and I will go ahead and reserve my time after we get done with our first round here. I will go ahead and allow Ranking Member Peters to start with questions.

Senator PETERS. Thank you, Madam Chair.

Actually I want to pick up on some of the comments you made, Dr. O'Toole. This question will be for the panel to expand on this.

The United States-China Economic and Security Review Commission recently released its annual report to Congress, and in that report, the commission highlighted that following the 2001 anthrax attacks, the United States was reliant on a single foreign source of the active ingredient, doxycycline, which the United States sought to treat possible greater exposure to anthrax.

In another capacity, I am the Ranking Member of the Homeland Security Committee, and we are actually in the process right now of drafting a report on our reliance on foreign pharmaceuticals in this country as a national security issue that we need to think about and the fact that in many cases it is 100 percent or 80 percent of critical drugs are manufactured off the shore of the United States.

It is my understanding that China is currently the world's largest producer of active pharmaceutical ingredients, known as APIs, which we rely on to make drugs, including those that would treat a biological weapon attack or a pandemic, as you mentioned, Dr. O'Toole.

My question to the panel is, to what extent is the United States reliant on foreign services for key drug products and medical supplies such as syringes and needles and other critical medical supplies that we would need to respond to a biological attack today? What is your assessment of that? Dr. O'Toole, if you want to start.

Dr. O'TOOLE. We are critically dependent on China for a lot of drugs, and we have been shipping our manufacturing capacity to Asia for over a decade now. There is not a CEO [Chief Executive Officer] of a major pharma company who has not been recruited by China to build facilities there.

You know, biology is not part of the DNA of the national security community in this country. We have not been paying attention to biology as a national security asset or as a possible threat, and that has to change.

The fragility of our supply chain in terms of drugs is a real problem. I would say that we have begun exploring the possibility of using synthetic biology to make these active pharmaceutical ingredients, at least some of them, which I think deserves serious consideration. If there were a natural pandemic in which the entire world needed drugs, I am sure China, as we would, is going to take care of their own people first. We do not have the surge capacity we need even to produce enough of a very common, well used medicine like doxycycline in time to deal with an epidemic.

It was also said after H1N1 that if we actually had been able to vaccinate the entire population of the United States with the flu vaccine that we eventually got against H1N1, though it was late for the epidemic, it would have taken 4 years' worth of needles to do that. I mean, we have very insecure supply chains for some of the most critical elements of what would be required medically.

Senator PETERS. Thank you.

Any other panelists like to join in, please?

Dr. GERBERDING. I will just add that I think our medical supply chain is vulnerable even under everyday circumstances. Of course, in the context of a global health threat, we would be severely chal-

lenged for not just countermeasures but for all kinds of medical products.

One area that particularly concerns me is the area of antibiotics because we know we are facing antimicrobial drug resistance on an accelerating scale. CDC just published its update last week outlining the severity of that threat, and we do not have a robust supply of antibiotics today.

One of the ways that we do invest to support that potential situation is through the Strategic National Stockpile, which is a very important U.S. asset, and I think it needs to be reexamined in light of the now known realities of market failures and the shortages of the durable goods that we are going to need for any significant threat.

Senator PETERS. I think it is important when you said we have some challenges right now because we see drug shortages across the board of many drugs that are simply not available, and it forces practitioners to move to a different drug that tends to be a whole lot more expensive, but it may not be any more effective clinically. Antibiotics as well. I understand we have critical shortages in antibiotics today without a biological crisis. You can imagine under a biological crisis, it would be catastrophic. It is something that we should be focusing on immediately.

Dr. Inglesby, would you like to add?

Dr. INGLESBY. Yes. I would just add that I completely agree with what you have just been saying, and I do think that we treat medicines too much like commodities that can be sourced for the lowest price somewhere in the world. But if we think about medicines we would need in a crisis when every part of the world would be looking for them at the same time, there should be at least a strategic examination of the kinds of things that we must have, and we should consider how we could bring some of those medicines back to the United States. Obviously, that cannot be done for all medicines. We are a very connected world, but there are some products that are important enough for national security, for public health crisis that we should be thinking about making them here.

Senator PETERS. Thank you.

Senator ERNST. Senator Hawley?

Senator HAWLEY. Thank you, Madam Chair.

Dr. O'Toole, let me come back to something you said just a moment ago, that China wants to own the biorevolution I think you said. What steps do you see China taking to succeed in that endeavor?

Dr. O'TOOLE. First of all, China has a very detailed 5-year plan, and biotechnology is in that plan in many different ways.

First of all, their goal is to make biotechnology 5 percent of their GDP by 2020. They have changed regulations for their own FDA [Food and Drug Administration] to be more like ours so that they can more easily market to the world. They have created a talent pipeline that incentivizes their own students to go into the life sciences and to bioengineering. They have at least 20 different programs, according to the House Oversight Committee, intended to bring scientific talent from the rest of the world, mostly the United States, back to China using very attractive incentives to bring even very senior American scientists back to do research in China.

As I said, they have enticed a lot of pharma companies both using incentives, as well as doing a lot of, I will call it, confiscation of IP [intellectual property] once they are over and operating in China.

They have changed their financial regulations to benefit Chinese biotech companies.

I think this is important to understand because they have such a long-term well thought-out plan. They are building infrastructure in the form of whole universities, incubators, bio-office parks, primate research facilities, high containment labs very deliberately in order to give themselves the capability of basically being the major biopharma power of the world. But they are not just aiming at biopharma.

We did an examination of their capabilities in synthetic biology. If you map synthetic biology and the different pieces of science and technology that you need to do this to make organisms into manufacturing plants, you will see that the United States is all over the map. We have all kinds of creative companies who are working in all aspects of synthetic biology. If you compare that to China, what they are doing is building from the bottom up, from the fundamental infrastructure up to the more creative parts, and they are doing it at scale. We have nothing like this. This is something that I know DOD is getting interested in at this point. We ought to encourage that. We ought to take on synthetic biology as a national security priority in view.

Senator HAWLEY. What other defensive measures would you suggest? Or maybe “defensive” is the wrong word. Maybe “proactive” is better. But what measures from a policy perspective would you suggest and recommend that this country take in order to not only prevent China from owning the biorevolution but making sure that we do, for lack of a better expression?

Dr. O'TOOLE. Well, this has been called the Sputnik moment in terms of the biorevolution. What we did back then worked pretty well. I think taking a look at the National Defense Education Act and really revving up science and technology education in this country—I would love to do it pre-kindergarten through whatever. But I think we need talent fast. I would look at incentives to encourage young people to go into biology and biotech, but I would also look at how we get them into government because government really needs more technical expertise than it has easy access to right now. These people have a lot of options in terms of jobs. That is where I would start, is the talent pipeline.

I also would consider making one of the national labs responsible for advancing some of these foundational biotechnologies, particularly the analytical part, the big data part of biology, so that we can strengthen the foundational technologies of genomics, and AI [artificial intelligence] applied to biology is going to be a very big deal. I could go on, but I do not want to take the whole hearing.

Senator HAWLEY. That is very helpful. Thank you very much.

Thank you, Madam Chair.

Senator ERNST. Yes. Thank you.

This is a very helpful discussion today. I really do appreciate it.

I know there are a number of other committees that might have jurisdiction over these types of topics, whether it is USDA, whether

it is Homeland Security. Here in the Senate Armed Services Committee, we have not had a hearing on this topic for 20 years. Yes, pretty shocking. It is time. It is time to do this. Again, thank you for doing that.

The reason I get very excited about this and so interested in it is the fact that every time I do meet with different agriculture commodity groups, in particular our Iowa pork producers, when I am back in Iowa, one of the key concerns that they have is actually how do we secure and protect our livestock against biological threats.

My question to all of you is, with agriculture being such a significant part of not only our Iowa economy, but also the American heartland, how significant of a threat is there, and what can we do to mitigate that?

Dr. GERBERDING. I will start by just acknowledging that mother nature is a really good terrorist. China today is experiencing a dreadful outbreak of swine fever that has probably caused the death or culling of at least 50 percent of their entire population of pork, which is the major source of protein for people in China. This is a major socioeconomic threat to the stability of the state of China today, and that is mother nature.

To my knowledge, every state that has engaged in offensive weapons development has also looked not just at human terrorism or human biologic, but also animal and agricultural biologic capabilities. We have to assume that that is still an ongoing issue in state-based efforts, not to mention what might be cooked up in the garage of a terrorist somewhere along the way. These are easy things to do. We have very little surveillance and very little capacity in most of the vulnerable places in the world to do anything about it. I think it is a huge and unrecognized, under-mitigated threat.

Senator ERNST. Thank you.

Yes, Dr. Inglesby.

Dr. INGLESBY. Yes. I completely agree with Dr. Gerberding. I would say that the first alarming statistic is that we spend probably about 100 times less on agricultural threats than we do on human threats. I think there are many reasons for this, but one of them includes a kind of a reluctance in the U.S. Government to talk about this threat until quite recently. I think if you go back 5 years or 10 years in the interagency discussions around bioterrorism, USDA was not a strong player because USDA has a mission of promoting the food industry, and I think people felt at the time that that was kind of giving mixed messages and concerns and fears. I think that has changed, and I have been impressed with how USDA has been stepping out and really kind of being a serious player in the interagency around the National Biodefense Strategy development. I think programs are stronger than they were.

But still they are small compared to the size of U.S. agriculture, the crops and the herds and the animals around the country. As Dr. Gerberding said, there are many natural threats that in terms of terrorism, simply moving a natural threat from one place in the world with some simple sample transfer into U.S. herds or crops would be relatively straightforward to do. There is a long list of dis-

eases both for animals and for crops that could cause a terrible impact in our country.

In general, I think there needs to be greater emphasis, greater funding for this problem. There is not an integrated risk assessment list for USDA. There are programs that focus on different diseases, but we could raise the entire enterprise by having a more organized list of what the biggest problems are: a stronger national veterinary stockpile, better surveillance programs for crops and wildlife. There are a number of concrete things that can be done, but building on recent successes in USDA—I think they are showing that they can really step up their programs, but they just need the support of the Congress.

Senator ERNST. Yes. Dr. O'Toole, do you have a comment?

Dr. O'TOOLE. I agree this is a big threat. The same forces that are driving natural epidemics are driving epidemics among animals. What is happening with African swine fever moving around the world is certainly going to happen again and again.

What we need to do is the same. We really, really, as a matter of national security, need to get better at managing epidemics. We keep making the same mistakes again and again and again. The technologies to change this either exist or are within reach. For animals, we need rapid, cheap, easily manufactured pen-side diagnostics, as they are called, to figure out if pig A is sick and pig B is not, as opposed to killing all the pigs within a certain radius of an animal who is diseased. We can get those kinds of options if we are willing to invest in them.

In agriculture, one of the advantages is you have a commercial push for these kinds of technologies if the U.S. were to lead some of the basic research that you do not have as easily in human outbreaks where the opportunity costs for the drug companies are so wildly out of sync that they are not going to develop new antibiotics, et cetera, as we have seen. But we can do a much better job at managing animal disease than we are doing now.

Senator ERNST. My message back to Iowa is we can get there. We just need to step it up. Is that right?

Dr. INGLESBY. Yes.

Senator ERNST. Okay. Thank you very much.

Ranking Member Peters?

Senator PETERS. Thank you, Madam Chair.

I think I will continue the line of thought by Chairman Ernst, protecting the agricultural industry. Michigan is also a big agricultural State, in fact, the second most diverse agricultural State next to California, with all sorts of crops. As Ranking on Homeland Security, I authored a bill to increase our agricultural inspectors at the border, which is critically important to protect that industry, as well as public health. We are understaffed when it comes to agricultural inspectors. We will hopefully change that if the House acts on the bill that we just passed out of the Senate. Not only human inspectors but probably the most sophisticated tool you can use, which are canine teams. Sophisticated noses of dogs is pretty amazing as to what they can pick as things are crossing the border.

My question is—and especially, Dr. Inglesby, you are talking about how we need to do more—I will get the assessment of the panel. What sort of coordination is going on between USDA, the

Department of Defense, the CBP [U.S. Customs and Border Patrol], or Homeland Security folks? We have to be able to identify where some of these outbreaks are around the world, alert folks here who are on the border protecting us. We have got to have a real coordinated system. What is your assessment of how coordinated that is? Do we need to do a lot more, and what would be your advice? Whoever would like to start. I would love to have all your thoughts.

Dr. O'TOOLE. Well, I will start.

I spent 5 years in Homeland Security. People do try to coordinate, but they do not have the tools they need to make this a very reassuring process.

Without the technology—dogs are great. Love dogs, have one. It is really hard to—

Senator PETERS. We need more than dogs you are saying.

[Laughter.]

Dr. O'TOOLE. We really need more than dogs.

Senator PETERS. But they are great.

Dr. O'TOOLE. They are good for some things. It is very difficult to quantitate how good they are or whether the dog is having a bad day. They are great as a first line of defense. They are not very reassuring as the line of defense.

If you go to a port and you see what CBP is faced with day after day in terms of trying to figure out whether exotic pests are coming in, a big threat to agriculture, for example, they actually disassemble trucks, loaded trucks, and go through them box by box, packing straw by packing straw to find bugs and then compare them to the charts on the wall, what bug is this. We need more technology to do this more effectively. That is all there is to it.

I think people are trying to coordinate amongst the agencies. I do not think they have the tools that they want. I agree with Dr. Inglesby. Agriculture has been late to the table. They need a much bigger research budget. I do not think you can do much about that from this committee. But again, we are under-investing in these areas in terms of R&D [research and development] and the translational science that has to come out of it. These things now are in the arena of national security.

Senator PETERS. Does anybody else want to add?

Dr. INGLESBY. Yes. I would just add just a couple of sentences.

I would say one very encouraging thing was when the National Biodefense Strategy was getting developed in the lead up to 2018 fall, there were four agencies that were co-conspirators or co-leads on the effort, and USDA was one of them, alongside DHS [U.S. Department of Homeland Security], HHS, and the Department of Defense. That was surprising to many people in the field because USDA had been kind invisible before. That was a sign of them really being either pulled or stepping up into the interagency. They are part of an integrated lab network that looks at CBRN [chemical, biological, radiological, and nuclear] threats alongside HHS and EPA [U.S. Environmental Protection Agency] laboratories. There is some kind of interaction there. They definitely do engage internationally with the Food and Agriculture Organization, which is the big organization around food safety in the world. I think there is some interaction, but I completely agree with Dr. O'Toole

that they are on the rise, but they are still kind of starting from a lower position in terms of research and budget.

Dr. GERBERDING. I would just add a very small but important perspective, and that is the vast majority of the new or reemerging infectious diseases that are being evolved naturally are zoonotic diseases, meaning they arise from animals. The criticality of the integration between USDA and the CDC for infectious disease surveillance and adding into that the EPA because some of these diseases also involve the ecosystem—we really need a one-health approach to understanding emergence. Again, the technologies are sorely lacking because there is not an investment in that kind of not just interagency but interdisciplinary research and tech translation.

Senator PETERS. It is clear we need a whole-of-government approach here, and we are far from actually doing that now. I think that is certainly a big takeaway from that exchange from you, which I appreciate.

I was just at the Detroit Metropolitan Airport seeing a demonstration of those dogs and others.

But the one thing that was particularly concerning to me is the amount of actual biological material and viruses and others that are coming across. The people who are researchers—they are bringing all sorts of agents in, which they should not. In fact, I understand half of all the biological material that is stopped at the border is at Detroit Metropolitan Airport. I said is it because it is Detroit or because you are really good at it. The answer was probably a little bit of both. But it is concerning as to what are we not stopping. For whatever we stop, I am sure there is a lot that is getting through, which is why this is so critical that we put that together.

If I may, I am a little over time, Madam Chair. If I may just ask another question.

Dr. Gerberding, you mentioned the study, the Cycle of Crisis and Complacency. In your testimony here today as well, your oral testimony, you talked about where pandemics are occurring or where they start—the outbreaks are occurring around the world—they are usually places of great disorder, a lot of things happening there. The security issues are incredibly challenging where they come from. The Ebola outbreak in Congo is an example of that occurring in a place with regional conflict.

In 2014, in the Ebola outbreak, the United States was able to deploy a real massive, kind of a heavy lift of folks to help deal with that situation. Three thousand combat engineers, mobile hospitals, and marshaled a combined team of medical professionals from the Army, the Navy, the Public Health Service. Actually the Michigan National Guard was engaged in Liberia, our partnership state there. We had a number of our guards people there that forward deployed as well.

My question to you is to what extent do you think the DOD, when responding to these issues, really has to be doing more than just providing medical services? They are going actually have to stabilize a region. That is a broader mission than we normally think about when we are dealing with a potential outbreak of a pandemic, and yet the consequences of not containing that pandemic can be catastrophic. How do we square all that, and how

should we think about deploying DOD assets in these kinds of emergencies?

Dr. GERBERDING. I think it is a very complicated set of issues. In the case that you cited in Liberia, our military was welcomed into the environment, and the mission there was primarily logistics, building infrastructure to support the relief efforts that were ongoing, hospitals, infrastructure, et cetera. Our Department of Defense is accustomed to providing that kind of humanitarian logistic support in all sorts of natural disasters, et cetera.

But we were not there to provide security. Generally, we would like to think that the UN [United Nations] security forces or the local governments would have that responsibility, but as we have seen in the DRC, that is not always the case nor is it always successful. I think that challenges the role of the Defense Department in providing the security when the threat in one region could extend to be much broader or a threat to the United States. I think that is an area where we need a lot of strategic policy work on an ongoing basis.

The other side of the coin and part of the reason why the commission report recommends the development of this ready corps is because we need to bring a certain kind of technical expertise, which is not the military's forte, but the surveillance, the epidemiology, the tech transfer, the diagnostics, et cetera, et cetera, that we need deployable troops who are trained to be able to go in and instigate those capabilities in environments that are not intrinsically secure. We do not have that capability right now. That is why it has been so challenging for the CDC, for example, to be in the DRC because we do not have the security context and we do not really have that kind of deployable, well trained, well exercised unit to serve in that sort of environment. It is an unmet need and one that I hope we would really put a higher priority on addressing going forward.

Senator PETERS. Thank you.

Dr. INGLESBY. I would maybe just add a comment.

Senator PETERS. Yes, please.

Dr. INGLESBY. In the West Africa Ebola response in 2014–2015, in my view and I think the view of many, it really was a threshold moment when the President decided that the Department of Defense would become fully engaged in the operations around response. DOD did not send doctors and nurses, but they sent heavy lift. They sent their ship. They started building things. They already had laboratories there that were working on diagnostics. That was a real threshold moment.

I think in the aftermath of that, as people have reviewed the DOD experience in West Africa, there still is a tension within the Department of Defense about the extent to which the Department of Defense should be involved in foreign operations around infectious disease crises. In my view, they are indispensable in terms of operations. If you really want something to be done by the U.S. Government, DOD has by far the most operational capacity, and there are going to be moments to do that. But I understand that in DOD leadership in the command leadership, that there is reluctance to have doctors and nurses, in particular, involved because of the way that it will affect overall operations.

I think it is an open issue. I would urge the DOD to be involved in those kinds of operations, but I do not believe it is resolved within the strategy.

The second thing I would say, just to echo Dr. Gerberding, is that in the current DRC Ebola response, the CDC has been indispensable in the last 20 Ebola responses since Ebola was discovered. In this response, they were held back by the U.S. Government for safety and security reasons because we had no way for the U.S. Government to determine that there was no safe way to have them in the field for a long period of time. That is beginning to change.

But it does show that we will need in the future, since more and more outbreaks are happening in disordered, broken places in the world where things could spiral, get a foothold and then create chaos in the region—we are going to need, as Dr. Gerberding said, ways to operate in unsafe environments, ways to have our scientists and experts and public health officials be in places where outbreaks are out of control even if they are unsafe. I do think it is an important issue that we have not really resolved.

Senator PETERS. Probably new specialized units that are specifically trained for that.

Dr. INGLESBY. Yes. Units that are part of that that are on the DOD side, units on the CDC side, scientific side. I think they will need to be able to work together in ways we have not sorted out.

Senator PETERS. Thank you.

Dr. O'TOOLE. May I comment on that?

Senator PETERS. Yes.

Dr. O'TOOLE. I am all for training the special units, but I think the situation on the ground is going to outrun even the U.S. Government's ability to take care of it unless we have better technologies. We are much better off trying to figure out how we could make vaccines on demand and then distributing those than we are sending thousands of members of the armed services just to quell disorder. We have to get a strategic approach to epidemics that has got to look very different from what we are doing now. I think technology is the way through. Because of the biorevolution, there are possibilities out there that we could make good on if we invested in them.

Senator ERNST. Thank you, Dr. O'Toole.

