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

J. Stephen Morrison



CSIS

CENTER FOR STRATEGIC & INTERNATIONAL STUDIES



Strengthening America's Health Security

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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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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.

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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

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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.¹ 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 (GHSA) 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 Proposed Increase Over **Current Level** Recommendation Programs and Initiatives *Figures Presented in Millions **USD^A** 1. Restore health security leadership at the White House National Security Council. 2. Commit to full and sustained multi-year \$35 funding for the Global Health Security Agenda to build partner capacity. CDC 3. Establish a Pandemic Preparedness Challenge at the World Bank to incentiv-Pandemic Preparedness Challenge \$30 ize countries to invest in their own preparedness. CDC Infectious Diseases Rapid \$200^B 4. Ensure rapid access to resources for **USAID Emergency Reserve Fund** \$248 health emergencies. WHO Contingency Fund for Emergencies \$25 Global Health Crises Response Corps 5. Establish a U.S. Global Health Crises Response Corps. CDC Support to National Partners \$36 6. Strengthen the delivery of critical health services in disordered settings. \$30 Women and Girls Coalition for Epidemic Preparedness \$40 7. Systematically confront two urgent technology challenges: the need for new Universal Flu Vaccine Vaccine Confidence \$25 vaccines and therapeutics and the public Biosafety **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.^{A,4} 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 2019.⁵ 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 poliovirus, 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 humanitarian actors.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. 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. 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. 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."



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.²² 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. 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. 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. 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.

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.



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

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



Cost the global economy **over** \$53 billion.

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

2015



Cost South 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.

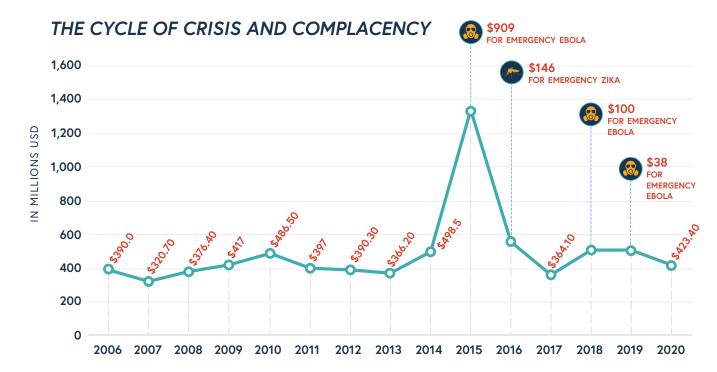
In October 2019, the Global Health Security Index reaffirmed the GPMB's findings. The Global Health Security Index is the first comprehensive assessment and benchmarking of health security and related capabilities across all 195 countries that make up the states parties to the International Health Regulations (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-Program-Area/Global-Health-Security/Agency/?view=range-years&startYear=2006&endYear=2020.

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

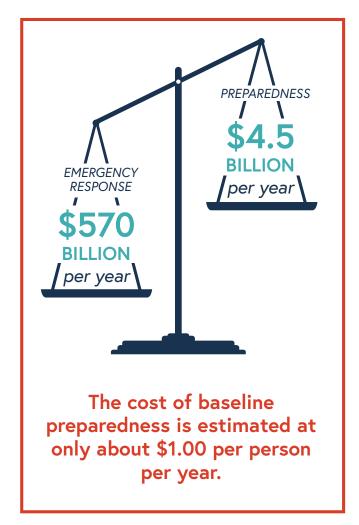
The countries that are the most vulnerable are not yet making the investments needed, even after conducting careful assessments and preparing national plans.³⁴ For many cash-strapped governments, budget commitments in health security compete against other worthy, politically sensitive, and very concrete 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 lowand 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



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."

"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.^B

B. 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 development 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.

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.^{47,48}

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.

"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."

"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 2019.⁴⁹ 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.⁵⁰

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.⁵¹ 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.⁵² 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.⁵³ 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.⁵⁴ 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.⁵⁵

While clear successes have resulted from these initial efforts, significant challenges remain, including corruption, lack of transparency, and distrust of commercial firms.⁵⁶

 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 threats, 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.⁵⁷

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."

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."

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. ⁶² 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



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:^C

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 report.

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."



"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-

- sures, 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



"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 have drawn 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."

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."

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.