I want to continue on a little bit with some of that technology. You had mentioned that the integration of artificial intelligence is important in staying ahead of various biotreats. If we can just discuss that briefly, I think that would be very helpful for me. Can you elaborate on how this type of technology would impact both the potential offensive and defensive applications with respect to biotech?

Dr. O'TOOLE. Artificial intelligence of different kinds, machine learning, deep neural networks, and so forth, is already being used, for example, in drug discovery to hasten drug discovery. It is being used in medical imaging and in digital health in many different ways. But it is going to have, I think, the greatest near-term impact in biology on these foundational technologies, on genomics and synthetic biology in particular.

If you think of genomics as you are trying read a code of a single genome—and today we are trying to understand what a particular

gene does by comparing it to many genomes and trying to figure out this person is sick because that gene there is missing, to take a simple case. In that case, the bigger your library, the more genomes you have sequenced and put into a library that keeps things accurate and easy to access, you are advantaged. What AI is going to do is not only make it faster to sequence genomes, but they will be done so more accurately. Google has already done this and shown one way to do it, mostly using machine vision.

What you then want to know is you want to understand how to read and write the genome once it is sequenced. What AI allows you to do is intelligently go through all of these multitudinous possibilities much faster and more accurately. Then you can iterate on it.

It is going to improve sequencing. It is going to improve DNA synthesis, and it is going to improve DNA editing. There are already basic science experiments going on in all those fields.

China, for example, has of course a philosophy that the state and the private sector are one and the same. The military and the private sector are one and the same. They have combined their big Internet giants, Alibaba, Tencent, and so forth with their biotech companies. Alibaba is investing in biotech. Tencent is helping BGI, Beijing Genomics, Inc., with their sequencing problems. They have recognized and are industrializing this combination of AI and biotech. It is mostly going to be beneficial. It is going to help us get new medicines faster. It is going to help us understand toxicity earlier. It is going to create whole new realms of products that we have not imagined yet. But they, as I said, are institutionalizing it. We are experimenting with it.

Senator ERNST. I appreciate that. Again, we need to step up in this area and find those solutions.

Your estimation—and I am drawing from that that there is a lot of work that we need to do. But how well postured is the Department of Defense in leveraging AI in a biodefense strategy?

Dr. O'TOOLE. I do not think they have thought about it yet.

Senator ERNST. I would probably agree with that assessment.

Anybody else care to comment on that?

[No response.]

Senator ERNST. Dr. Gerberding, if we could go back a little bit. We were just talking about the collaboration between different governmental agencies. The Health Security Commission report released today by CSIS recommends restoring health security leadership at the White House National Security Council. When was this position established? Then why was it eliminated?

Dr. GERBERDING. In my experience in the context of some of the most difficult and threatening infectious disease outbreaks, inevitably someone is pulled to be the czar of the occasion for that particular situation. But in 2016, the White House did appoint a senior White House official reporting through the National Security Council to be responsible for a directorate that was charged with the preparedness and response to biologic threats. That directorate was established. It began its work, and then in 2017 it was disbanded. I do not know why it was disbanded. I think there were lots of changes. The administration changed and so forth. But I think the mentality often has been that these are important during

a crisis, but the need for them dissipates once the acuity of the crisis has subsided.

Senator ERNST. But the recommendation would be that it needs to be a consistent, stable position within the National Security Council.

Dr. GERBERDING. It has been an essential role for cross-government collaboration in every single infectious disease situation I have ever observed.

Senator ERNST. Do you believe then having that position in place, that person would be able to assist maybe in orchestrating the breakdown of various silos that exist between agencies?

Dr. GERBERDING. That would be a primary function, and that applies both to the planning and strategy that we have been talking about is missing across a number of our agencies, but also in the actual operations and in the aftermath. It is a continuous cycle, and it needs that constant strategic, iterative improvement over long arcs of time.

Senator ERNST. Okay. We are going to go ahead. Senator Peters will have just a couple more questions.

Senator PETERS. Thank you, Madam Chairman.

Dr. Gerberding, this was in your report as well. As you know, the Department has used the Cooperative Threat Reduction (CTR) program, which is also known as the Nunn-Lugar program, for the past 20 years to help us reduce some of the danger of biothreats in the United States. The program started out in the former Soviet Union to secure bioweapons stockpiles in their program, but we have continued to use that program. Your study specifically calls out this program as something that should be protected and sustained. Dr. Inglesby, I know you were involved in that as well.

My question to you is what should the CTR program focus on in the future with respect to securing biological threats that could harm the United States in your estimation. If both of you could answer that and, Dr. O'Toole, if you want to jump in too.

Dr. GERBERDING. Yes. I will start.

I had an introduction to this capability a number of years ago when there was an outbreak of plague in one of the countries that was formerly a part of the USSR [Union of Soviet Socialist Republics]. The question was, the plague that we were observing in animals was actually a sign that there was some offensive weapon development and deploying going on, and that resulted in an investigation comparing biologic fingerprints and so on and so forth. It revealed to me how important this effort was to provide resources and support for scientists to redeploy their technical capabilities in constructive directions and so forth. Since that time, this has come up in a number of other areas of the world.

My own opinion is this is an extremely important methodology for repurposing scientific know-how and acumen, but also harnessing that expertise in ways that truly can hopefully transition into more constructive biotechnology solutions. I see it as a high priority for continuation, and I would look forward to Tom's view because I know we have had this conversation before.

Dr. INGLESBY. Yes. I also think it is quite a valuable program, and I think it is a place in the government that helps other labs and research facilities in the world develop biosafety practices and

biosecurity practices that increase the chance that pathogens will stay safe in their refrigerators and not walk out with people or not be susceptible to theft or diversion.

I think they also do a lot of important training programs to try and train trainers in different parts of the world. I know that CTR BTRP [Biological Threat Reduction Program], the bioprogram in CTR, recently had a training program in North Africa which trained biosafety and biosecurity leaders from a variety of North African countries in the context of violent extremist organizations trying to kind of think about the overlap between terrorism and potential diversion of samples. I think that is the kind of thing that they do very well. I think they are in nearly 30 countries, 29 countries in the world, and are doing things that other parts of the government are not doing.

They also are trying to help build surveillance systems. I mean, there are many other agencies, especially CDC, that do a lot of very critical disease surveillance. I think with their relationships that they have established in laboratories, they can be helpful to that larger mission.

Senator PETERS. Dr. O'Toole, my last question to you, just to pick up on what you were you talking about with the advances in synthetic biology and CRISPR, all these new technologies that are going to change the world dramatically. It is an exciting time to live, but it is also a scary time to live at the same time.

My question to you is that whenever you are dealing with advanced research in biology, it can often raise a whole host of moral and ethical issues that need to be addressed. Given the value system that we have in this country, we want to adhere to that at every step possible. However, other countries may have a different set of moral and ethical principles. How do you see those different principles in terms of biological research? How do you think about that? Is that a concern for you? As a committee, how should we be thinking about countries that are not going to be constrained in the same way we are likely to be constrained in this country when it comes to biomedical research?

Dr. O'TOOLE. This is an area of profound questions that I think have to be approached very carefully and very seriously. We will be disadvantaged compared to China in some areas of biology, stem cells for example, because they are moving forward faster than we are. In the end, they may make more mistakes and we may get to the happy place sooner. As a physician, I believe very strongly in doing everything we can to avoid doing harm. Science is very empirical. Sometimes you make mistakes and you have to pull back and think again. I think this is going to be a knotty problem that deserves very sustained, high-level attention.

When we started the human genome project in this country, we built in the funding for the project money to pay for research in ethics. I would recommend that we do the same thing again for synthetic biology, for gene engineering, and so forth. What it did was it laid the groundwork for a national dialogue, which I think was extremely constructive. All of the anxiety and true fear that popped up when we first started doing recombinant DNA back in the 1970s has proved not to have led to a terrible tragedy I think partly because we moved very thoughtfully forward. We have to

create the foundation and the infrastructure for doing that again for these sciences.

I would say about China, though, that they are in a terrible place vis-à-vis the health of their population. The reason they are moving forward so aggressively is that they are desperate for progress. When you look at the opinions of the Chinese people, they are much more acceptable of risk than I think Americans are in this realm. They are very interested in new technologies that they think could help cure disease, change birth defects, et cetera, et cetera. I do not read the gene-edited baby episode as China being negligent so much as I think it is a more nuanced view of that particular situation is warranted on our part. They have terrible problems that they are trying to fix, and that is part of their appetite for risk.

Senator PETERS. Thank you.

Dr. Inglesby?

Dr. INGLESBY. Yes. I would just certainly agree. I would just add that the U.S. has had the opportunity to set standards in the world around science for a generation, and often when the U.S., especially in the world of science, the NIH [U.S. National Institute of Health], in partnership with other agencies, has taken positions or the recombinant DNA conference back in the 1970s which helped set standards for how to manage recombinant DNA science—I think those things do have a chance of taking hold elsewhere in the world. The more that we can kind of promulgate and seek partnerships around this, I think it is real. I think it can help.

I am particularly worried about a very small realm of science, which has emerged in the last few years, which is science intending to create very pathogenic strains of pathogens. I think we have not taken the position we took in other kinds of technologies like gene editing or recombinant DNA science. We have actually gone in the other direction. We have been, I think, way in front of our headlights, and other countries are observing how we are operating and how we are funding that science. I think there are things that we could do in our own governance of science which would be, I think, a little bit more responsible. But generally speaking, I think the U.S. is able to help set some standards that other people pay attention to.

I know China, just to speak about China—there was a meeting this summer where a number of Chinese scientists came over to talk about the gene-edited baby experience. I think there are many leading scientists in China who were shocked and appalled about how that all happened. I think they certainly have to think about their disease risks in their population, but they are also worried about how scientists kind of got out in front of their scientific establishment. I do not think it is a homogenous national reaction to gene editing. I think there are proponents of it, and there are people who are worried about it as well, even in China.

Senator PETERS. Thank you. I appreciate it.

Senator ERNST. I am going to wrap up the hearing with just a quick question, and all of you can participate in this. I am going to give you the big four that we have. Near peer adversaries—but what is the current estimate of biological warfare capabilities? So, for example, the range of delivery, extent of biological weapons

available, amount of biological weapons, so on and so forth. Low, moderate, or high for North Korea. What would your assessment be of North Korea and their biological capabilities? It is a fun little exercise. Very enlightening.

Dr. O'TOOLE. I think every country in the world has the capability of delivering a devastating biological weapon, North Korea included. I think they are probably more intent on it. It is very difficult to collect intel out of North Korea. There are indications that they have a BW [biological warfare] program. Beyond that, we would have to be in a classified space.

Senator ERNST. Absolutely.

Dr. GERBERDING. I would just say it behooves us to assume they do, whether we have evidence to back that up or not. I think it is more likely than not.

But I would also just like to say one more time the best terrorist of all is mother nature.

Senator ERNST. Yes, Dr. O'Toole.

Dr. O'TOOLE. That gets said a lot, and I think it is no longer true. I think we have to understand that the capacity to build new, very powerful, very, for want of a better word, sneaky biological weapons has been unleashed, and it is widely accessible. We got to start thinking about this in a national security context.

Senator ERNST. Can we say that is probably true then of North Korea, Russia, China, Iran?

Dr. O'TOOLE. Yes.

Senator ERNST. Dr. Inglesby?

Dr. INGLESBY. I agree that any country with any kind of industrial capability, any kind of basic science program, which is almost all countries on the planet, if they chose to make biological weapons, they would succeed. There are not any technical barriers that would prevent a country from doing that.

I think what is really useful at the moment is that we have a Biological Weapons Convention, which creates a very, very strong taboo against it, an international pariah status if you are caught making biological weapons. It is not a perfect treaty, and there are obviously countries that have cheated on it. But it is a helpful norm given that any country could certainly step up and develop and use biological weapons if they chose.

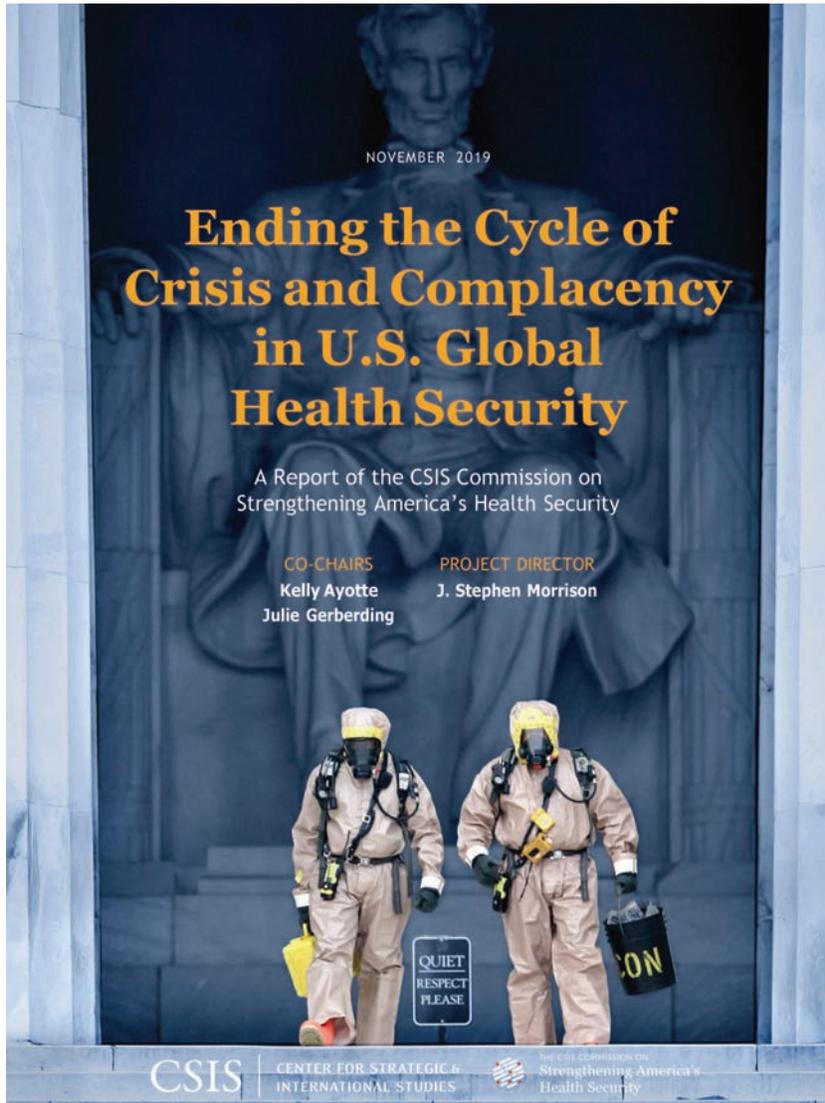
Senator ERNST. Very good.

On that happy note, I think we will go ahead and wrap up this hearing this afternoon. I do appreciate the input that has come from our panel of experts in this topic. It underscores the fact that we as the United States Government, as DOD, also need to truly step up what we are doing on biological warfare preparedness, as well as making sure that we are breaking down those silos that exist between DOD and maybe all of the other agencies that are working in these areas as well.

With that, I want to thank you once again for joining us today. This will conclude our Emerging Threats and Capabilities hearing.

[Whereupon, at 4:17 p.m., the subcommittee adjourned.]

APPENDIX A



NOVEMBER 2019

Ending the Cycle of Crisis and Complacency in U.S. Global Health Security

A Report of the CSIS Commission on
Strengthening America's Health Security

CO-CHAIRS

Kelly Ayotte
Julie Gerberding

PROJECT DIRECTOR

Stephen Morrison

CSIS | CENTER FOR STRATEGIC &
INTERNATIONAL STUDIES



THE CSIS COMMISSION ON
Strengthening America's
Health Security

About CSIS

Established in Washington, D.C., over 50 years ago, the Center for Strategic and International Studies (CSIS) is a bipartisan, nonprofit policy research organization dedicated to providing strategic insights and policy solutions to help decisionmakers chart a course toward a better world.

In late 2015, Thomas J. Pritzker was named chairman of the CSIS Board of Trustees. Mr. Pritzker succeeded former U.S. senator Sam Nunn (D-GA), who chaired the CSIS Board of Trustees from 1999 to 2015. CSIS is led by John J. Hamre, who has served as president and chief executive officer since 2000.

Founded in 1962 by David M. Abshire and Admiral Arleigh Burke, CSIS is one of the world's preeminent international policy institutions focused on defense and security; regional study; and transnational challenges ranging from energy and trade to global development and economic integration. For the past eight years consecutively, CSIS has been named the world's number one think tank for defense and national security by the University of Pennsylvania's "Go To Think Tank Index."

The Center's over 220 full-time staff and large network of affiliated scholars conduct research and analysis and develop policy initiatives that look to the future and anticipate change. CSIS is regularly called upon by Congress, the executive branch, the media, and others to explain the day's events and offer recommendations to improve U.S. strategy.

CSIS does not take specific policy positions; accordingly, all views expressed herein should be understood to be solely those of the author(s).

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Center for Strategic & International Studies
1616 Rhode Island Avenue, NW
Washington, DC 20036
202-887-0200 | www.csis.org

About the CSIS Commission on Strengthening America's Health Security

The CSIS Commission on Strengthening America's Health Security is a two-year effort organized by the CSIS Global Health Policy Center. The Commission brings together a distinguished and diverse group of high-level opinion leaders who bridge security and health, comprising six members of Congress, past administration officials, and representatives from industry, private foundations, universities, and nongovernmental organizations. The Commission is advised by a group of preeminent subject experts. The Commission's core aim is to chart a bold vision for the future of U.S. leadership in global health security — at home and abroad.

In recent years, U.S. senior policymakers have shown greater appreciation of the growing importance of health security to U.S. national interests and of the need for a stronger, more coherent, integrated, better resourced, and more reliably sustained U.S. doctrine for global health security. There is recognition that increasing levels of global disorder and conflict across the world are resulting in destruction of public health infrastructure and capacity, reduced access to critical services for vulnerable populations, and heightened risk of sudden outbreaks. These health threats undermine the economic and political security of nations.

While formidable obstacles remain, we are convinced there is a ripeness to health security, an opportunity to press for strengthening America's policy approaches in a way that can drive forward overall U.S. global health engagement, bring about new resources, and heighten the engagement of industry and security institutions, in partnership with other partner countries, multilateral institutions, and civil organizations.

The Commission is directed by J. Stephen Morrison, CSIS senior vice president and director of the Global Health Policy Center. The Commission's Secretariat is supported by Anna Carroll and Samantha Stroman. More information on the Commission can be found on its dedicated microsite at <https://healthsecurity.csis.org>.

Acknowledgments

The following report is the culmination of a year and half of work by the CSIS Commission on Strengthening America's Health Security, directed by J. Stephen Morrison, CSIS senior vice president and director of the Global Health Policy Center.

CSIS staff members Anna Carroll and Samantha Stroman were indispensable to the research and writing of this report, as well as overseeing the organization and execution of the Commission's many far-flung activities. They deserve enormous praise for the high quality that has resulted from their exceptional skill and commitment.

The Commission would like to extend a special thanks to the team that laid the groundwork for and launched the Commission, including Chris Millard of the CSIS Global Health Policy Center and Rebecca Hersman, Sarah Minot, and Alice Hunt Friend of the CSIS International Security Program. The Commission would also like to thank Emily Foecke Munden for her extraordinary commitment in supporting and advancing the work of the Commission during its first year.

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DISCLAIMER

The Commissioners participated in their individual capacity, not as representatives of their respective organizations. This report represents a majority consensus; no member is expected to endorse every single point contained in the document. In becoming a signatory to the report, Commissioners affirm their broad agreement with its findings and recommendations. Language included in this report does not imply institutional endorsement by the organizations that Commissioners represent.

Letter from the Co-Chairs

Over the course of our careers, we have witnessed, often up close, a mounting number of severe health security incidents, including the 2001 anthrax attacks, SARS in 2003, and the recurrent, dangerous outbreaks of influenza and Ebola, to name but the most conspicuous. Not only did these moments demonstrate the staggering public health, economic, and political costs borne of infectious disease outbreaks and biological attacks, they have convinced us that the United States needs a far better line of defense.

Since our time serving in the U.S. government, there has been a decisive shift in U.S. policy circles—one that we each welcome and wholeheartedly embrace. Today, there is a broad consensus that health security is national security, in a world that has become more dangerous, and where the most dangerous zones are in fact where outbreaks are often arising. There is recognition that increasing levels of global disorder and conflict around the world are resulting in the destruction of public health infrastructure and capacity, reduced access to critical services for vulnerable populations, and heightened risk of sudden outbreaks. There is greater awareness of emerging and re-emerging infectious disease epidemics, the rapid spread of drug-resistant pathogens, and the risk of unregulated advances in biotechnology. A growing number of policymakers now appreciate how health security risks undermine the social, economic, and political security of nations.

Now is the time for greater U.S. leadership and action in global health security. In 2017, CSIS President and CEO John J. Hamre invited us to chair a Commission that would chart a bold vision for the future of U.S. leadership in global health security—at home and abroad. The CSIS Commission for Strengthening America's Health Security brought together a distinguished and diverse group of high-level opinion leaders who bridge security and health, comprising six members of Congress, past administration officials, and representatives

from industry, private foundations, universities, and nongovernmental organizations (NGOs).

This Commission has convened experts from across sectors and disciplines to shed light on the convergence and intensification of global health security threats we face today and to inform policy options for the U.S. government to address these threats more adeptly and cost effectively. Since its public launch in April 2017, the Commission met three times, held seven public events, published 15 policy briefs and commentaries, and convened 20 working group and roundtable discussions.

To an exceptional degree, each Commissioner actively contributed substantial time and effort to these events and publications. The Commission's impressive productivity is a testament to the Commissioners' belief in the importance of global health security issues, the power of U.S. leadership, and their conviction that we must do better.

This report is the culmination of our nearly two-year effort, a genuine consensus document. The report advances a doctrine of continuous prevention, protection, and resilience in the face of a growing number and variety of health security threats—naturally occurring, accidental, and deliberate.

The report focuses on a strategic set of recommendations that are timely, impactful, and compelling and that will result in greater efficiencies in the use of scarce resources. It calls for White House leadership; adequate, sustained, and rapid financing of pandemic preparedness and response; strengthened capacities to operate in a disordered world; and heightened attention to technological challenges. We urge the Congress and the administration to take action on these critical fronts and chart a united, bipartisan path toward strengthened global health security.

Co-Chairs

Kelly Ayotte
Former Senator (R-NH)



Julie Gerberding
Merck & Co, Inc

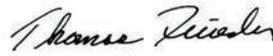


Members of the CSIS Commission on Strengthening America's Health Security

U.S. Congressman Ami Bera
(D-CA-7)



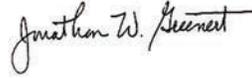
Tom Frieden
Resolve to Save Lives



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(R-IN-5)



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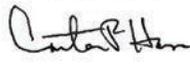
Jim Greenwood
Biotechnology Innovation Organization



Steve Davis
PATH



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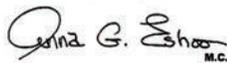
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Margaret "Peggy" Hamburg
National Academy of Medicine



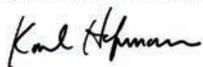
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(D-CA-18)


M.C.

Rebecca Hersman
CSIS



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Population Services International



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Nuclear Threat Initiative



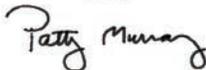
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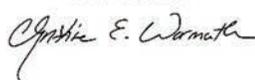
Trevor Mundel
Bill & Melinda Gates Foundation



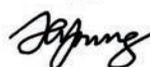
U.S. Senator Patty Murray
(D-WA)



Christine Wormuth
RAND Corporation



U.S. Senator Todd Young
(R-IN)



Juan Zarate
CSIS and Financial Integrity Network



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Executive Summary

When health crises strike—measles, MERS, Zika, dengue, Ebola, pandemic flu—and the American people grow alarmed, the U.S. government springs into action.

But all too often, when the crisis fades and fear subsides, urgency morphs into complacency. Investments dry up, attention shifts, and a false sense of security takes hold.

In reality, the American people are far from safe. To the contrary, the United States remains woefully ill-prepared to respond to global health security threats. This kind of vulnerability should not be acceptable to anyone. At the extreme, it is a matter of life and death.

The CSIS Commission on Strengthening America's Health Security urges the U.S. government to replace the cycle of crisis and complacency that has long plagued health security preparedness with a doctrine of continuous prevention, protection, and resilience. Such a strategic approach can restore U.S. leadership, strengthen financing and the speed of response, foster resilient health systems abroad, enhance the U.S. government's ability to operate in disordered settings, and accelerate select technological innovations to secure the future. It will only be successful, however, if backed by sufficient political will, skilled execution, and a sustained commitment to accountability and efficiency in the use of scarce resources.

The United States faces heightened danger in an increasingly interconnected world. As the global population presses towards 9.7 billion by 2050 and expands into wild frontiers, as agriculture becomes more intensive, as cities of greater density and scale proliferate, and as the earth grows hotter, the threat of new emerging infectious diseases rises steeply.⁷ Outbreaks proliferate that can spread swiftly across the globe and become pandemics, disrupting supply chains, trade, transport, and ultimately entire societies and economies.

At the same time, dangerous insecurity and conflicts are proliferating throughout the world, especially in those very places where outbreaks occur.

The business case to invest early in preparedness is crystal clear—and powerful. The United States must either pay now and gain protection and security or wait for the next epidemic and pay a much greater price in human and economic costs. The long-term costs of strategic protection and prevention programs are but a tiny fraction of the

astronomic costs of episodic, often chaotic responses to sudden, emergent crises. Investing strategically now is smart and cost-effective, brings proven results, and would draw support from across the political spectrum.

The Commission urges Congress and the administration to adopt the following integrated package of critical actions:

1. Restore health security leadership at the White House National Security Council.

Health security is national security. Strong, coherent, senior-level leadership at the National Security Council (NSC) is essential to guarantee effective oversight of global health security and biodefense policy and spending, speed and rigor in decisionmaking, and reliable White House engagement and coordination when dangerous pandemics inevitably strike. Leadership on the NSC can bring about key, targeted new investments while achieving much-needed reform of fragmented programs and higher efficiencies in the use of scarce resources.

2. Commit to full and sustained multi-year funding for the Global Health Security Agenda to build partner capacity.

U.S. direct investments remain essential to build health system capacity. The U.S. government can best protect the American people by stopping outbreaks at their source. The Global Health Security Agenda (GHS) has a proven track record in building health security preparedness in low- and middle-income countries through new innovative partnerships with national governments, the private sector, and civil society groups. It is common sense for the United States to continue to support that successful agenda, not disrupt it.

3. Establish a Pandemic Preparedness Challenge at the World Bank to incentivize countries to invest in their own preparedness.

U.S. multilateral leadership is necessary to address the financing gap for preparedness, one of the starkest problems in health security. Congress should press for U.S. leadership to launch a challenge initiative at the World Bank that will incentivize long-term investment by fragile and conflict-affected countries in their own basic health security capacities. Such country ownership is the ultimate and only sustainable solution to the finance gap.

4. Ensure rapid access to resources for health emergencies.

Stopping a global health security crisis requires swift and early action, backed by quick-disbursing resources. Congress should increase contingency fund levels for the U.S. Centers for Disease Control and Prevention's (CDC) Infectious Diseases Rapid Response Reserve Fund and the U.S. Agency for International Development's (USAID) Emergency Reserve Fund for infectious disease outbreaks. The U.S. government should also make annual contributions to the World Health Organization (WHO) Contingency Fund for Emergencies (CFE).

5. Establish a U.S. Global Health Crises Response Corps.

Small teams of select, highly experienced U.S. civilian public health and humanitarian experts, working alongside local partners and national leaders, form the "cerebral cortex" of outbreak response. Their combined presence can be a high-impact game changer. As seen in the Democratic Republic of the Congo (DRC), when U.S. and other critically important experts are barred from outbreak zones due to insecurity, the implications are grave. The world has grown more dangerous, and the danger zones are precisely where the greatest health security risks frequently reside. Risk aversion has impeded USAID and CDC deployments into several outbreak zones besides the DRC: South Sudan, Iraq, Syria, and Nigeria. Additionally, Yemen and Afghanistan offer minimal access. Caution among policymakers has understandably increased in response to this trend, brought vividly to the fore by tragedies such as the fatal attacks upon U.S. personnel in Benghazi, Libya, in 2012. But the United States simply cannot afford to remain on the sidelines of rapidly emerging health crises. A U.S. Global Health Crises Response Corps answers today's stark new realities. It will build systematically upon—not duplicate—existing rapid response capabilities at the CDC and USAID.

6. Strengthen the delivery of critical health services in disordered settings.

The proliferation of chronic and emerging conflicts, humanitarian crises, and fragile and disordered states places an immense strain on already weak health systems, jeopardizing outbreak response. This problem has moved to center stage in U.S. global health security policy. The U.S. government should strengthen and adapt programs and capacities to deliver health services in fragile and conflicted settings that meet the special needs of acutely vulnerable popula-

tions, especially women and children. The U.S. government should prioritize the continuity of immunization systems, strengthening the protection against—and response to—gender-based violence (GBV), and strengthening the delivery of maternal and reproductive health and family planning assistance.

7. Systematically confront two urgent technology challenges: the need for new vaccines and therapeutics and the public health communications crisis.

There is a race underway to develop new vaccines, therapeutics, and diagnostics in light of the mounting risks of emerging infectious diseases and growing resistance. It is essential to plan strategically, with strong private-sector partners, to support targeted investments that will accelerate the development of new technologies for epidemic preparedness and response. The U.S. government should invest directly in the Coalition for Epidemic Preparedness Innovations (CEPI). There should be a heightened focus on the development of a universal flu vaccine and new antibiotics. These tools should be developed in safe and secure ways that maximize societal benefit while minimizing the potential for misuse. Across programmatic and disease areas, it should be a U.S. policy priority to adopt and integrate digital tools to improve the quality and use of data.

An unforeseen, historic communications crisis in public health is unfolding, at home and abroad. Fueled by social media, ideology, societal discontent, and the rise of online networks of anti-vaccination activists, there has been a sharp decline in popular trust in science, public health authorities, and industry. When disinformation crowds out facts, confidence can erode precipitously, and control of diseases such as measles and polio can regress. Sudden unforeseen "digital wildfires," often at moments of crisis, can derail outbreak responses. Congress should press for the U.S. government to expand its efforts to better understand this complex phenomenon, effectively communicate accurate science, restore trust and confidence, and reclaim social media as a force for good in public and global health. Knowledge and expertise outside public health will be essential in this effort: in media technology, cybersecurity, legal and regulatory regimens, communications, culture, and sociology. Innovative digital tools will lie at the center of concrete solutions.

SUMMARY OF RECOMMENDED FUNDING		
Recommendation	Recipient/Program	Proposed Increase Over Current Level <i>*Figures Presented in Millions USD*</i>
1. Restore health security leadership at the White House National Security Council.	N/A	N/A
2. Commit to full and sustained multi-year funding for the Global Health Security Agenda to build partner capacity.	USAID	\$35
	CDC	\$100
3. Establish a Pandemic Preparedness Challenge at the World Bank to incentivize countries to invest in their own preparedness.	Pandemic Preparedness Challenge	\$30
4. Ensure rapid access to resources for health emergencies.	CDC Infectious Diseases Rapid Response Reserve Fund	\$200 ^A
	USAID Emergency Reserve Fund	\$248
	WHO Contingency Fund for Emergencies	\$25
5. Establish a U.S. Global Health Crises Response Corps.	Global Health Crises Response Corps	\$50
	CDC Support to National Partners	\$36
6. Strengthen the delivery of critical health services in disordered settings.	Immunizations	\$6
	Women and Girls	\$30
7. Systematically confront two urgent technology challenges: (1) need for new vaccines and therapeutics and (2) the public health communications crisis.	Coalition for Epidemic Preparedness Innovations	\$40
	Universal Flu Vaccine	\$60
	Vaccine Confidence	\$25
	Biosafety	\$10
	Biosecurity	\$10
TOTAL:		\$905

A. Recommended funding amounts include both annual investments and one-time investments. For further detail, please see Appendix I: Illustrative Costing for Recommended Programs and Initiatives.

B. It is proposed that the CDC Infectious Diseases Rapid Response Reserve Fund and the USAID Emergency Reserve Fund be set and maintained at a level of \$250 million each, replenished on an annual basis as warranted.

A World of Peril

We live in a world of heightened microbial danger. Infectious disease outbreaks are far more frequent, far more extreme, and impose far higher costs.²

An Ebola outbreak in eastern Democratic Republic of the Congo (DRC), the tenth such outbreak in the country since the virus was discovered there in 1976, has continued to simmer since August 2018 and threatens both global health and global security.³ The international response has been gravely impeded by armed conflict and community resistance within the complex political and security context of eastern DRC. The World Health Organization (WHO) declared the outbreak a Public Health Emergency of International Concern (PHEIC) on July 17, 2019, almost one year after the outbreak was announced.^{4,5} As of October 2019, the outbreak has not been brought under control, and the future remains highly uncertain.

More than 3,200 cases have been confirmed, and over 2,100 people have died as of early October 2019.⁶ There

A. Refer to Appendix III: Glossary of Key Terms for more information on the PHEIC and other key terms and programs cited in this paper.

have been confirmed cases in Uganda and suspected cases in Tanzania.^{6,7} Cases have also appeared in Goma, a populous transit hub on the Congolese border with Rwanda, the most densely populated country in Africa.⁸ In this fragile context, the DRC is simultaneously experiencing concurrent outbreaks of vaccine-derived polio, measles, and cholera.^{9,10}

The situation in the DRC is emblematic of widening global disorder, comprised of chronic and emerging conflicts, humanitarian crises, fragile states, countries prone to repression and gross malgovernance, and stateless corners of the world. This disorder is not abating, and it has deep health security and national security implications for the United States. Increasing numbers of infectious disease outbreaks occur in these contexts, along with increasing attacks upon vital health infrastructure and increased displacement of vulnerable populations, interrupting access to critical health services. Disease and disorder fuel one another, as terrorist groups and violent extremist ideologies stoke health crises and mass migration by attacking vaccinators and other health workers from Pakistan to Syria, Yemen, Somalia, Afghanistan, and elsewhere.¹¹





"The breakdown of health and other social services in disordered settings can easily be exploited and exacerbated by terrorist groups and violent extremists. By addressing the health needs of vulnerable populations in crisis zones, we can help to strengthen community resilience, defend against terrorist exploitation, and inoculate against violent radicalization."

— Juan Zarate, CSIS and Financial Integrity Network

THE DISORDERED WORLD

The disordered world spans chronic and emerging conflicts, humanitarian crises, fragile states, places with gross malgovernance, and stateless spaces.¹² Chronic wars and unstable and fragile states have proliferated in recent years. The number of major violent conflicts has tripled since 2010, and the average duration of civil wars in progress has increased to more than 20 years.^{13,14} From 2005 to 2017, the number of active crises receiving an internationally-led response almost doubled, jumping from 16 to 30.¹⁵ This proliferation of insecurity and fragility has fueled the highest levels of displacement on record. More than 68.5 million people were forcibly displaced worldwide as of June 2018, compared to 33.9 million in 1997.

The disordered world is evolving swiftly and is generating new, destabilizing health security threats. Access to basic health services degrades significantly as security is reduced and populations are displaced. A persistent state of crisis, violence, and instability leads to the flight of indigenous health care providers and the collapse of health infrastructure. This is accelerated by the deliberate targeting of health care providers and other humanitarians.¹⁶

Current global health infrastructure is largely built on national governments and government health systems, but the disordered world is defined by the weakness or absence of effective partner governments willing or able to participate in international cooperation for health security. At the same time, the rise of populist

nationalism around the world is disrupting the liberal international order and challenging traditional models of global health.

This is our new reality, and there are no quick fixes. While some actors have already begun to adapt, the challenges of the disordered world demand a more significant shift in how we operate. The recommendations proposed in this report reflect this new reality.

Today, disorder is fueling geopolitically volatile health security crises not only in the DRC but also in Syria, Yemen, Afghanistan, Pakistan, and Venezuela. The world has become more dangerous, precisely where many acute health security threats reside. This stark reality exposes several serious challenges: how are U.S. and other essential civilian public health and humanitarian experts to deploy safely into these austere environments in order to partner with local officials to detect and arrest highly dangerous outbreaks? How can the U.S. government and its partners meet the acute health and protection needs of the most vulnerable populations, in particular women and girls? And how can the U.S. government and its partners protect immunization and other critical health infrastructure prone to damage and disruption?

Seasoned U.S. civilian personnel with essential expertise from the U.S. Agency for International Development (USAID) and the U.S. Centers for Disease Control and Prevention (CDC) initially deployed to the most acutely affected areas of eastern DRC in August 2018, soon after the Ebola outbreak was declared. They were quickly

withdrawn after significant security incidents and have not been permitted to return since.¹⁷ The absence of small teams of highly skilled U.S. experts from the hot zones, where they normally would join with local and international partners to provide invaluable guidance, has proven enormously costly in eastern DRC. CDC and USAID teams have experienced similar blockages to deployment on security grounds in South Sudan, Iraq, Syria, and Nigeria. Access to Yemen and Afghanistan remains starkly minimal. The CSIS Task Force on Humanitarian Access has explored the impact of intensifying blocked humanitarian access—including roadblocks or attacks on aid workers, bureaucratic constraints, and donor regulations—all of which limit the ability of humanitarian actors to reach the most vulnerable.¹⁸

In the coming years, the United States and its partners can expect to see repeated instances of blocked access to serious outbreaks in insecure settings. That challenge begs for a solution, namely, a dedicated commitment to prudently manage—not prohibit—such lifesaving deployments of U.S. experts.

A second peril is the threat of losing altogether an essential disease-fighting tool, antibiotics. Antimicrobial resistance (AMR) is a complex, long-range global crisis menacing the foundations on which modern medicine is built. The problem lies not just in the lack of new antibiotics; it encompasses their gross misuse in human and animal health. Drug-resistant infections now cause 700,000 deaths per year, with 230,000 of those deaths from drug-resistant tuberculosis alone.¹⁹ Without action, annual deaths from resistant infections could rise to 10 million people per year by 2050 and cause an economic crisis

similar in scale to the 2008 Great Recession.²⁰

New, better vaccines and antibiotics are one essential answer to the expansion of resistance, along with strategic planning, better microbial stewardship, more careful antibiotic use, and better basic health systems. Vaccines and antibiotics have revolutionized infectious disease prevention and treatment, saved millions of lives worldwide, and advanced economic stability and growth. Yet their discovery and development increasingly occur in a deeply problematic and urgent context, characterized by market failures and uncertain economic and budgetary environments.

Advances in biotechnology may foster the development of these new vaccines and therapeutics, but they also pose an additional risk. As scientists develop and apply new biotechnologies, they may increase the transmissibility and pathogenicity of naturally occurring microbes. With these changes come greater biosafety and biosecurity concerns and the rising possibility of accidental or intentional exposure of people, animals, or the environment to dangerous, novel microbes, and even the initiation of a global pandemic.

A third swiftly evolving peril is vaccine hesitancy and the power of weaponized social media. In 2019, the WHO recognized for the first time the recent, steep decline of public trust and confidence in vaccines as among the top 10 global health challenges.²¹ That striking judgment reflects a broader phenomenon: the rise of sophisticated anti-vaccine online networks and the growing mistrust of science, public health authorities, the private sector, and government, fueled by the rapid, deliberate spread of disinforma-



"The systems that have been built to combat specific diseases provide the foundation to build a strong and resilient system for health that can prevent, detect, and respond to current and new health threats. It is important that the U.S. government continue to work to manage and control endemic infectious diseases, such as tuberculosis, malaria, and HIV."

— Mark Dybul, Georgetown University Medical Center



This picture taken on April 5, 2019 shows a nurse waiting for patients at the Rockland County Health Department in Haverstraw, Rockland County, New York. A measles outbreak there sickened scores of people and caused the county to bar unvaccinated minors in public places.

JOHANNES EISELE/AFP VIA GETTY IMAGES

tion, including conspiracy theories on social media and other digital platforms. Insular ethnic and religious communities are especially vulnerable, as are young parents.

Trust and confidence in vaccines can rapidly collapse, as has already occurred across many diverse settings, often among anxious parents who face a confusing array of information as they seek to make the best choices for their children.²⁴ Concurrently, vaccine advocates find themselves targeted and intimidated by the adversaries of vaccines.

Vaccine hesitancy has contributed to a regression in immunization coverage across a number of disease areas, including polio, cervical cancer, and measles. It strikes at home and abroad, in rich and poor countries alike. In 2000, measles was declared eliminated from the United States. As of August 2019, more than 1,200 cases had been identified in 30 U.S. states, the highest case count in 25 years.²⁵ Massive measles outbreaks are also unfolding in Ukraine, Israel, the Philippines, Madagascar, and elsewhere. Europe had nearly 83,000 cases in 2018, an

astonishing number.²⁴ The DRC has had around 115,000 cases as of July 2019.²⁵

While vaccine hesitancy is fundamentally a public health problem, the solutions and the skill sets required to understand this complex phenomenon and rebuild confidence and trust lie, in part, outside the discipline of public health: in communications and messaging; legal and regulatory measures; opinion tracking; intelligence; knowledge of local networks, trust building, and other focal areas for anthropological study; and cyber security and the understanding of social media technology.