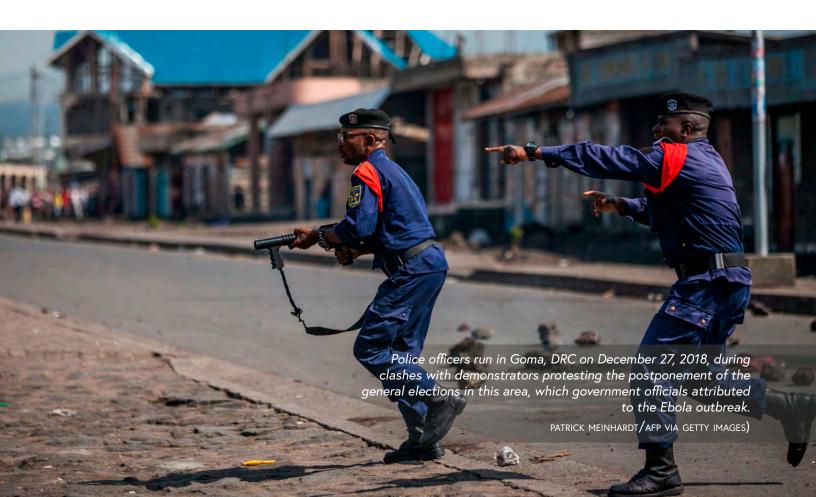
The USAID Disaster Assistance Response Team (DART) platform, refined over the past three decades, has developed protocols and operational capacities to integrate the CDC, the Department of State, and others, as well as to interface with the U.S. military, as needed, in deploying into humanitarian emergencies. 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



Rapid Response Team (Global RRT). They will receive special training and 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 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, except under extraordinary conditions. 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



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. Twenty million people currently cannot receive vaccines due to weak primary health systems, poverty, unstable governments, and war. PDD 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.80 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 2019.81 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). Part 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. \$5 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.⁸⁶

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.⁸⁷ 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.⁸⁸ 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.⁸⁹ Some training 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.⁹⁰

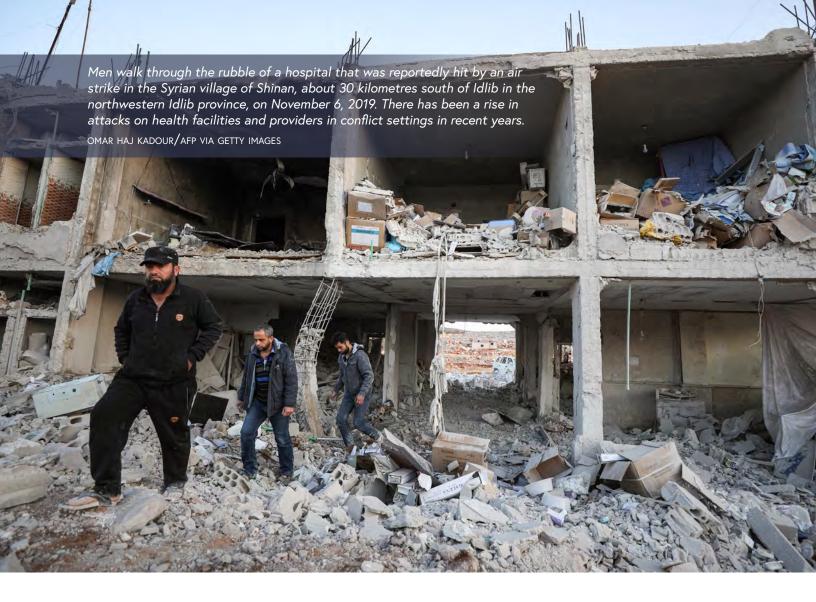
This additional flexible funding is essential to spearhead this effort and incentivize U.S. agencies and their partners to rapidly begin execution of the program. The funding is intended to attract higher-level financial commitments from existing programs at USAID and the U.S. Department of State Bureau 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.⁹¹ 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." of these women are pregnant and face additional health complications and challenges. ⁹² 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 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.93

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.



Secretariat: The responsibility for operationalizing this model should be shared between the USAID assistant administrator for the Bureau 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.⁹⁴
- 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."



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.