Bad Habits, Barriers, and Vulnerabilities

Confronting twenty-first century health security threats demands a continuous, strategic response.

Yet the United States has long been mired in a cycle of crisis and complacency—resulting in ad hoc, stop-go approaches and a short-sighted dependence on emergency interim funding which inevitably sputters to its end, returning us to a state of vulnerability.

Over several successive administrations, the White House has seldom exercised sufficiently authoritative, high-level leadership, creating acute threats to U.S. national interests when dangerous outbreaks occur at home and abroad. U.S. programs on global health security are fragmented, scattered across diverse executive agencies, and not clearly prioritized. The weakness of White House leadership has left unanswered the persistent question of how to streamline programs, eliminate redundancies, and achieve higher efficiencies in the use of scarce resources.

Too often, the U.S. government has succumbed to complacency, failing to recognize the value of investing in preparedness and the huge costs of inaction, only to pay a steep price later. Having not sufficiently invested in health systems and preparedness in West Africa, the U.S. government expended nearly \$2.4 billion (roughly half of the total international investment) to support the Liberian, Sierra Leonean, and Guinean efforts to arrest the 2014-2016 Ebola outbreak.²⁶ A recent study estimates the social and economic burden of the West Africa outbreak ultimately totaled more than \$53 billion, at an average of more than \$1.8 million per Ebola case.²⁷ Other recent outbreaks proved even more costly. The MERS outbreak in South Korea in 2015, a mere 186 cases, cost South Korea \$10-13 billion—more than \$50 million per case.²⁸

Unforeseen biological threats can be intrinsically confusing and can require responses from multiple U.S. agencies. It is often difficult to categorize an emerging health threat definitively as a natural event, a lab accident, or a malevolent act. Outbreaks may involve pathogens the world has not seen before, emerging in unexpected places and geographies, involving heretofore unknown actors.

2003 SARS EPIDEMIC

Cost the economies of southeast Asia between \$40-45 billion.

That is equivalent to about \$5 million per case.

2014 - 2016 EBOLA OUTBREAK

Cost the global economy over \$53 billion.

That is equivalent to more than \$1.8 million per case.

2015 MERS EPIDEMIC IN SOUTH KOREA

Cost Korea between \$10-13 billion.

That is equivalent to more than \$50 million per case.



"Today we are facing the threat of a pandemic that could kill up to 80 million people and wipe out five percent of the global economy. The Global Preparedness Monitoring Board is doing critical work in partnership with the World Health Organization and the World Bank to ensure that more countries are prepared for global health crises."

— Trevor Mundel, Bill & Melinda Gates Foundation

THE WORLD IS UNPREPARED

Two recent reports underscore the lack of pandemic preparedness across the globe and ponder the question of what more needs to happen now. The Global Preparedness Monitoring Board (GPMB) was co-established by the WHO and the World Bank in the aftermath of the 2014-2016 West Africa Ebola crisis. The GPMB is an independent body tasked with monitoring preparedness for global health crises.²⁹ It has the promise to become an authoritative, credible global oversight mechanism. In September 2019, the GPMB released its first annual report, *A World at Risk*, providing a "snapshot" of the international community's ability to prevent, detect, and respond to a global health threat.³⁰ The findings of the GPMB were unequivocal: the threat is growing, and the world is not prepared.

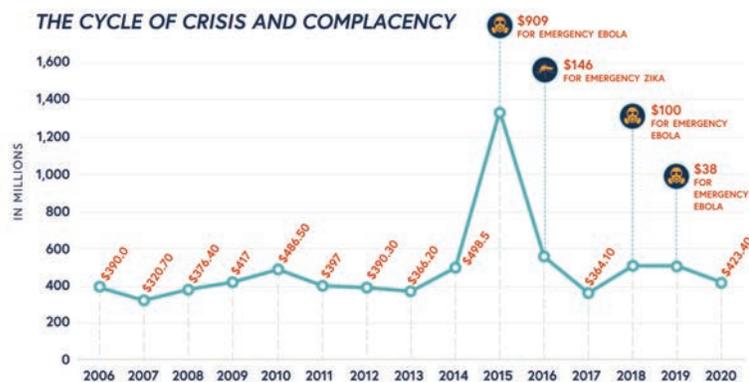
In October 2019, the Global Health Security Index reaffirmed the GPMB's findings. The Global Health Security Index is the first comprehensive assessment and benchmarking of health security and related capabilities across all 195 countries that make up the states parties to the International Health Regulations (IHR 2005).³¹ The Index is unprecedented in its comprehensiveness and granularity, drawing from volumes of open-source information and the input of hundreds of scientists and public health experts. The Index proved that it is possible to design and implement a rigorous methodology to systematically measure pandemic preparedness. The Global Health Security Index candidly and soberly found that no country is fully

prepared for epidemics or pandemics, concluding that collectively, international preparedness is weak. The average overall Global Health Security Index score among all 195 countries assessed was 40.2 of a possible score of 100.³²

The GPMB report and the Global Health Security Index each appeal to heads of state and international leaders to acknowledge the enduring, stark risks posed by global health insecurity and to heighten their engagement on a sustained basis. Both reports appeal to governments, from low-income to the most advanced economies, to invest more of their own resources in preparedness.³³ The CSIS Commission on Strengthening America's Health Security applauds these efforts, which align closely with the Commission's own findings and recommendations.

Preparedness can be a tough sell. It is asking governments to invest in things that are difficult to see. The goal of preparedness is to prevent bad things from happening, which means that success is rarely flashy but more often happens quietly and out of view.

The overwhelming responsibility to lead lies with the U.S. government and its partner governments. While the private sector, foundations, and international organizations are all essential to long-term health security solutions, they cannot be relied upon to lead. In the case of the AMR crisis, for example, it is inadvisable to assume the biopharmaceutical industry will devise solutions on its own. The number of companies conducting antibiotic research and development is declining, a reflection of complex scientific, regulatory, and market challenges. The U.S. government needs to



SOURCE: Kaiser Family Foundation, "Global Health Security Funding," accessed October 2019, <https://www.kff.org/interactive/budget-tracker/summary/?filter=ProgramArea%2FGlobal-Health-Security%2FAgency?view=range-years&dataStartYear=2006&endYear=2020>.

provide more incentives and better answers as to how to reverse this trend and preemptively tackle this health security threat.

The countries that are the most vulnerable are not yet making the investments needed, even after conducting careful assessments and preparing national plans.³⁴ For many cash-strapped governments, budget commitments in health security compete against other worthy, politically sensitive, and very concrete priorities, including defense, education, and infrastructure. That financing gap is among the gravest challenges in health security. Chronic underinvestment has hindered genuine capacity building by low- and middle-income countries. This creates considerable innate risk of runaway outbreaks that may not be very visible at the outset but can quickly threaten U.S. national security interests as they spread. The U.S. government should develop programs which incentivize investment by the most vulnerable nations themselves.

A Moment to Change Course

Despite the barriers, new opportunities are arising.

As health security incidents occur more frequently and with higher visibility, velocity, and costs, leaders in the public, private, international, and social sectors (including philanthropies, NGOs, and academic institutions) have begun to take notice and think anew about what long-term strategy is required. Today, economists across sectors increasingly acknowledge the overwhelming business case for investment in health security. An exercise conducted in the aftermath of the 2014-2016 West Africa Ebola crisis calculated the inclusive costs of a severe influenza pandemic could be as high as \$80 billion in annual economic losses and \$490 billion in annual costs tied to illnesses and premature deaths, for a total of \$570 billion per year.³⁵ In contrast, a landmark study published by the National Academies of Sciences, Engineering, and Medicine determined that the cost of investing in basic health security is a relatively modest \$4.5 billion per year.³⁶ There is increasing understanding that the United States can afford to invest—and simply cannot afford not to invest in preventative strategies.

The cost of baseline preparedness is estimated at only about a dollar per person per year—and building and sustaining preparedness need not be an open-ended donor commitment.³⁷ Countries are capable of transitioning to self-reliance with the correct incentives and support. Low- and middle-income partner countries such as Vietnam, Uganda, Cameroon, Ethiopia, and Cambodia have already demonstrated their willingness to step forward, embrace independent assessments of their health security preparedness, develop national action plans, and join in capacity-building collaborations. The

The costs of preparedness are a fraction of the resulting costs of pandemics.



COST OF PANDEMICS
(in average economic losses)

\$570
BILLION
per year

WHO has been central to this effort and has made significant reforms to improve its own outbreak and emergency capacity and its ability to work with key partners.

In the United States, a stable bipartisan Congressional consensus has emerged in which health security has been



"When it comes to investing in America's global health security, an ounce of prevention is a pound of cure. Modest, sustained investment in public health preparedness each year is more effective and less expensive than paying enormous sums to respond and recover from a dangerous, major outbreak."

— Christine Wormuth, RAND Corporation



"I am proud to have forged bipartisan leadership in Congress on global health security issues. People across the country expect the federal government to be prepared to keep them safe during times of natural disasters or biological, chemical, radiological or nuclear threats to our public health and national security. Unfortunately, we remain largely reactionary in our response to pandemics and biological threats. Proactive efforts are critical to our national and health security. Bringing policymakers together to discuss these critical issues as well as the Commission's final recommendations are an essential element of advancing a coherent vision for U.S. global health security policy."

— U.S. Congresswoman Susan Brooks (R-IN-5)

largely insulated from political polarization. Though several committees and sub-committees have jurisdiction and funding authorities in this area, it has been possible to forge a unified vision of core goals and principles around pressing health security challenges.⁸

8. Refer to Appendix II: Congressional Authorities and Oversight of U.S. Government Efforts to Advance Global Health Security for more information on relevant committees and subcommittees.

RECENT U.S. CONGRESSIONAL ACTION

There is strong bipartisan support in the U.S. Congress for global health security, as evidenced by the recent introduction of a number of bills in this area. Included below are highlights of recent proposed legislation related to global health security, although this is by no means an exhaustive list. The Commission is encouraged by and supportive of these efforts. They provide a foundation for sustained action by the U.S. Congress to strengthen global health security.

DEVELOPING AN INNOVATIVE STRATEGY FOR ANTIMICROBIAL RESISTANT MICROORGANISMS (DISARM) ACT OF 2019:

In June 2019, Senators Johnny Isakson (R-GA) and Bob Casey (D-PA) introduced the DISARM Act.³⁸ This proposal seeks to strengthen the research and development pipeline for antimicrobials and would allow Medicare to reimburse qualifying hospital-administered antibiotics used to treat serious or life-threatening infections.

EBOLA ERADICATION ACT OF 2019: The Ebola Eradication Act was introduced by Senator Bob Menendez (D-NJ) in May 2019 and directs USAID to support efforts in the DRC, South Sudan, and Burundi to combat the ongoing Ebola outbreak.³⁹ The Senate passed the act in September 2019 (S.1340) by unanimous consent, authorizing activities to combat the Ebola outbreak in the DRC.⁴⁰ At time of writing, it awaits action in the House of Representatives.

FLU VACCINE ACT: The Flu Vaccine act was introduced by Congresswoman Rosa DeLauro (D-CT) and Senator Edward Markey (D-MA) in February 2019.⁴¹ The Flu Vaccine Act calls for \$1 billion (\$200 million annually for fiscal years (FY) 2020 through 2024) to support the National Institutes of Health's (NIH) efforts to develop a universal flu vaccine.



As a leader in Congress of bipartisan efforts to strengthen international and domestic public health security preparedness and response programs, I believe Congress must maintain this momentum by continuing to address pressing health security issues, including vaccine hesitancy. Vaccinating children against deadly diseases, such as measles, is essential to U.S. health security, and I am committed to improving our efforts to reach parents with quality science and win their trust and confidence."

— U.S. Congresswoman Anna Eshoo (D-CA-18)

THE LOWER HEALTH CARE COSTS ACT OF 2019: The Lower Health Care Costs Act was introduced by Health, Education, Labor and Pensions (HELP) Committee Chairman Senator Lamar Alexander (R-TN) and Ranking Member Senator Patty Murray (D-WA) in June 2019 and reported out of the committee with broad bipartisan support in July 2019.⁴² The bill includes provisions addressing vaccine hesitancy and strengthening public health data management, both of which are included in companion legislation in the House of Representatives.

PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND ADVANCING INNOVATION ACT (PAHPAI) OF 2019: In June 2019, President Trump signed PAHPAI into law.⁴³ PAHPAI was originally introduced in the House by Energy and Commerce Health Subcommittee Chairwoman Anna G. Eshoo (D-CA) and Congresswoman Susan Brooks (R-IN) and by Senators Richard Burr (R-NC) and Bob Casey (D-PA) in the Senate. The legislation reauthorizes and builds upon public health preparedness and response programs at the U.S. Department of Health and Human Services (HHS) and the CDC. PAHPAI authorizes \$611.7 million for the Biomedical Advanced Research and Development Authority (BARDA) to implement strategic activities to address a range of public health security threats, including pandemic influenza and AMR, a \$50 million increase over FY 2019 funding levels.⁴⁴ This increased investment will further support BARDA in the develop-

ment of surveillance technology, diagnostics, and countermeasures for emerging and high-consequence infectious diseases with pandemic potential.

VACCINE AWARENESS CAMPAIGN TO CHAMPION IMMUNIZATION NATIONALLY AND ENHANCE SAFETY (VACCINES) ACT OF 2019: The VACCINES Act was introduced in May 2019 by Representatives Kim Schreier (D-WA), Michael Burgess (R-TX), Eliot Engel (D-NY), Brett Guthrie (R-KY), Kurt Schrader (D-OR), and Gus Bilirakis (R-FL) and Senators Gary Peters (D-MI), Pat Roberts (R-KS), and Tammy Duckworth (D-IL).⁴⁵ The VACCINES Act authorizes \$6 million annually for FY 2020 through FY 2024 for the CDC to study and monitor vaccine hesitancy and conduct an expanded public awareness campaign on the importance of immunizations.

VACCINE INFORMATION AND PROMOTION (VIP) ACT OF 2019:⁴⁶ The VIP Act was introduced in June 2019 by Representatives Sheila Jackson Lee (D-TX), Eleanor Holmes Norton (D-DC), Gwen Moore (D-WI), Terri Sewell (D-AL), Ayanna Pressley (D-MA), Eddie Bernice Johnson (D-TX), Carolyn Maloney (D-NY), Donald Payne Jr. (D-NJ), and Lucy McBath (D-GA). The VIP Act authorizes \$50 million annually for FY 2020 through FY 2024 for HHS to counter the rise of vaccine hesitancy through expanded vaccination education programs, public awareness, and communications campaigns.



"Health security challenges are innately complex, and require all of us working together, across agencies, jurisdictions, and even across countries, to come together and form a better line of defense. No government or private company or NGO can solve them alone. We have to come together in private-public partnerships to overcome these formidable challenges."

— Julie Gerberding, Merck & Co, Inc



"We have seen time and again that diseases do not respect national borders. We have to act simultaneously at home and abroad. At the same time that we invest in global preparedness, we must also focus on the needs within our borders: strengthening leadership, coordination, and funding to respond to public health and biological threats at home."

— Peggy Hamburg, National Academy of Medicine

The executive branch has made considerable policy progress, as evidenced recently in the evolution of the Global Health Security Agenda (GHSA), the issuance of the updated National Biodefense Strategy in 2018—aided by the high-quality work of the Bipartisan Commission on Biodefense—and the White House Global Health Security Strategy in 2019.^{42,48}

STRENGTHENING DOMESTIC PREPAREDNESS

This report highlights actions the U.S. government can take to counter health security threats around the world. Even as the Commission emphasizes the importance of stemming disease beyond U.S. borders,

it also fully recognizes the vital importance of investing in domestic public health infrastructure and preparedness, which continue to lag dangerously behind what is required to protect Americans.

In this respect, the Commission complements the work of the Bipartisan Commission on Biodefense (formerly known as the Blue Ribbon Study Panel on Biodefense), which assesses and provides recommendations on strengthening the state of U.S. biodefense. It is critically important that the U.S. government invest at a higher level, on a sustained basis, in state and local public health capacity, as these officials will be on the front lines in the case of an outbreak in the United States.



"Real-time data at the fingertips of decision makers on the front lines of an epidemic speeds response efforts. The U.S. government has promoted the use of digital health tools to improve collection, analysis and use of health data, but more effort is needed by the United States and others to ensure these technologies are effectively used and safeguards for data sharing are in place prior to a crisis."

— Steve Davis, PATH

We have seen exceptional innovations emerge from the 2014-2016 Ebola crisis in West Africa, led by the private sector. An experimental Merck vaccine developed in that period underpins today's Ebola response in the DRC, where more than 230,000 persons have been immunized as of October 2019.²⁹ A second Ebola vaccine by Johnson & Johnson, also first developed in West Africa, is now being introduced on an experimental basis in Uganda and the DRC.³⁰

More recently, randomized field trials of four experimental Ebola treatments conducted during the DRC outbreak have produced preliminary results indicating that two therapies, one developed by Ridgeback Biotherapeutics and the other by Regeneron Pharmaceuticals, can significantly increase survival if administered early.³¹ Both therapies are public-private partnerships, with the National Institute of Allergy and Infectious Diseases (NIAID), BARDA, and the Department of Defense (DOD) all playing key supporting roles.³² Together, these promising therapies have the potential to change the course of Ebola outbreaks. For the immediate crisis in the DRC, that will require overcoming chaos and violent disorder, including violent, opaque networks attacking health providers; creating a far better dialogue with mistrustful, alienated communities; and better motivating citizens to step forward early to seek treatment.

That same Ebola crisis of 2014-2016 inspired the creation of the Coalition for Epidemic Preparedness Innovations (CEPI), an alliance comprised of governments, foundations, companies, non-profits, and researchers, with a mandate to finance and coordinate the development of new vaccines to

prevent and contain infectious disease epidemics.³³ CEPI is off to a promising start in its first two and a half years, investing \$456 million in new partnerships with the private sector, academic institutions, and other non-profit product development enterprises to develop new vaccines.³⁴ It is a particularly compelling innovation in health security.

DIGITAL HEALTH AND HEALTH SECURITY

Timely and accurate information to assess disease burdens, track emerging outbreaks, and support disease prevention and control measures is essential in epidemic response. Over the past decade, countries have increasingly transitioned from paper-based to digital information systems and have gained new capabilities and insights by engaging in the corresponding data. When optimized, the convergence of digital technologies and new data models with health systems, also known as "digital health," can allow countries to make more accurate and timely decisions for preventing, detecting, and responding to outbreaks.³⁵

While clear successes have resulted from these initial efforts, significant challenges remain, including corruption, lack of transparency, and distrust of commercial firms.³⁶

- Many health information systems are siloed and capture duplicate data, putting significant strain on

health workers who collect, manage, and use this information.

- Health information systems are not always interoperable. Their inability to reliably “talk” to one another hinders evidence-based decisionmaking.
- Many low- and middle-income countries need to boost stakeholders’ capacity to design, manage, and support digital health systems, as well as effectively use data.
- Many countries lack the necessary governance structures, policies, and coherent national plans to ensure transparency and accountability, guard against corruption, and support the utilization of data to inform epidemic response decisions and actions.
- The U.S. government has not sufficiently leveraged the American technology sector’s potential to advance digital health and global health security goals. Part of that process involves building trust and confidence in private-sector partners.

The United States, in collaboration with private-sector technology partners, is a global leader in creating and adopting digital health technologies for epidemic response. The U.S. government is in a strong position to leverage its resources and build on proven strategies to meet existing gaps that are prohibiting true scaling of digital technologies. Deploying these technologies and ensuring coordination with global and national partners can ensure that the necessary data and information are available in the right place, at the right time, and to the right people to speed epidemic response.

**A
U.S. Doctrine
of
Continuous
Prevention,
Protection,
and
Resilience**

The seven recommendations below will enable the United States to replace the crisis-complacency cycle with a doctrine of continuous prevention, protection, and resilience—investing strategically in preparedness now so the United States can manage threats and avoid catastrophic costs later.

The doctrine aims to restore White House leadership, strengthen financing and the speed of response, build reliable partners abroad, enhance the U.S. government's ability to operate in disordered settings, and accelerate technological innovations to secure the future. It aims to strengthen accountability, prioritization, and reform of fragmented programs.

The Commission urges Congress and the administration to pursue the following integrated package of actions:



1. Restore health security leadership at the White House National Security Council.

RECOMMENDATION

The U.S. government should re-establish a directorate for global health security and biodefense on the National Security Council (NSC) staff and should name a senior-level leader in charge of coordinating U.S. efforts to anticipate, prevent, and respond to biological crises. These actions will ensure that the necessary leadership, authority, and accountability is in place to protect the United States from a deadly and costly health security emergency.

RATIONALE

Global health security and biodefense challenges pose a national security threat to the American people and require centralized leadership at the highest level of the U.S. government. While the administration has released its National Biodefense Strategy and Global Health Security Strategy and strengthened the roles of departments and agencies, top-level leadership is still needed at the White House. Global health security threats touch the equities of multiple executive agencies—including the Departments of State, Health and Human Services, Defense, and Justice, as well as the intelligence community—and require informed, coordinated attention to an array of capabilities and responses spanning medical technologies and public health interventions, intelligence gathering and preemption, and sustained high-level diplomacy to mobilize international coalitions. By definition, this zone of national security requires a strong interagency process led by the White House.

In the fall of 2016, in the aftermath of the slow, uncoordinated, and resource-intensive response to the Ebola crisis in West Africa, the White House NSC staff created the Global Health Security and Biodefense directorate. Designed to plan for and oversee rapid, efficient, government-wide responses to global health security, the directorate pooled NSC staff focused on domestic and international biodefense and health security issues. Led by a senior director, the directorate reported to the national security advisor and the deputy homeland security advisor, the latter of whom was designated as the lead for coordinating the U.S. response to a biological crisis. The White House also released a companion executive order in November 2016 advancing the GHSA.²⁷

In the spring of 2018, the administration dissolved the NSC directorate for Global Health Security and Biodefense, and



"Health security is fundamental to U.S. national security. It is encouraging that despite a polarized U.S. Congress, this is an area where we have made meaningful progress on a bipartisan basis. We all have an interest in national security, in our health, and in making sure that we do the right thing to protect the American people."

— Kelly Ayotte, Former Senator (R-NH)

oversight of these issues was incorporated into the directorate for Weapons of Mass Destruction and Biodefense.⁵⁸ In the fall of 2018, the White House released a National Biodefense Strategy designed to strengthen the country's defenses against biological threats to health and safety.⁵⁹ President Trump also signed a National Security Presidential Memorandum on Support for National Biodefense, which reaffirmed U.S. support for the GHSA, extending through 2024, and established a Biodefense Steering Committee chaired by the secretary of Health and Human Services and responsible for the monitoring, coordination, and implementation of the strategy.⁶⁰ In May 2019, the White House released a Global Health Security Strategy, the first of its kind, which "defines the actions the Administration will take to prevent, detect, and respond to infectious disease threats, whether naturally occurring, accidental, or deliberate," and which reiterated the administration's support for the GHSA.⁶¹

The administration should be commended for advances in the national biodefense and global health security strategies. However, critical leadership gaps remain. It remains unclear who would be in charge at the White House in the case of a grave pandemic threat or cross-border biological crisis, whether natural, accidental, or deliberate. Over the past year, the sluggish White House response to the Ebola outbreak in the DRC is but the latest example of this problem.

And while the Biodefense Steering Committee plays an important role in implementing the National Biodefense Strategy, senior leadership in the White House is required to successfully coordinate the large number of government agencies and programs across health, security, development, and defense, as well as private-sector actors that

would be involved in a response to an international public health threat. In the case of a health security emergency, White House leadership will also be critical in navigating challenging political issues like quarantines and travel bans and in communicating to and reassuring the American public. The authorities currently in place at HHS are insufficient to address these critical, complex, and often urgent interagency demands.

In addition to coordinating the interagency process, a global health security and biodefense directorate at the NSC can reform fragmented programs and ensure higher efficiencies, strengthened accountability, and better spending of scarce resources. Together with the Office of Management and Budget (OMB), it can identify, rationalize, and align funding in the U.S. president's budget across agencies.

ESTIMATED COST: N/A



2. Commit to full and sustained multi-year funding for the Global Health Security Agenda to build partner capacity.

RECOMMENDATION

U.S. direct investments remain essential to build health system capacity. To stop outbreaks at the source, Congress should authorize stable funding through the GHSA's 2020-2024 phase for capacity-building programs in priority countries, including the original 17 GHSA partner countries, plus other select high-risk countries, such as the DRC. Experts advise that this will involve returning the GHSA-re-



"To contain a naturally occurring outbreak, a lab accident, or a bioterrorist attack, the first response has to be the health system that identifies the pathogen, does the surveillance, finds its origin, and promotes measures to limit its damage. We must expand and sustain funding for the GHSA, the world's vehicle for building resilient public health infrastructure."

— Ambassador Jimmy Kolker, U.S. Department of Health and Human Services (former)

lated budgets of the principal executive agencies implementing the GHSA (the CDC, USAID, the U.S. Department of State, and the DOD) to FY 2015 baseline levels, with Ebola supplemental funding.

RATIONALE

The GHSA is a multi-partner initiative that facilitates burden sharing and builds local health system capacity.⁶³ The \$1 billion in emergency supplemental funding that the U.S. government has committed to the GHSA so far (FY 2015-FY 2019) has gone a long way in helping countries to prevent or stem the spread of infectious disease outbreaks.⁶³ The question now is what comes next, as the emergency supplemental funding ends at the conclusion of FY 2019.

A cornerstone of the effort is the voluntary, collaborative assessment process designed to measure a country's capacity to prevent, detect, and rapidly respond to public health threats.⁶⁴ These assessments, known as Joint External Evaluations (JEEs), have been conducted in 100 countries in six regions since the GHSA was launched in 2016, and 21 additional JEEs are scheduled as of this

writing.⁶⁵ Most of these assessments have been published to facilitate understanding and enable urgent gaps to be filled. The United States has been actively engaged in the JEE processes, participating in JEE missions and providing technical support to countries as they develop National Action Plans. The GHSA Private Sector Roundtable brings the private sector into this process by connecting GHSA countries with companies in the health care, finance, technology, and logistics sectors.⁶⁶

Several U.S.-assisted GHSA countries have experienced infectious disease outbreaks in recent years, and the improved health system and preparedness capacities built with the help of U.S. agency support and other international partners have proven decisive. In October 2017, a U.S.-assisted laboratory confirmed a positive case of Marburg virus in eastern Uganda. Marburg is a lethal virus in the same family as Ebola, and this laboratory confirmation proved the first critical step in a rapid and effective Uganda-led response. The Uganda Ministry of Health deployed a rapid response team to the affected region, which was staffed in part by U.S.-supported Field Epidemiology Training Program (FETP) graduates. Ultimately, three cases were confirmed, all of



A laboratory official examines mosquito samples at the National Institute of Hygiene and Epidemiology in Hanoi in August 2018. Building health system capacity, including laboratory capacity, is critical to responding to mosquito-borne diseases and other health security challenges.

NHAC NGUYEN/AFP VIA GETTY IMAGES

which were fatal. But through effective contact tracing and community education, the Ugandan rapid response team stopped the spread of the virus.⁶⁷

Fully funding the GHSA into the future will help the U.S. government stop outbreaks at their source—the best way to protect the American people. As the emergency supplemental funding comes to an end, there are funding gaps that should be addressed. Experts estimate that an additional \$100 million per year above the enacted FY 2019 budget will be required for the CDC, and an additional \$35 million per year for USAID. These investments should be understood as part of a 10-year strategy for building self-reliance among partner countries.

As part of that investment, the CDC and USAID should give serious consideration to investing \$20 million per year to strengthen digital health information systems in priority countries.⁶⁸ In today's digital world, interoperable health information systems are becoming essential to facilitate evidence-based decisionmaking. That requires effective regulatory and legal oversight to ensure transparency and accountability; surveillance and laboratory systems to track emerging outbreaks and support disease control measures; digital monitoring of supply chains to ensure commodities are available when needed; and monitoring of vaccine and therapeutic delivery.

Key programs within the Departments of Defense and State should also be protected and sustained. These include the DOD Cooperative Threat Reduction (CTR) Biological Threat Reduction Program (CTR/BTRP), DOD Global Emerging Infections Surveillance and Response (GEIS) Program, and the State Biosecurity Engagement Program (State/BEP). These budgets support global health security efforts aimed

at preventing deliberate and accidental outbreaks, linking law enforcement and public health officials, and detecting emerging threats as early as possible.

ESTIMATED COST:⁶⁹

CDC: \$100 million beyond FY 2019 levels (annually for 10 years).

USAID: \$35 million beyond FY 2019 levels (annually for 10 years).

C. Refer to Appendix I: Illustrative Costing for Recommended Programs and Initiatives for illustrative costing of all recommendations outlined in this section.

THE DOD AND HEALTH SECURITY

The DOD contributes to overall U.S. health security through a number of programs that are aimed at countering biological threats from all sources.⁶⁹

U.S. military medicine has a long history of landmark successes against tropical diseases affecting troops from temperate zones operating in tropical environments. Examples include the efforts against yellow fever, which were led by U.S. Army Majors Walter Reed and William Gorgas during the Spanish American War, and extensive epidemiological studies during the 1918 worldwide influenza epidemic.

Today, the DOD operates a worldwide public health, infectious disease research, and disease surveillance network to protect U.S. and allied forces against



"Historically, more military service members have died from dangerous infectious disease than from bullets. Over the last century, the U.S. military has made extensive investments to protect U.S. and allied forces from health security threats and confront and defeat these global threats. These investments remain essential to protect both the military and the general public."

— Admiral Jonathan Greenert, U.S. Navy (former)



"Global health security is national security. If we want to see truly strengthened health security, we need to better integrate the Department of Defense's unique research, mobility, and security capacities."

—General Carter Ham, U.S. Army (former)

infectious diseases and other biological hazards. These extensive programs benefit both the military and the general public.⁷⁰ A few examples include:

- The U.S. military GEIS Program, established in 1997, works closely with the DOD overseas and domestic infectious disease research laboratories, the CDC, the WHO, and others.⁷¹
- The Defense Threat Reduction Agency's (DTRA) Biological Threat Reduction Program (BTRP) supports international partnerships and capacity-building efforts to combat the threat of intentional, accidental, and naturally occurring biological threats.⁷² BTRP works closely with regional geographic combatant commanders (GCCs) to support activities in Asia, Africa, the Middle East, and Europe. These efforts have become increasingly coordinated with activities of other programs and organizations aligning with international frameworks, such as the IHR and the GHSA
- The Military Infectious Diseases Research Program (MIDRP) manages research on naturally occurring infectious diseases, focusing on the development of vaccines and drugs, diagnostics, and vector control on illnesses most likely to impact military operations. MIDRP supports basic science, preclinical studies, and clinical trials leading to Federal Drug Administration (FDA) approval. Most of this work is carried out at DOD laboratories located in Maryland—the Walter Reed Army Institute of Research (WRAIR), the U.S. Naval Medical Research Center (NMRC), and the U.S. Army Research Institute of Infectious Diseases (USAMRIID)—as well as the overseas DOD laboratories located throughout the world.
- The DOD supports many other activities developing detection capabilities, medical countermea-

ures, and personal protective equipment against biological threats.

- Finally, U.S. military forces are available for disaster response anywhere in the world when necessary to augment civilian capabilities. Operation United Assistance, the DOD support for the U.S. government response to the Ebola outbreak in Liberia in 2014-2015, is the most recent and prominent example.



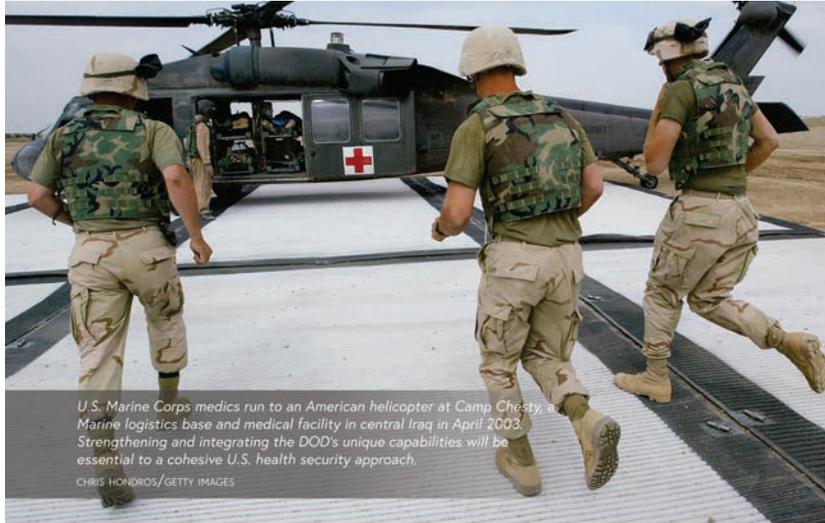
3. Establish a Pandemic Preparedness Challenge at the World Bank to incentivize countries to invest in their own preparedness.

RECOMMENDATION

U.S. multilateral leadership is necessary to address the financing gap for preparedness, one of the starkest problems in health security. Linked to its support for the GHSA 2024 framework, in FY 2020 the U.S. government should assemble an international consortium of public and private donors to launch a five-year, \$750 million Pandemic Preparedness Challenge to catalyze domestic investment in health security preparedness in the 32 fragile states eligible for financing from the World Bank's International Development Association (IDA). The United States would pledge one-fifth of the donor shares, leveraged against contributions by other donors of the remaining four-fifths.

RATIONALE

The financing gap for preparedness is one of the starkest problems in health security, especially among fragile states. The lack of preparedness in fragile and conflict-affected states—where infectious disease outbreaks are increasingly common—directly impacts and threatens



U.S. Marine Corps medics run to an American helicopter at Camp Chesty, a Marine logistics base and medical facility in central Iraq in April 2003. Strengthening and integrating the DOD's unique capabilities will be essential to a cohesive U.S. health security approach.

CHRIS HONDROS/GETTY IMAGES



"As the 2014-2016 West Africa Ebola crisis reminded us, pandemics do not respect national borders. The only long-term, sustainable solution is for governments to invest in their own preparedness. We are determined to push forward to motivate countries to address this glaring financing gap."

— U.S. Senator Todd Young (R-IN)

U.S. economic, health, and national security interests. Investments in preparedness are cost-effective and affordable, but many fragile state governments continue to underinvest at dangerously low levels. In the poorest and most fragile countries, where many needs are pressing and resources are constrained, political leaders often face difficult trade-offs between investing in longer-term preparedness versus shorter-term, more tangible efforts like building roads or schools.

However, experience suggests that with the right incentives and support, developing countries will invest their

money in preparedness. In Uganda, Cameroon, Ethiopia, Vietnam, and Cambodia, for example, the governments drew upon their own budgetary resources and talent to bolster their preparedness, with support provided by donors under the GHSA framework. While there are several multilateral mechanisms in place to support emergency outbreak responses, much more effort is needed to partner with countries to invest in their own long-term preparedness.

Thirty-two countries eligible for IDA financing, with a total population of about 400 million people, are classi-

fied by the World Bank as fragile and conflict-affected states.⁷³ As of August 2019, 24 of these countries have completed JEEs of their preparedness gaps, and 15 have developed National Action Plans to address those gaps.⁷⁴ Yet most of these countries are unable to marshal sufficient domestic resources to fully fund their National Action Plans, rendering their health and preparedness systems acutely vulnerable.

To help fragile countries turn their plans into reality and build self-sustaining capacities, Congress should press the U.S. government to partner with public and private donors to launch a five-year, \$750 million Pandemic Preparedness Challenge. The United Kingdom, Germany, Japan, France, Australia, Finland, Denmark, and Sweden would likely be strong partners in this effort. Saudi Arabia, the United Arab Emirates, South Korea, and others might join as well.

Administered by the World Bank, the Challenge will work in tandem with IDA financing to supplement direct investments by states themselves in capital and operational costs to strengthen preparedness. Countries whose plans and budgets are approved by the Challenge's board may be awarded up to a maximum of five years of grant funding to cover start-up and recurrent costs.

To promote self-reliance and sustainable domestic financing, the Challenge investments will be time-bound and will cover a declining share of a country's recurrent costs each year (e.g., up to 80 percent in year one and 20 percent by year five). Each Challenge country will have an exit strategy, with success measured by increases in JEE scores over the life of the investment plan. The U.S.

government's share of the Challenge will be \$150 million, or \$30 million a year for five years, for a 1:4 leverage with other donor funding.

ESTIMATED COST:
\$30 million per year for five years.



4. Ensure rapid access to resources for health emergencies.

RECOMMENDATION

To ensure that flexible funds are available early in a crisis, the USAID and CDC contingency accounts should be set and maintained at a level of \$250 million each, replenished annually as needed. The United States should also pledge \$25 million annually to the WHO Contingency Fund for Emergencies (CFE), using that contribution to leverage other donors to bring the CFE to its targeted \$100 million level.

RATIONALE

Stopping a global health security crisis requires fast, early action. Today, demand for such action is swiftly rising as the number of major health and humanitarian crises increases, as can be seen in the DRC, Venezuela, Yemen, Afghanistan, and Syria. Expanding support for contingency funds will allow the United States to support emergency response activities by nongovernmental and international organization partners in insecure and disordered settings, where direct engagement by U.S. agencies may be more difficult or simply not feasible.



"Investing in global health security helps to ensure that the world remains a safe place and American citizens are protected from harm. To stop outbreaks at their source, we need rapid response contingency funds and we need to help other countries to invest in their own preparedness.

Through the appropriations process, Congress has worked on a bipartisan basis to ensure that funding goes to countries to build and sustain health security preparedness."

— U.S. Congressman Tom Cole (R-OK-4)

In the aftermath of the slow and cumbersome response to the 2014-2016 West Africa Ebola outbreak, the U.S. government recognized the clear need for contingency funds that could be readily accessible in the case of an infectious disease emergency. A second major lesson learned from the 2014-2016 Ebola outbreak is that the CDC and USAID each play a unique and essential role in a global health security crisis, and neither is sufficient on its own. The resulting establishment of the CDC Infectious Diseases Rapid Response Reserve Fund and the USAID Emergency Reserve Fund for infectious disease outbreaks was a significant first step in addressing the gap in quick-disbursing finances.

However, independent experts have estimated that the USAID and CDC contingency accounts, at their current levels, are not sufficient to respond to the increasing number and intensity of global health crises. In FY 2019, \$50 million was appropriated for the CDC contingency fund, and \$2 million for the USAID contingency fund.^{75,76} Experts recommend that these accounts be set and maintained at a level of \$250 million each, replenished on an annual basis as warranted. It will be important to amend current policies to permit rapid disbursement of these funds during the early stages of infectious disease outbreaks.

In parallel, a U.S. annual pledge of \$25 million to the WHO CFE will significantly bolster the WHO's capacity to move expeditiously in deploying staff and funding early responses to dangerous outbreaks. A contribution to the WHO CFE will allow the United States to support emergency response activities by NGOs, national governments, and international organizations in difficult-to-access settings where direct U.S. government engagement is not possible. The United States should use that contribution to leverage other donors to

contribute to achieving and maintaining a \$100 million CFE. No less important, the United States should prioritize expanding and ensuring sufficient financing flexibility and speed in the World Bank's emergency response facilities.

ESTIMATED COST:
CDC Infectious Diseases Rapid Response Reserve Fund: Increase to \$250 million and maintain at that level.
USAID Emergency Reserve Fund: Increase to \$250 million and maintain at that level.
WHO Contingency Fund for Emergencies: \$25 million per year.



5. Establish a U.S. Global Health Crises Response Corps.

RECOMMENDATION

To engage and operate effectively and safely in austere, unsafe settings, the U.S. government should establish a U.S. Global Health Crises Response Corps. The Corps should be constructed on USAID and CDC existing capabilities, augmented by joint team training exercises, and provided with security, intelligence and data, and communications support. The mandate of the Corps is to respond early, with local partners, to stop outbreaks at their source, and to strengthen local capacities.

RATIONALE

Small teams of select, highly experienced U.S. civilian public health and humanitarian experts, working alongside local partners and national leaders, form the "cerebral cortex" of outbreak response.



"Today the world faces a volatile convergence of instability, state weakness, and conflict. These conditions are hindering the ability of the United States to support health service delivery and outbreak response in a number of critical regions. We need to be able to deploy our best and brightest civilian experts into disordered settings where outbreaks strike."

— Rebecca Hersman, CSIS

CDC civilian experts provide on-the-ground interpretations of fast-moving, complex outbreaks and immediate advice on the precise mix of public health interventions, geographic priorities, and communications with communities and partners necessary to halt outbreaks. In addition, the CDC possesses essential expertise in epidemiology, data systems, contact tracing, and training of the local health work force.

The USAID Disaster Assistance Response Team (DART) platform, refined over the past three decades, has developed protocols and operational capacities to integrate the CDC, the Department of State, and others, as well as how to interface with the U.S. military, as needed, in deploying into humanitarian emergencies.⁷⁷ USAID has essential aptitudes in large-scale logistics, contracting, and supply chain management and expertise in the critically important development sectors of water, food, and health infrastructure.

Their combined presence can be a high-impact game changer, as witnessed in the Ebola outbreaks in West Africa in 2014-2016. Inversely, when U.S. and other critically important experts are barred from outbreak zones due to insecurity, as currently seen in the DRC, disease may spread, with grave consequences.

The world has grown more perilous, and the worst danger zones are precisely where the greatest health security risks frequently reside. Yet risk aversion has impeded USAID and CDC deployments into several outbreak zones, including the DRC, South Sudan, Iraq, Syria, and Nigeria, while Yemen and Afghanistan offer only minimal access. Moreover, danger is not likely to abate in the future. If anything, it will worsen. Policymakers are understandably cautious—but failing to engage is ultimately trading one risk for another. The United States simply cannot afford to leave its key civilian capabilities on the sidelines of rapidly emerging health crises.

In combination, U.S. civilian teams from the CDC and USAID are often able to engage partner governments, civil society, and other nongovernmental providers far more authoritatively and bluntly than the WHO. Their unique impact warrants assuming higher risks than might otherwise be the case, along with making higher investments in training, support, and protection.

The Corps will be drawn from the ranks of current U.S. public health and humanitarian experts in the CDC, USAID, and the U.S. Public Health Service. The majority, it is expected, will have significant experience serving on USAID-led DART teams and as members of the CDC Global



Police officers run in Goma, DRC on December 27, 2018, during clashes with demonstrators protesting the postponement of the general elections in this area, which government officials attributed to the Ebola outbreak.

PATRICK MEINHARDT / AFP VIA GETTY IMAGES

Rapid Response Team (Global RRT). They will voluntarily agree to special training and to be on-call to deploy, as needed, in civilian expeditionary teams introduced for rotational assignments away from their normal duties into insecure environments. The Corps will have two tiers: Fifty highly experienced and highly trained advanced responders will be committed to deploy as teams on very short notice; and a second tier of 400-500 experts will be available for deployments that can be made with careful prior planning.

The Corps will bring to the field public health expertise and operational experience in select, vitally important disciplines: incident and data management; community engagement to build trust and confidence; epidemiology; laboratory-based pathogen surveillance; and emergency humanitarian response services, including in non-health areas such as water, food relief, and shelter. The Corps should systematically invest in strengthening the capacity of local, in-country, and regional partners, including NGOs and civil society groups. Though not intended to deliver clinical health services, it can play an essential role in facilitating and expediting service delivery by local partners.

The Corps will be trained to deploy into gray zone settings prone to intermittent, localized violence that falls below the level of open armed conflict conducted by armies and irregular forces. Teams from the Corps will be equipped to deploy to two to three countries in the first one to two years. The teams will be charged with aligning their work in support of partner institutions and agencies, including the host nation, the WHO and related UN bodies, and operational NGOs.

All members of the Corps will receive training in operating as structured teams, critical languages (experts recommend French, Arabic, Portuguese, and Spanish), negotiation of local access, communications, use of local intelligence, building trust with local communities, means to minimize risks and optimize protection, and entry and extraction protocols. Training will emphasize speed and self-sufficiency in deployment, and it will be critical to ensure unencumbered access to critical supplies.

For the Corps to operate in insecure circumstances will require overt acknowledgement of the need to accept significant risks when the risks of not acting are grave. It will also require acknowledgement of the need for the Corps to receive quality, real-time, granular intelligence. To rebalance risk calculations, Congress or the administration should issue a policy statement declaring that putting U.S.

civilian health response experts on the frontlines of health crises is a compelling U.S. national security interest. Follow-on steps will be needed to clarify what that means in practice in terms of revised risk calculations.

As envisioned, security will be managed on a case-by-case basis. It should be provided by the UN, host nation forces, or local police forces. The Corps will include appropriate DOD advisers, but will not call for DOD to provide security forces.

Depending on the specific situation, either the CDC or USAID should be designated as the lead agency with lead operational responsibilities, acting in close partnership with the other. The lead agency will direct a dedicated interagency process that deliberates over when to engage in public health emergencies and at what level, linked to metrics such as: severity of the outbreak; levels of insecurity and risk of escalation; health and security risks to the population and health personnel; whether there is a PHEIC declaration; and other international, regional, or national security factors. The lead agency will be charged with coordinating recruitment, training, and deployment of the Corps. It will be critically important that the relationship between the CDC and USAID be more constructive and functional. To that end, it will be important to clarify the specific roles and responsibilities of the CDC and USAID within an agreed response framework.

Ultimately, the White House will decide when and where to deploy, based on close consultation with the CDC director, the USAID administrator, the Department of State and chief of mission in the affected country, relevant Department of State security personnel, and DOD personnel, as well as through consultations with the WHO and the host government. Teams will not be deployed without host government request or consent and will deploy under the authority of the chief of mission. It will be necessary to develop protocols that establish the security parameters under which the chief of mission could authorize deployment of the Corps.

ESTIMATED COST:

U.S. Global Health Crises Response Corps: \$50 million per year for five years.

Strengthening the FETP, the Public Health Emergency Management (PHEM) Fellowship program, and National Public Health Institutes (NPHIs): \$36 million per year for five years.



"The U.S. government has unrivaled civilian and military capabilities in detecting, preventing, and responding to global health security threats, but these capabilities don't always achieve jointness. Ensuring joint training, exercises, and deployment will only strengthen the U.S. global health security posture."

— Ambassador Karl Hofmann, Population Services International



6. Strengthen the delivery of critical health services in disordered settings.

The United States should strengthen, refocus, and adapt programs and capacities to ensure the continuity and expansion of necessary health services, including the delivery of immunizations, gender-based violence (GBV) programs, and maternal and reproductive health and family planning services in crisis settings. The health and protection needs of acutely vulnerable women and girls should be prioritized.

Immunization Programs

RECOMMENDATION

The U.S. government should lead an effort to strengthen immunization programs in disordered settings through an improved comprehensive data system to anticipate and prevent vaccine-preventable disease (VPD) outbreaks, particularly in fragile and conflicted countries; rapid response funding to likely outbreak "hotspots"; and enhanced training programs to build the capacity of community health workers operating in disordered settings to deliver immunizations.

RATIONALE

Disorder disrupts immunization programs, acutely impacting coverage and raising the risks of outbreaks. In 2017, at least 60 percent of children who were not reached with routine immunization services lived in just 10 countries, including 5 of the top 15 most fragile states in the world.⁸⁶ Twenty million people currently cannot receive vaccines due to weak primary health systems, poverty, unstable governments, and war.⁸⁷ VPD outbreaks are much deadlier in

disordered settings and have a greater probability of crossing borders into more secure environments.

Global immunization partners, including U.S. agencies, have long cooperated to monitor immunization coverage, assess outbreak potential, and mobilize resources and technical assistance to deliver vaccines in disordered settings.⁸⁸ The U.S. government funds global immunization programs at the WHO and the United Nations Children's Fund (UNICEF), through the Department of State and the CDC, and at Gavi, the Vaccine Alliance, through USAID. At the January 2015 Gavi replenishment conference, the United States pledged \$1 billion for the 2015 to 2018 period, and it has approved a contribution of \$290 million in 2019.⁸⁹ The United States should be prepared to make a robust, multi-year commitment at the 2020 Gavi Replenishment meeting in London as well. Through USAID, the DOD, and HHS, including the CDC and the NIH, the U.S. government also supports overseas immunization programs with bilateral development and research support, technical assistance, and participation in multilateral governing structures, such as the World Health Assembly, the Gavi Board, and the GHSA.

Strengthen Data: The U.S. government should strengthen data systems to enhance national immunization registries and anticipate outbreaks. A network of data hubs integrating geospatial, demographic, political, and health information will help the global community assist fragile countries in anticipating and mobilizing to prevent potential VPD outbreaks. This network could be modeled on USAID's Famine Early Warning Systems Network (FEWS NET).⁹⁰ The CDC should share its experience establishing the Atlanta-based Global Disease Detection Operations Center, where analysts monitor global polio



"Our ability to operate in insecure settings is contingent on our ability to strengthen health system capacity in insecure settings. The U.S. government needs to push to expand its work with international organizations and partner governments around the world to secure global preparedness."

— Tom Frieden, *Resolve to Save Lives*

developments and other outbreaks.⁸³ The capacities of the DOD GEIS Program and overseas research laboratories, the National Geospatial Intelligence Agency, and NASA's Goddard Space Flight Center should also be harnessed to contribute to this work, much as they contribute to FEWS NET. An expert estimate of the initial pilot cost of a comprehensive data system is \$4.77 million a year over five years.⁸⁴

Emergency Funds: The United States should designate emergency immunization funds that can be quickly deployed to assist countries in delivering immunizations to predicted "hotspots" and should urge implementing and donor countries, as well as multilateral agencies, to do the same. As a Gavi donor, the United States could advocate that Gavi incorporate the flexibilities necessary to release funds quickly in response to data warning of a

possible outbreak. The U.S. government should also have contingency funds available for emergency immunization activities.

An expert estimate of the necessary cost for emergency immunization funds is \$20 million a year over five years.⁶⁵ These funds could be drawn from the CDC Infectious Diseases Rapid Response Reserve Fund or the USAID Emergency Reserve Fund for infectious disease outbreaks, as needed and as appropriate. This report recommends these funds be set and maintained at a level of \$250 million each, ensuring ample funding for responding to immunization emergencies, as well as other infectious disease emergencies (refer to Recommendation 4 for more detail).

Training Community Workers: The United States, through USAID and the CDC, should strengthen and expand agency contributions to training programs meant to enhance the capacity of community health workers to deliver immunizations and related services in disordered settings. Flexible emergency training mechanisms are critical to provide training at the community, subnational, and national levels and enable health workers in zones identified as “at risk” to gather on-the-ground information about community immunization coverage needs and work within the local security context to deliver vaccine products quickly and safely to vulnerable communities. Ensuring that trusted community and locally based health workers, rather than outsiders, can deliver vaccines is critical. An expert estimate of the initial cost of this training program is \$975,000 a year over five years.⁶⁶

The CDC should develop and deliver context-specific, short-term training modules preparing community health workers to assess and report on local immunization coverage and needs and deliver vaccines safely within disordered settings. This training should include a focus on culturally and linguistically competent messaging and effective communication to build vaccine confidence. This training could build on the FETP and the Stop Transmission of Polio (STOP) program, which is focused on VPDs.⁶⁷ The Training Programs in Epidemiology and Public Health Interventions Network (TEPHINET) and its parent organization, the Task Force for Global Health, link alumni of such initiatives as the CDC’s FETP with their counterparts across the world.⁶⁸ The CDC could work with partners within TEPHINET and the task force to embed experts within country immunization programs.

The USAID-supported CORE Group Polio Project, an international network of civil society groups and local community health organizations that provides financial and technical assistance to help countries eradicate polio and

address other infectious diseases, could also serve as a model in this area.⁶⁹ Some trained initiatives could be integrated into existing CORE Group work.

ESTIMATED COST:
\$6 million per year for five years.

Health of Women and Girls

RECOMMENDATION

The U.S. government should prioritize women’s and girls’ health and protection in disordered and emergency settings. Congress should authorize \$30 million in flexible funding annually for five years to ensure that the extensive capacities of the U.S. government in the areas of maternal health, reproductive health, family planning, and GBV prevention and response are moved from the sidelines to the heart of crisis response.⁷⁰

This additional flexible funding is essential to spearhead this effort and incentivize U.S. agencies and their partners to rapidly begin execution of the program. The funding is intended to attract higher-level financial commitments from existing programs at USAID and the U.S. Department of State Bureau of Population, Refugees, and Migration (PRM)—a catalytic, incremental approach that will ultimately ensure existing U.S. government resources and capacities are channeled to those disordered settings where the needs of women and girls are greatest.

The \$30 million in flexible funding will be used to launch an integrated model of service delivery for women’s and girls’ health and safety. This model should be piloted in two to three priority emergency settings to demonstrate impact and generate data and lessons to inform future expansion and replication. This model should adapt, refocus, and integrate programs at USAID’s Bureau for Global Health and Office of U.S. Foreign Disaster Assistance (OFDA), PRM, and the CDC, where appropriate.

RATIONALE

The United States has unrivaled financial and programmatic capacities in maternal health, reproductive health, family planning, and GBV prevention and response. However, the U.S. government seldom marshals these extensive capacities in emergency settings, where the needs and vulnerabilities of women and girls are most severe.

Thirty-four million women and girls of reproductive age are estimated to be in emergency situations, often explicitly targeted with sexual violence as a weapon of war.⁷¹ Five million



"One of my priorities as a Commissioner has been to make sure we don't lose sight of how health security threats impact families, especially how they impact women and children. When we plan for disaster, we need to make sure the needs of women and girls are prioritized from the start—not tacked on as an afterthought. We know, when crisis strikes, women often bear the brunt of the burden, as access to health care, including maternal care and family planning services, decreases. The U.S. government needs new capacities to deliver these critical services in the midst of disorder."

— U.S. Senator Patty Murray (D-WA)

of these women are pregnant and face additional health complications and challenges.⁴⁹ Inadequate or interrupted maternal health and family planning services contribute to maternal and neonatal mortality, unintended pregnancies, and unsafe abortions. The alarmingly high risks of GBV and severely limited access to maternal health, family planning, and reproductive health services are too often overlooked in these and other crisis settings.

A categorical shift is required for the United States to prioritize women's and girls' health and protection in emergency settings to advance resiliency and health security. Practitioners and policymakers increasingly recognize that failing to address these gaps significantly worsens the impact and trauma of crises and significantly undermines global health security. Conversely, engaging women, girls, and communities in decisionmaking and program design can help build public trust and confidence, which is sorely lacking in many health security crises around the world.

This proposed initiative would ensure that the extensive capacities of the U.S. government in the areas of maternal health, reproductive health, family planning, and GBV prevention and response are brought to bear to ensure the health and safety of women and girls in disordered settings.

Existing U.S. Government Capacity and Gaps: The United States is the global leader in supporting humanitarian response, primarily through OFDA and PRM, which in recent years have expanded their commitment to and investments in preventing and responding to GBV, in addition to their commitment to women's health. PRM funds a range of international organizations, UN agencies, and NGOs to provide GBV prevention and response services, including through Safe from the Start, the U.S. government's flagship initiative on GBV in emergencies. OFDA leads U.S. responses to disasters overseas based on humanitarian need, focused especially on internally displaced populations, including through the deployment of DARTs. USAID's Bureau for Global Health is a global leader in supporting maternal health, reproductive health, and family planning. In April 2019, USAID announced a new \$200 million five-year program called the MOMENTUM project—Moving Integrated, Quality, Maternal, Newborn, and Child Health and Family Planning and Reproductive Health Services to Scale.⁵⁰

These extensive capacities provide a strong foundation upon which to build a more robust, comprehensive, and impactful approach to women's and girls' health and safety needs in disordered and crisis settings.



Pregnant women stand in line to receive birth kits from a local NGO at a camp for Internally Displaced People (IDPs) in Kibati, north of the provincial capital city of Goma, Democratic Republic of the Congo, on November 12, 2008.

YASUYOSHI CHIBA/AFP VIA GETTY IMAGES

Secretariat: The responsibility for operationalizing this model should be shared between the USAID assistant administrator for Democracy, Conflict and Humanitarian Assistance (DCHA), the USAID assistant administrator for the Bureau for Global Health, and the PRM assistant secretary, in close coordination with the CDC. A working group of core subject matter experts should support the secretariat in operationalizing the model, ensuring alignment of planning and investments and promoting enhanced coordination between women's and girls' health and protection across the interagency process. The agencies should report to Congress on the impact, outcomes, and lessons learned.

Where: In its initial pilot phase, the model should be implemented in two to three crisis settings, such as the DRC, South Sudan, Syria, Venezuela, or Yemen, with the intention of generating learnings to inform potential replication in other disordered settings. To determine where the model should be operationalized, careful consideration should be given to the maternal mortality rate, the percentage of unmet need for contraception, the level of services available for adolescent girls, whether U.S. agencies or partners have access to the communities in need, and impact of the crisis on U.S. health security and foreign policy interests.

Funding and Operational Requirements: Congress should authorize quick disbursing and flexible programmatic funding through USAID—including the Bureau for Global Health and USAID missions—and PRM, in close consultation with other relevant U.S. government agencies. This funding should be used in two to three priority crisis settings to spearhead this integrated service delivery model and incentivize U.S. agencies and their partners to rapidly begin execution of the program. The additional flexible funding is

just the first step. This funding will be catalytic and is intended to attract higher-level financial commitments from existing programs at USAID and PRM.

The following operational requirements should be put in place:

- Ensure that OFDA's DARTs and their implementing partners, as well as the CDC and DOD when involved, prioritize women's and girls' health and safety as part of the essential package of services offered in crisis situations.⁶⁴
- ◊ Direct PRM to dedicate increased funding for women's and girls' health and safety in refugee and forced displacement settings and to develop criteria and accountability for its UN and NGO partners to demonstrate expertise and capacity in these areas.
- ◊ Strengthen local capacity for health care providers, community outreach workers, and NGOs to provide essential health and protection services for women and girls.
- ◊ Systematically evaluate the benefits, challenges, and costs of implementation in the first two to three cases to judge the impact of the model, improve effectiveness of integrated services and the enabling environment, and capture learnings to inform whether this model should be sustained and introduced in additional crisis settings.
- ◊ Engage diplomatically at high levels to encourage other donor countries, multilateral organizations, and UN agencies to contribute and participate in this strengthened model and to hold U.S. programs and partners accountable.

ESTIMATED COST:
\$30 million per year for five years.



"The United States is the world leader in science, technology, and in global health. We need to be faster and bolder in developing new therapeutics, vaccines, and diagnostics to arrest future outbreaks. America's leadership in these areas will be essential in strengthening global health security."

— U.S. Congressman Ami Bera (D-CA-7)



7. Systematically confront two urgent technology challenges: the need for new vaccines and therapeutics and the public health communications crisis.

RECOMMENDATION

We are in the midst of a global technological revolution, which presents both opportunities and threats to global health security. In the face of emerging infectious disease and growing antimicrobial resistance, the United States should lead the global community in harnessing science and technology to save lives through the development of novel diagnostics and therapeutics. These efforts will require working with particularly dangerous pathogens. To prevent the accidental or intentional release of such pathogens, the United States should also make the small investments necessary to ensure that this research can be conducted safely and securely.

At the same time, the credibility of the scientific and medical communities is increasingly jeopardized, as

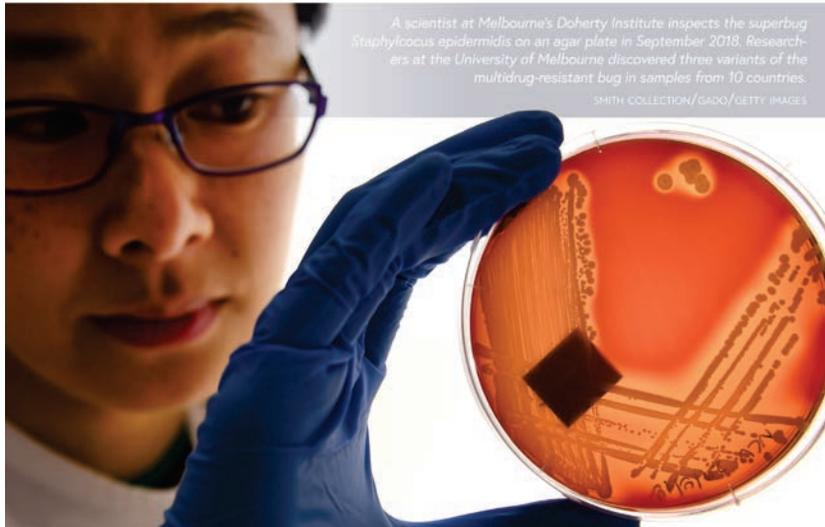
misinformation and disinformation spreads rapidly across the expanding digital domain. This poses a new and urgent global health security challenge, one that the United States should lead in addressing through a concerted effort to reclaim digital and social media as a force for good.

RATIONALE

The United States is the global leader in biotechnology capacity and innovation, a result of decades of strong market conditions and public- and private-sector investment in education, research, and development. In recent months, both Congress and the administration have demonstrated their commitment to biotechnology efforts across several fields that are central to strengthening global health security. The U.S. government should build upon these recent efforts with targeted investments in the following critical areas.

Vaccines and Therapeutics

Coalition for Epidemic Preparedness Innovations (CEPI): As the infectious disease threat grows, the cost of investing in vaccine development remains prohibitively



A scientist at Melbourne's Doherty Institute inspects the superbug *Staphylococcus epidermidis* on an agar plate in September 2019. Researchers at the University of Melbourne discovered three variants of the multidrug-resistant bug in samples from 10 countries.

SMITH COLLECTION/GADO/GETTY IMAGES

high. An investment in CEPI will enable the United States to further this critical preparedness mission while pooling resources and risk across multiple sovereign and philanthropic partners. The U.S. government should become a CEPI coalition partner with an annual investment of \$40 million. This initial investment will support CEPI's mission to accelerate the development of vaccines and platform technologies against emerging infectious diseases and ensure equitable access to these vaccines during outbreaks.

Furthermore, if the United States becomes a coalition partner, it will acquire a seat at the table early in the evolution of this promising new partnership, which will enable it to influence CEPI's decision process. A U.S. commitment to CEPI should not detract from the work of BARDA. On the contrary, in becoming a coalition partner of CEPI, the United States could better align CEPI investments with other U.S. programs and direct bilateral investments and motivate other donors, companies, and philanthropies to join the coalition.

As CEPI develops these new technologies, it will increasingly confront serious gaps in the systems and capacities needed to ensure their meaningful delivery in the case of an outbreak. Countries vulnerable to CEPI's priority diseases (e.g., MERS-CoV, Nipah virus, and Lassa virus) often lack the necessary cold chain, human resource, diagnostic, and data management capacities to effectively implement vaccination campaigns with experimental products. Creation of these capacities will likely involve partnership with Gavi, UNICEF, the WHO, product development partners, and other organizations and could have broader impacts on immunization systems beyond these priority diseases.

ESTIMATED COST
\$40 million per year for five years.

Universal Flu Vaccine: Influenza is widely recognized as today's foremost health security threat. The CDC estimates that seasonal influenza has killed between 12,000 and 79,000 Americans annually since 2010, costing the United States over \$10.4 billion in direct medical costs and \$87 billion in total economic burden every year.⁵⁵ An influenza pandemic would be even more catastrophic. A landmark 2016 study found that a moderately severe influenza pandemic could cause as many as 700,000 deaths annually and cost as much as \$570 billion globally per year.⁵⁶

The U.S. government should increase support for the creation of a universal influenza vaccine, which would save

thousands of lives every year and significantly mitigate the pandemic influenza threat. The United States is at the forefront of this scientific effort and should demonstrate leadership with investment and commitment. Experts estimate that \$200 million annually over five years is necessary to reach this crucial milestone, as was proposed in the Flu Vaccine Act.⁵⁷ This constitutes an additional \$60 million annually over current funding levels at the NIH. Funding for later stage universal flu vaccine research at BARDA should be maintained, as its efforts are crucial for bringing new flu products to the market. There should also be serious consideration given to expanding the CDC's complementary research on emerging and circulating influenza viruses, vaccine effectiveness, and the production of vaccine candidates for newer production platforms, as well as issues of access to this vaccine in low- and middle-income countries after it is developed.

ESTIMATED COST
\$60 million over current funding levels per year for five years.

Antimicrobial Resistance: To address the growing threat of AMR, Congress should fund the implementation of the National Action Plan on Combating Antibiotic Resistant Bacteria (CARB) 2020-2025. At time of writing, the funding requirements for this effort are not publicly available. The CARB 2020-2025 plan (to be released in early-2020) is expected to provide updated data and a revised plan to enable U.S. agencies to work with partner governments and multilateral partners to stem the emergence and spread of antimicrobial resistance overseas. This includes strengthening public health interventions, including infection control and surveillance and improved antibiotic use and stewardship, as well as the development of improved vaccines and novel drugs and technologies to prevent, diagnose, and treat resistant infections.

It is critically important that U.S. agencies work with partner governments to strengthen and sustain infection control in health care facilities globally such that facilities can detect, monitor, and prevent the transmission of the most urgent antibiotic-resistant bacterial threats. In addition, by supporting countries to build surveillance systems that can collect and integrate AMR data from the medical, veterinary, agricultural, and environmental sectors, the United States can strengthen its own capacity to detect and prevent the spread of resistance. Additional technical support in this field will also enable partner governments to enact and enforce rules limiting over-the-counter availability of antibiotics and overprescribing,



"The reason why so few antibiotics are being developed is simple – the market is broken. In recent months, lawmakers on both sides of the aisle have come together to introduce important policies designed to spur the development of new antibiotics. However, to protect the American people from resistant superbugs, bold action is needed from Congress and the Administration to stimulate innovation and produce new antimicrobials that patients and society can count on."

— Jim Greenwood, Biotechnology Innovation Organization

raising standards in those countries with the least stringent standards and highest burden of drug-resistant infections.

When developing new antibiotics, the private sector remains the primary actor in bringing new drugs to market. However, the lack of a predictable, strong market for new antibiotics has caused private-sector investment to drop significantly, with the few pharmaceutical companies and biotechnology firms that remain engaged struggling to remain viable. Amid the unresolved furor over drug pricing, policymakers and the public at large may be understandably hesitant to support giving taxpayer dollars to incentivize drug companies. Nevertheless, government intervention is needed to create a robust and sustainable antimicrobial research and development ecosystem, such that companies are rewarded for the development of novel antimicrobial products and developers get a certain return.

Congress and the administration should redouble their efforts to formulate pull-incentive packages that guarantee drug developers a certain return for the development of novel antimicrobial products that address the greatest public health need. Such incentive packages are likely to win bipartisan support and should include robust stewardship and surveillance requirements, requiring developers to ensure the responsible use and accessibility of the antimicrobial product both for Americans and for patients around the globe. The DISARM Act of 2019 is a welcome step toward a sustainable marketplace that supports the antibiotic research and development pipeline while allowing health care providers to use novel antibiotics when needed.⁹⁸

Digital Disinformation

VACCINE CONFIDENCE

The crisis in confidence in science, medicine, and vaccines is an emergent and intensifying health security threat that the United States is not yet equipped to address.

The White House should establish a new capacity under the auspices of the NSC directorate for global health security and biodefense that can lead collaboration across agencies and sectors to address this fundamentally multisectoral issue. This should include a comprehensive assessment of U.S. government capacities to monitor and counter online disinformation and misinformation around science and medicine. The focal person for this effort should engage with social media platforms and technology companies, independent media, biopharmaceutical companies, medical providers, and cybersecurity experts to inform policy formulation on this pressing issue.

The U.S. government should also establish an expanded, integrated, and sustained effort at the CDC to strengthen vaccine confidence and demand both in the United States and abroad. This should integrate all relevant capacities across the CDC and should include:

- A strategic communications initiative that is informed by behavioral psychology research to understand the determinants of local group belief systems and that provides consistent, science-based information to all audiences, both domestic and global, to



"Research and biotechnology development are critical for identifying and preparing for future infectious disease outbreaks. It is equally important that the U.S. and countries around the world bolster mechanisms to identify and reduce biological risks associated with advances in technology. Congress should allocate additional resources for biosecurity and biosafety innovation."

— Laura S. H. Holgate, Ambassador (Ret.), Nuclear Threat Initiative

counter misinformation and disinformation across multiple media platforms;

- Expanded research and survey work with global and university partners on the behavioral and social drivers of public trust and vaccine confidence and the acceptability and accessibility of services, including a U.S. Government Accountability Office (GAO) report on public attitudes toward vaccinations;
- An expanded program for the provision of technical expertise to partner governments, and U.S. states and municipalities, to generate vaccine demand;
- Expanded efforts to identify communities with low vaccination coverage and at high risk of outbreaks related to vaccine-preventable diseases, conduct targeted and culturally and linguistically appropriate communications campaigns in those communities, and improve vaccination rates in such communities through improved surveillance, vaccination interventions and campaigns, and research initiatives; and
- Expanded support for the Global Demand Hub, an established international platform that convenes public health officials, international organizations (including the WHO, UNICEF, and Gavi), social media firms, and civil society to research, incentivize, and coordinate vaccine demand work.

Experts estimate a minimum of \$50 million in additional annual funding will be required to support this initiative over a five-year period. This increase to CDC's multi-billion-dollar annual funding for immunization could potentially be pivotal in mobilizing multiple interests

behind renewing and stabilizing broad popular support for vaccines at home and abroad.⁹⁹ This proposal is broadly consistent with what is outlined in the bipartisan VACCINES Act of 2019 and the VIP Act of 2019, as well as Senate action through the Lower Health Care Costs Act of 2019.^{100,101,102}

ESTIMATED COST:

\$50 million per year for five years.

Biosafety and Biosecurity

Much of the funding called for in this section relates to research on especially dangerous pathogens, including pathogens with pandemic potential, and often involves the isolation, growth, and manipulation of dangerous viruses. A small fraction of the funds spent on researching dangerous pathogens should be set aside to ensure that this research is conducted safely and securely to prevent the accidental and intentional release of dangerous pathogens.

This will require investments in biosafety (to prevent the accidental exposure of people, animals, and the environment to dangerous microbes), and biosecurity (to prevent the deliberate exposure of people, animals, and the environment to dangerous microbes).^{103,104}

Biosafety: Congress should allocate funding to the National Institute for Occupational Safety and Health (NIOSH) for the empirical study of safety in biological laboratories.¹⁰⁵ This funding will support the research needed to upgrade biosafety in the age of synthetic biology and escalating risk. Experts estimate that an initial phase of research should be funded at \$10 million a year.¹⁰⁶

Biosecurity: Congress should allocate funding to HHS to conduct comprehensive biosecurity oversight, in close coordination with other departments and agencies. This should include risk mitigation measures associated with life sciences dual-use research and overseeing innovations in biosecurity and microbial forensics that can reduce biological risks associated with advances in technology and better detect emerging, unusual, or engineered pathogens.

The U.S. government should expand DTRA's Biological Threat Reduction Program (BTRP) authorities to increase flexibility in detecting and countering the emergence of novel, highly communicable diseases, such as multidrug-resistant tuberculosis and artemisinin-resistant malaria.¹⁰⁷ The U.S. government should expand DTRA's geographic authorities to operate in all continents where health security threats exist, including South America. Furthermore, support for military overseas infectious research laboratories should be sustained. DOD biological research and development programs often focus on diseases not studied in other venues and result in medical countermeasures that would otherwise be delayed or not developed at all.¹⁰⁸

ESTIMATED COST:

Biosafety: \$10 million per year for five years.

Biosecurity: \$10 million per year for five years.

Time to Act

We opened the Commission's report sounding the alarm that the U.S. government is caught in a cycle of crisis and complacency, that the American people are far from safe, and that U.S. policymakers need to think anew.

The "microbial sky" under which the United States and the rest of the world live today is increasingly crowded with health security threats, yet preparedness lags at home and abroad. At the same time, the world is increasingly disordered, and the most dangerous and inaccessible areas are also where many dangerous outbreaks emanate. These realities should make anyone nervous and uncomfortable.

Over the course of deliberating on these complex challenges and the actions required to defend U.S. national interests, the Commission has settled on what we believe are cost-effective, proven, commonsense solutions that can draw support across the political divide. Now is the time for Congress and the administration to move these actions forward. It is a moment to hold ourselves and our government to greater account, to insist upon White House leadership, and to demand a higher level of rigor and discipline in the use of scarce resources. The U.S. government cannot afford waste, redundancy, or mistargeted investments.

The changes we advocate do come at a price. There is no denying that. But it is a smart investment when set against the staggering costs of inaction. We are calling for targeted investments in country partnerships, in quick response capacities, and in the U.S. government's ability to operate in insecure, disordered settings. We are calling for smart investments that will help accelerate new technologies and focus U.S. energies and the energies of others on the public health communications crisis in the age of misinformation, social media, and distrust.

The steps we have laid out are the foundation of the Commission's proposed U.S. doctrine of continuous prevention, protection, and resilience. If the U.S. government acts strategically to advance this doctrine, it can, once and for all, break the cycle of crisis and complacency and put the United States' global health security approach on a sound footing for the future.

Appendix I

Illustrative Costing for Recommended Programs and Initiatives

This appendix captures proposed, current, and historical funding levels (when available) for the recommended programs and initiatives. Figures presented are in USD (millions). We have calculated the incremental difference, or additional cost beyond current funding levels, to be approximately \$905 million.⁹ Unless otherwise noted in the text, all recommended funding levels are annual investments over five years. It is recommended that funding levels be reassessed after five years. While the proposed funding levels represent expert estimates, additional work may be required to cost certain expanded initiatives and new program proposals.

D. The estimated incremental difference is not reflective of FY 2019 levels for new program proposals or vaccine confidence, as those numbers are unavailable.

GLOBAL HEALTH SECURITY AGENDA ¹												
Executive Agency	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	Proposed	Difference
USAID (NON-ADD)	\$201	\$48	\$58	\$55	\$73	\$385	\$218	\$73	\$173	\$138	\$173	\$35
CDC (NON-ADD)	\$62	\$51	\$56	\$54	\$63	\$652	\$55	\$58	\$108	\$108	\$208	\$100

1. Sources: Kaiser Family Foundation (KFF) analysis of appropriations bills and Congressional budget requests; Watson et al., "Federal Funding for Health Security in FY2019," Health Security 16, no. 5 (October 2018): <https://doi.org/10.1089/hs.2018.0077>. Sources of proposed funding levels include the Global Health Council's Global Health Security Roundtable and the Global Health Security Agenda Consortium.

PANDEMIC PREPAREDNESS CHALLENGE			
	FY19	Proposed	Difference
PANDEMIC PREPAREDNESS CHALLENGE		\$30 ¹	\$30

1. Expert estimate of the annual investment over five years required by the United States to leverage donor funding necessary to launch a five-year, \$750 million Pandemic Preparedness Challenge.

CONTINGENCY FUNDS					
EXISTING FUND	FY17	FY18	FY19	PROPOSED	DIFFERENCE
CDC INFECTIOUS DISEASES RAPID RESPONSE RESERVE FUND			\$50 ¹	\$250 ¹	\$200
USAID EMERGENCY RESERVE FUND	\$70 ¹	\$35 ¹	\$2 ¹	\$250 ¹	\$248
WHO CONTINGENCY FUND FOR EMERGENCIES				\$25 ⁷	\$25

1. "FY2019 Operating Plan," CDC, accessed June 2019, <https://www.cdc.gov/budget/documents/fy2019/fy-2019-cdc-operating-plan.pdf>.

2. Expert estimate of the minimum funding levels for contingency funds at the CDC to support rapid response. Sources include the Global Health Council's Global Health Security Roundtable. These contingency fund levels are inclusive of the \$20 million in contingency funds for emergency immunization activities recommended in Recommendation 6.

3. "State, Foreign Operations, and Related Programs Appropriations Bill, 2017 Omnibus Agreement Summary," U.S. Senate Committee on Appropriations, accessed June 2019, <https://www.appropriations.senate.gov/imo/media/doc/FY17%20State%20Foreign%20Operations%20Conference%20Agreement%20Summary%20-%20Final.pdf>.

4. "President Signs FY18 Omnibus Bill," KFF, March 22, 2018, <https://www.kff.org/news-summary/congress-releases-fy18-omnibus/>.

5. "FY19 Conference Agreement Released, Includes State & Foreign Operations (SFOs) Funding," KFF, February 14, 2019, <https://www.kff.org/news-summary/fy19-conference-agreement-released-includes-state-foreign-operations-stops-funding/>.

6. Expert estimate of the minimum funding levels for contingency funds at USAID to support rapid response. Sources include the Global Health Council's Global Health Security Roundtable. These contingency fund levels are inclusive of the \$20 million in contingency funds for emergency immunization activities recommended in Recommendation 6.

7. Expert estimate of appropriate U.S. government contribution to the WHO CFE based on contributions of similar donor countries, including Japan (\$22 million contribution in 2019), Germany (\$8 million in 2019), and the United Kingdom (\$5 million in 2019). See: "Contingency Fund for Emergencies (CFE) contributions and allocations," WHO, accessed June 2019, <https://www.who.int/emergencies/funding/contingency-fund/allocations/en/>.

GLOBAL HEALTH CRISES RESPONSE CORPS			
Focus area	FY19	Proposed	Difference
GLOBAL HEALTH CRISES RESPONSE CORPS		\$50 ¹	\$50
SUPPORT NATIONAL PARTNERS	\$47.5	\$83.5 ²	\$36
PHEM (CDC)	\$1.5 ³	\$2.5 ⁴	\$1
FETP (CDC)	\$41 ⁵	\$71 ⁶	\$30
NPHI (CDC)	\$5 ⁷	\$10 ⁸	\$5

1. Expert estimate of the cost of a pilot program is based on estimated costs of: (1) personnel; (2) training costs, including existing agency training opportunities; and (3) deployment-related costs, including first aid supplies, food and water, lodging, travel (commercial flights, not designated transport), emergency communication measures, and personal security measures. Estimate takes into account original FY 2010 non-supplemental appropriation for the U.S. Civilian Response Corps, adjusted for the size and scope of this proposed Corps.

2. Experts estimate that additional investment in these three programs will help to ensure greater national capacity in outbreak detection and management.

3. U.S. Centers for Disease Control and Prevention, "FY2019 Operating Plan."

4. Expert estimate of the additional annual funding required to expand these programs to include a focus on operating in disordered environments.

5. U.S. Centers for Disease Control and Prevention, "FY2019 Operating Plan."

6. Expert estimate of the additional annual funding required to expand these programs to include a focus on operating in disordered environments.

7. U.S. Centers for Disease Control and Prevention, "FY2019 Operating Plan."

8. Expert estimate of the additional annual funding required to expand these programs to include a focus on operating in disordered environments.

STRENGTHEN SERVICE DELIVERY IN DISORDERED SETTINGS

Focus area	FY19	Proposed	Difference
IMMUNIZATIONS		\$6	\$6
STRENGTHEN DATA		\$5 ¹	\$5
TRAINING COMMUNITY WORKERS		\$1 ¹	\$1
WOMEN AND GIRLS		\$30 ¹	\$30

1. Expert estimate of the cost of a pilot program monitoring 20 countries is based on consultation on the FEWS NET program and estimated costs for: (1) personnel; (2) database conceptualization, development, testing, and maintenance; and (3) website development, maintenance, and hosting.

2. Expert estimate of the cost of training for 150 trainees is based on estimated average cost of \$6,500 per trainee for FETP-Frontline 3-month training for local public health staff.

3. Expert estimate of pilot program costs in two to three humanitarian crises, considering: (1) estimates of the number of affected women and girls in these crises from OCHA and UNHCR; (2) costs of assumed 20 percent uptake of family planning services, based on cost per couple-year of protection; (3) cost of assumed 20 percent uptake in maternal health care, based on average cost per pregnancy; (4) cost of GBV care, based on assumed 20 percent uptake; and (5) estimated cost of health care worker and community outreach worker capacity building.

CONFRONTING TECHNOLOGY CHALLENGES

Focus area	FY19	Proposed	Difference
VACCINES		\$290	\$125
CEPI		\$40 ¹	\$40
UNIVERSAL INFLUENZA VACCINE (NIH/NIAD)	\$140 ¹	\$200 ¹	\$60
VACCINE CONFIDENCE (CDC)		\$50 ¹	\$25
BIOSAFETY (CDC/NIOSH)		\$10 ¹	\$10
BIOSECURITY (HHS)		\$10 ¹	\$10

1. Expert estimate for initial annual funding level.

2. "Operating Plan for FY2019," National Institutes of Health, accessed June 2019, https://www.hhs.gov/sites/default/files/FY%202019%20NIH%20Operating%20Plan_0.pdf

3. U.S. Congress, Senate, Flu Vaccine Act, S.570, 116th Cong., 1st sess., introduced in Senate February 26, 2019, <https://www.congress.gov/116/bills/s570/BILLS-116s570is.pdf>.

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Appendix II

Congressional Authorities and Oversight of U.S. Government Efforts to Advance Global Health Security

As described in White House Executive Order 13747 on “Advancing the Global Health Security Agenda to Achieve a World Safe and Secure from Infectious Disease Threats” and the new Global Health Security Strategy, the U.S. government’s role in global health security is a whole-of-government enterprise.¹⁰⁹¹¹⁰ The executive order (EO) and the strategy lay out the roles and responsibilities of the Executive Office of the President (EOP); eight Cabinet-level departments (including the Departments of State, Defense (DOD), Health and Human Services (HHS), Agriculture, Homeland Security, Treasury, Interior, and Justice); and eight sub-Cabinet agencies (including the Centers for Disease Control and Prevention (CDC), U.S. Agency for International Development (USAID), National Institutes of Health (NIH), Food and Drug Administration (FDA) and Environmental Protection Agency (EPA)). As a result, multiple Congressional authorizing and appropriations committees have jurisdiction over various aspects of this agenda, underscoring the essential interplay between international and domestic efforts to protect Americans’ health and safety.

The Commission’s recommendations to strengthen U.S. government support for global health security focus on a subset of departments and agencies for priority action. This list includes the Department of State, including USAID; HHS, including the CDC and the Biomedical Advanced Research and Development Authority (BARDA); the DOD, including the Defense Threat Reduction Agency (DTRA); and the Department of Treasury. Below is a summary of the key Congressional committees with oversight of these agencies and their relevant programs. Note that most recent global health security-related authorizations have occurred via appropriations legislation, including through the five-year Ebola Emergency Supplemental spending bill which expires at the end of FY 2019.

Health and Human Services

AUTHORIZING COMMITTEES

- Senate: Health, Education, Labor and Pensions (HELP) Committee, Subcommittee on Primary Health and Retirement Security
- House: Energy and Commerce Committee, Subcommittee on Health

APPROPRIATIONS COMMITTEES

- Senate and House: Labor, Health and Human Services, Education, and Related Agencies

These committees have oversight and jurisdiction over the HHS agencies, institutes, and programs relevant for global health security, notably the activities of the CDC, FDA, NIH, and BARDA. Relevant authorizing legislation includes the Pandemic and All-Hazards Preparedness and Innovation Act (PAHPAI), which authorizes certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, including advancement of medical countermeasures. President Trump signed PAHPAI into law in June 2019.¹¹¹ The International Health Research Act of 1960 provides for international cooperation in health research, research training, and planning and authorizes the HHS secretary to enter into cooperative agreements for biomedical and health activities.

The primary relevant funding accounts or line items for global health security include: the CDC’s Division of Global Health Protection (including Global Disease Detection Centers and Field Epidemiology Training Programs (FETP)), Epidemic Intelligence Service, Emerging and Zoonotic Infectious Diseases, Public Health Preparedness and Response Program, Immunization and Respiratory Diseases, and the International Diseases Rapid Response Reserve Fund, which was established by Congress in the FY 2019 appropriations bill; HHS’s Office of Global Affairs; BARDA’s Emerging Infectious Diseases (EID) program under the Office of the Assistant Secretary for Preparedness and Response (ASPR); and NIH’s Fogarty International Center.

Department of State and USAID

AUTHORIZING COMMITTEES

- Senate: Committee on Foreign Relations, Subcommittee on Africa and Global Health Policy
- House: Committee on Foreign Affairs (HFAC), Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations

APPROPRIATIONS COMMITTEES

- Senate and House: State, Foreign Operations, and Related Programs

These committees have jurisdiction over all Department of State and USAID operations and assistance programs,

including global health related programs. Relevant authorizing legislation includes the State Department Authorities Act (last passed in 2017) and the Foreign Assistance Authorization of 1961. As there have not been regular authorization bills (with the exception of the PEPFAR authorization, whose extension was last authorized in 2018), most programs are authorized via appropriations. In the 116th Congress, the Global Health Security Act was introduced to codify the U.S. commitment to the Global Health Security Agenda and designate permanent leadership for coordinating the interagency response to a global health security emergency. The bill was referred to the HFAC as well as to Armed Services and the Permanent Select Committee on Intelligence.

The primary relevant accounts or line items for global health security include the USAID Emerging Pandemic Threats and Predict programs and the Emergency Reserve Fund; the Department of State's Office of International Health and Biodefense, the International Security and Nonproliferation Bureau's Biosecurity Engagement Program, and the Office of Global Health Diplomacy; the U.S. contributions for the World Bank's International Development Association (IDA); and the World Health Organization (WHO).

Department of Defense

AUTHORIZING COMMITTEES

- Senate and House: Armed Services Committee

APPROPRIATIONS COMMITTEES

- Senate and House: Defense

These committees have oversight and jurisdiction over all DOD-supported global health security programs. The annual National Defense Authorization Act (NDAA) is the principal authorizing legislation. The primary relevant funding accounts or line items for global health security include: the Cooperative Threat Reduction Program's Cooperative Biological Engagement Program (CBEP); the Armed Forces Health Surveillance Global Emerging Infections Surveillance and Response Program; the Defense Threat Reduction Agency (DTRA); the Army Medical Research and Materiel Command's Military Infectious Diseases Research Program; the Naval Medical Research Center and Naval Research Laboratory; the Walter Reed Army Institute of Research; and the Defense Advanced Research Projects Agency (DARPA). The geographic combatant commands also engage with their international military partners on health security cooperation.

Treasury

AUTHORIZING COMMITTEES

- Senate: Committee on Banking, Housing, and Urban Affairs, Subcommittee on National Security and International Trade and Finance
- House: Committee on Financial Services, Subcommittee on National Security, International Development and Monetary Policy

APPROPRIATIONS COMMITTEES

- Senate and House: Senate and House: State, Foreign Operations, and Related Programs

These committees have oversight and jurisdiction over U.S. membership in, and financial support for, the World Bank's IDA and International Bank for Reconstruction and Development (IBRD) and other multilateral development banks (MDBs) and international financial institutions. Relevant recent authorization bills include the World Bank Accountability Act, introduced in the House in 2017 to authorize IDA appropriations. However, as with other Department of State and Foreign Operations-funded programs, most authorizations have occurred through the annual appropriations bills.

Appendix III

Glossary of Key Terms

ANTIMICROBIAL RESISTANCE (AMR)¹¹³

Many common infections are becoming resistant to the antimicrobial medicines used to treat them, resulting in longer illnesses and more deaths. Antimicrobial resistant microbes are found in people, animals, food, and the environment. They can spread between people and animals, including from food of animal origin, and from person-to-person. Poor infection control, inadequate sanitary conditions and inappropriate food-handling encourage the spread of AMR. Misuse and overuse of antimicrobials is also accelerating AMR. Many common infections are becoming resistant to the antimicrobial medicines used to treat them, resulting in longer illnesses and more deaths, and not enough new antimicrobial drugs, especially antibiotics, are being developed to replace older and increasingly ineffective ones. AMR also increases the cost of health care, with lengthier stays in hospitals and more intensive care required. In 2016, the UN General Assembly issued a declaration calling for global action on AMR.¹¹³

BIOLOGICAL ADVANCED RESEARCH AND DEVELOPMENT AGENCY (BARDA)¹¹⁴

BARDA was established in 2006 through the Pandemic and All-Hazards Preparedness Act (PAHPA) and reports to the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS). BARDA is responsible for the development and procurement of medical countermeasures (MCMs) to enhance the capability of the U.S. government to guard against a broad array of public health threats, including chemical, biological, nuclear, and radiological threats, as well as pandemic influenza and emerging diseases such as Ebola and Zika. BARDA supports the transition of medical countermeasures such as vaccines, therapeutics, drugs, and diagnostics from research through advanced development toward consideration for approval by the Food and Drug Administration (FDA) and inclusion into the Strategic National Stockpile.

BIOLOGICAL THREAT REDUCTION PROGRAM (BTRP)¹¹⁵

The Defense Threat Reduction Agency's (DTRA) Cooperative Threat Reduction (CTR) Directorate prevents the proliferation or use of weapons of mass destruction (WMD) by working with partner nations to secure, eliminate, detect, and interdict WMD-related systems and materials. The CTR Biological Threat Reduction Program (BTRP) addresses the

biological threat aspect of this threat reduction mission. BTRP facilitates elimination, security, detection, and surveillance of especially dangerous pathogens.

COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS (CEPI)¹¹⁶

Launched at the World Economic Forum in January 2017, CEPI is a global partnership of public, private, philanthropic, and civil society organizations designed to accelerate the development of vaccines against emerging infectious diseases and to support equitable delivery of those vaccines in response to epidemics. CEPI focuses on vaccine development, licensure, and manufacturing for a target set of pathogens (currently MERS-CoV, Lassa, Nipah, Rift Valley fever, and Chikungunya) and is promoting the development of platform technologies that can be adapted to develop countermeasures to a future unknown pathogen with pandemic potential, "Disease X." It also promotes the development of platform technologies. As of April 2019, CEPI had secured \$750 million toward its \$1 billion funding target, with support from Australia, the Bill & Melinda Gates Foundation, Canada, Germany, Japan, Norway, and Wellcome Trust. The United States does not currently contribute to CEPI.

DISASTER ASSISTANCE RESPONSE TEAM (DART)¹¹⁷

The USAID Office of U.S. Foreign Disaster Assistance (OFDA) sends a DART to crisis-affected areas when required by the size and severity of a disaster. DARTs are comprised of humanitarian experts and technical advisers and are deployable within hours of an emergency. They work in cooperation with partners on the ground to assess and respond to a crisis situation. DARTs work overseas but are managed by a Response Management Team (RMT) based in Washington, D.C. RMTs work with other U.S. government agencies to plan and coordinate the response so that the DART can focus on providing support on the ground.

DEFENSE ADVANCED RESEARCH PROJECTS AGENCY (DARPA)¹¹⁸

DARPA's mission is to make pivotal investments in breakthrough technologies for national security. DARPA's research portfolio is managed by six technical offices charged with developing breakthrough technologies. One of those offices, the Biological Technologies Office (BTO), develops capabilities that embrace the unique properties of biology—adaptation, replication, complexity—and applies

those features to revolutionize how the United States defends the homeland and prepares and protects its soldiers, sailors, airmen, and marines.¹⁹⁸ The BTO helps the Department of Defense (DOD) to counter novel forms of bioterrorism, deploy innovative biological countermeasures to protect U.S. forces, and accelerate warfighter readiness and overmatch to confront adversary threats.

DEFENSE THREAT REDUCTION AGENCY (DTRA)¹⁹⁹

Created in 1998 by combining several DOD entities, DTRA facilitates and expedites research and development into some of the most complex, deadly, and urgent threats facing the United States and the rest of the world. DTRA's mission is to enable the U.S. government to counter the threats posed by the full spectrum of WMD, including chemical, biological, radiological, nuclear, and high-yield explosives; counter the threats posed by the growing and evolving categories of improvised threats, such as improvised explosive devices (IEDs), car bombs, and weaponized consumer drones; and ensure that the U.S. military maintains a safe, secure, effective, and credible nuclear weapons deterrent.

FIELD EPIDEMIOLOGY TRAINING PROGRAM (FETP)²⁰⁰

The U.S. Centers for Disease Control and Prevention (CDC) established the first FETP in 1980 to help epidemiologists in developing countries gain the necessary skills to collect, analyze, and interpret disease information. By training disease detectives in their own countries, the FETP helps meet the global health security goal of establishing a trained public health workforce that helps stop outbreaks at their source. There are more than 10,000 FETP graduates from 65 countries trained in disease detection and response.

GAVI, THE VACCINE ALLIANCE²⁰¹

Created in 2000, Gavi, the Vaccine Alliance is an international public-private partnership with the mission of improving access to new and underused vaccines for children in lower-income countries. Gavi's partnership model combines the technical expertise of the development community with the business knowledge of the private sector. Gavi partners include the WHO, UNICEF, the World Bank, the Bill & Melinda Gates Foundation, civil society organizations, private-sector companies, donor and implementing country governments, and research agencies. Gavi pools demand from low-income countries and works with vaccine manufacturers to bring down prices. While donors provide long-term, predictable financing support to Gavi's efforts, all Gavi-supported countries pay a share of the vaccine cost, and that share increases as the country's

income grows. Gavi's current strategy aims to reach 300 million children between 2016 and 2020, saving five to six million lives in the long term.

GLOBAL HEALTH SECURITY²⁰²

Global health security refers to the capacity to prepare for, detect, and respond to infectious disease threats and reduce or prevent their spread across borders. At the core of global health security are strong health systems with the resources and trained personnel needed to identify threats, respond quickly, and prevent the spread of infectious diseases. Key capacities include public health capabilities such as laboratory and digital information networks, supply chains, and frontline health workers.

GLOBAL HEALTH SECURITY AGENDA (GHSA)²⁰⁴

Launched in February 2014, the GHSA is a growing partnership comprised of more than 65 nations, international organizations, and nongovernmental stakeholders to help build countries' capacity to create a world safe and secure from infectious disease threats and elevate health security as a national and global priority. Through a set of "Action Packages," GHSA member countries collaborate toward specific objectives and targets. This international engagement includes ministries of agriculture, defense, health, development, and others, representing a whole-of-government approach. The United States has reaffirmed its commitment to the GHSA through 2024, in support of the GHSA 2024 Framework.²⁰³ The U.S. government provides support for capacity building for 17 priority GHSA partner countries and sits on the GHSA Steering Committee.

GLOBAL HEALTH SECURITY STRATEGY (GHSS)²⁰⁵

Issued by the White House in May 2019 in response to a request from Congress in the FY 2018 omnibus appropriations bill, the GHSS outlines the U.S. government approach to strengthening global health security, including accelerating the capabilities of targeted countries to prevent, detect, and respond to infectious disease outbreaks. Together with the National Security Strategy, the National Biodefense Strategy, and the executive order on "Advancing the Global Health Agenda to Achieve a World Safe and Secure from Infectious Disease Threats," the GHSS delineates the roles and responsibilities of Executive Branch agencies in protecting the United States and its partners abroad from infectious disease threats by working with other nations, international organizations, and nongovernmental stakeholders.

GRAY ZONE²⁰⁷

Recent analyses of challenges to U.S. security have identified the gray zone, a phenomenon in which actors across the

globe engage in malign activities that fall somewhere in the space between routine statecraft and open warfare. These gray zone approaches and incidents create dilemmas for the United States and its security interests but largely side-step thresholds for military escalation.

GLOBAL RAPID RESPONSE TEAM (GLOBAL RRT)¹²⁸

The CDC Global Rapid Response Team can be deployed within the United States and overseas to respond to global public health concerns. The Global RRT is comprised of public health experts and can be deployed to support field-based logistics, communications, management, and operations support in a public health emergency. The Global RRT can also provide long-term staffing for international emergency responses both in the field and at CDC headquarters in Atlanta, Georgia.

INTERNATIONAL DEVELOPMENT ASSOCIATION CRISIS RESPONSE WINDOW (IDA - CRW)¹²⁹

IDA is the part of the World Bank that funds the world's poorest countries. Overseen by 173 shareholder nations, with the United States as the largest shareholder, IDA is one of the largest sources of assistance for the world's 75 poorest countries, 39 of which are in Africa, and is the single largest source of donor funds for basic social services and poverty reduction efforts in these countries.¹³⁰ IDA provides loans (called "credits") and grants to boost economic growth, reduce inequalities, and improve people's living conditions. The CRW was established in 2011 to help IDA countries access additional resources to respond to severe economic crises and major natural disasters and return to their long-term development paths. In 2015, the CRW eligibility criteria were expanded to include public health emergencies and epidemics.

INTERNATIONAL HEALTH REGULATIONS (IHR)¹³¹

A legally binding instrument of international law adopted by the World Health Assembly in 2005 in the wake of the SARS pandemic, the purpose of the IHR is to provide a universal framework for international public health emergency preparedness and response. The IHR aim to control the international spread of disease in ways that are commensurate with public health risks and avoid unnecessary interference with international traffic and trade. The IHR also guide the strengthening of public health surveillance and response capacities globally and require countries to report specific disease outbreaks and any event that may pose a risk to international public health. The WHO has few effective means of enforcing the IHR; however, the Joint External Evaluation (JEE) process launched in the wake of the 2014-2016 Ebola

epidemic in West Africa has helped shine a light on the need for countries to strengthen their IHR compliance.

JOINT EXTERNAL EVALUATIONS (JEEs)¹³²

The JEEs are country-owned, voluntary, collaborative, multisectoral assessments of a country's core capacity to prevent, detect, and rapidly respond to public health risks, whether naturally occurring or due to deliberate or accidental events. The JEE process is managed by the WHO and consists of a national self-assessment and an external evaluation team with experts from all relevant sectors, such as human and animal health, food safety, agriculture, defense, and public safety. JEE results are published on the WHO website.¹³³ At time of writing, over 100 countries, including the United States, had completed JEEs.¹³⁴

NATIONAL BIODEFENSE STRATEGY¹³⁵

The National Biodefense Strategy, mandated by Congress and released on September 18, 2018, sets the course for the U.S. government to effectively counter threats from naturally occurring, accidental, and deliberate biological events. The strategy orchestrates, for the first time, a single coordinated effort across the U.S. government to assess, prevent, detect, prepare for, respond to, and recover from biological threats. The accompanying National Security Presidential Memorandum directs the secretary of Health and Human Services to serve as the federal lead in coordination and implementation of the strategy and establishes a cabinet-level Biodefense Steering Committee.

NATIONAL PUBLIC HEALTH INSTITUTES (NPHIs)¹³⁶

NPHIs provide leadership and coordination for public health at the national level. NPHIs consolidate in-country public health functions, bringing together data and expertise while coordinating efforts across sectors. The CDC provides technical expertise in support of NPHIs' development, targeted to fit countries' public health priorities.

PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND ADVANCING INNOVATION ACT (PAHPAI)

After the September 11, 2001 attacks and the 2001 anthrax attacks, Congress mandated a dedicated effort to develop and stockpile drugs, vaccines, and diagnostics needed to protect the American people from chemical, biological, radiological, nuclear (CBRN), and pandemic threats. The first 2006 Pandemic and All-Hazards Preparedness Act (PAHPA) created the position of the assistant secretary for Preparedness and Response (ASPR) to lead the government's response to national health emergencies.¹³⁷ The bill also created BARDA to provide industry partners with funding and technical assistance in the advanced research

and development of medical countermeasures. Key federal programs reauthorized and funded every five years through the PAHPA legislation include the BioShield Special Reserve Fund (SRF), BARDA, and the Strategic National Stockpile (SNS), which helps strengthen the pipeline and stockpile of medical countermeasures vital for national safety and defense. PAHPAI was signed into law by President Trump in June 2019 and reauthorized PAHPA.¹³⁸

PANDEMIC EMERGENCY FINANCING FACILITY (PEF)¹³⁹

The PEF was established by the World Bank in 2016 to be a quick-disbursing financing mechanism that provides a surge of funds to enable a rapid response to a large-scale disease outbreak. Eligible countries can receive timely, predictable, and coordinated surge financing if they are affected by an outbreak that meets the PEF's activation criteria. The PEF is the first-ever insurance mechanism for pandemic risk, offering coverage to all low-income countries eligible for IDA financing.

PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN (PHEIC)¹⁴⁰

Some serious international public health crises may be designated PHEICs. A PHEIC is defined under the IHR (2005) as "an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease; and (ii) to potentially require a coordinated international response."¹⁴¹ The designation of a PHEIC implies that such situations are serious, unusual, or unexpected, carry implications for public health beyond the affected country's national border, and may require immediate international action. The WHO director-general makes the final determination on designating PHEICs based on technical advice from the IHR Emergency Committee.

PUBLIC HEALTH EMERGENCY MANAGEMENT (PHEM) FELLOWSHIP¹⁴²

Established in 2013, the CDC's PHEM Fellowship program builds capacity among members of the international public health community through standardized training, mentorship, and technical assistance in public health emergency management functions and operations. The program was established in 2013 and is conducted twice a year at the CDC in Atlanta. It targets mid-career professionals who work in public health preparedness and response in countries who have signed on to the IHR.

PULL INCENTIVES¹⁴³

Pull incentives reward the successful development of medical countermeasures by increasing or ensuring future

revenue and market viability. Pull incentives can take many forms, including advanced market commitments, higher reimbursement, priority review vouchers, market exclusivity rewards, market entry rewards, patent extensions, data protection, and liability protection.

U.S. PUBLIC HEALTH SERVICE¹⁴⁴

The U.S. Public Health Service is a division of the HHS. Its mission is to protect, promote, and advance the health and safety of the United States. It is an elite team of over 6,500 health professionals, including physicians, dentists, nurses, therapists, pharmacists, engineers, dietitians, veterinarians, environmental health specialists, and scientists. Members of the U.S. Public Health Service serve in public health and clinical roles within the nation's federal government departments and agencies, supporting the provision of care to underserved and vulnerable populations.

VACCINE HESITANCY¹⁴⁵

One of the top 10 global health threats according to the WHO, vaccine hesitancy refers to the reluctance or refusal of people to vaccinate despite availability of vaccination services. Vaccine hesitancy has been reported in more than 90 percent of countries in the world and is being fueled by a number of factors, including the spread of misinformation and disinformation about vaccine safety; complacency; inconvenience and inaccessibility; and lack of confidence. The rise of vaccine hesitancy threatens to reverse the tremendous global progress made in preventing vaccine-preventable diseases. For example, immunization for measles, a vaccine-preventable disease that was largely eliminated following widespread use of the measles-mumps-rubella (MMR) vaccine, has now decreased below the threshold set by the WHO as that required for herd immunity.

WORLD HEALTH ORGANIZATION CONTINGENCY FUND FOR EMERGENCIES (CFE)¹⁴⁶

Set up as part of a series of WHO institutional reforms in the wake of the scathing criticism it received for its late response to the 2014-2016 Ebola crisis in West Africa, the CFE gives the WHO the resources to respond immediately to disease outbreaks and humanitarian crises with health consequences. The ability to respond quickly—in as little as 24 hours—before other funding is mobilized can stop a health emergency from spiraling out of control, saving lives and resources. As of March 2019, 16 countries, led by Germany, Japan, and the United Kingdom, had contributed \$70 million to support the CFE.

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