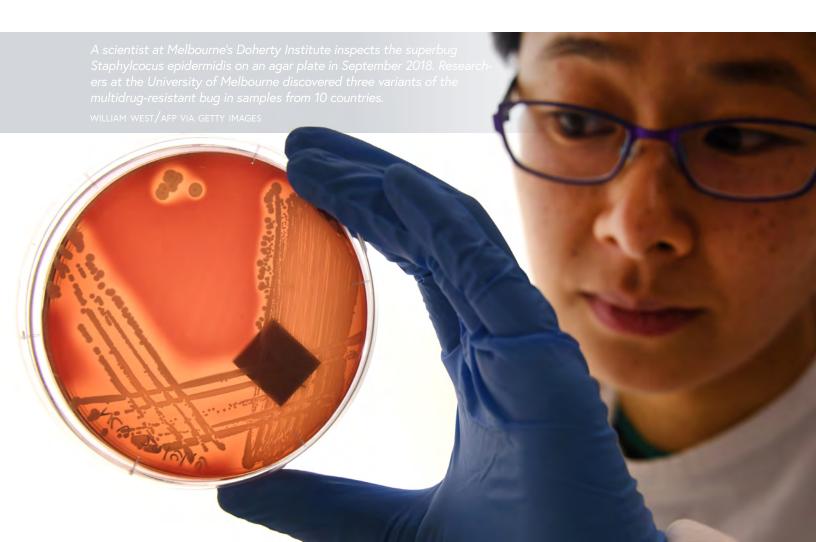
At the same time, the credibility of the scientific and medical communities is increasingly jeopardized, as misinformation and disinformation spreads rapidly across the expanding digital domain. This poses a new and urgent global health security challenge, one that the United States should lead in addressing 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



high. An investment in CEPI will enable the United States to further this critical preparedness mission while pooling resources and risk across multiple governmental 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. ⁹⁵ 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. ⁹⁶

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.97 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, to conduct targeted and culturally and linguistically appropriate communications campaigns in those communities, and to 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 VAC-CINES 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. 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 disease 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 arise. 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 are presented in millions USD. We have calculated the incremental difference, or additional cost beyond current funding levels, to be approximately \$905 million. 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.

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.

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

CONTINGENCY FUNDS					
EXISTING FUND	FY17	FY18	FY19	PROPOSED	DIFFERENCE
CDC INFECTIOUS DISEASES RAPID RESPONSE RESERVE FUND			\$50¹	\$250²	\$200
USAID EMERGENCY RESERVE FUND	\$70³	\$35⁴	\$2 ⁵	\$250 ⁶	\$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%20 Conference%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 (SFOPs) Funding," KFF, February 14, 2019, https://www.kff. org/news-summary/fy19-conference-agreement-released-includes-state-foreign-operations-sfops-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		\$50¹	\$50		
SUPPORT TO NATIONAL PARTNERS	\$47.5	\$83.5²	\$36		
PHEM (CDC)	\$1.5³	\$2.54	\$1		
FETP (CDC)	\$41 ⁵	\$716	\$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		\$5¹	\$5			
TRAINING COMMUNITY WORKERS		\$1 ²	\$1			
WOMEN AND GIRLS		\$30³	\$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		
		\$40¹	\$40		
	\$140²	\$200³			
		\$50⁴			
BIOSAFETY (CDC/NIOSH)		\$10⁵	\$10		
BIOSECURITY (HHS)		\$10 ⁶	\$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%20 NIH%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.
- 4. Expert estimate of the additional annual funding required to expand, sustain, and integrate existing CDC programs and initiatives.
- 5. Expert estimate for minimum annual funding levels to support basic biosafety research. In comparison, the budgets of the Chemical Safety Board and the Nuclear Regulatory Commission each exceed \$1 billion annually. For more detailed recommendations on this issue, refer to Rocco Casagrande, "Federal Funding for Biosafety Research is Critically Needed," CSIS, Commentary, August 6, 2019, https://healthsecurity.csis.org/articles/federal-funding-for-biosafety-research-is-critically-needed/.
- 6. Expert estimate for initial annual funding level.

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. 109, 110 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 the 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 expired 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 Advancing 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 the Global Disease Detection Program and the Field Epidemiology Training Program (FETP)), the Epidemic Intelligence Service, Emerging and Zoonotic Infectious Diseases, Public Health Preparedness and Response, Immunization and Respiratory Diseases, and the Infectious 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 Department of State Authorities Act (last passed in 2017) and the Foreign Assistance Act 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 Program and its PREDICT project and the Emergency Reserve Fund; the Department of State's Bureau of Oceans and International Environmental and Scientific Affairs Office of International Health and Biodefense and Bureau of International Security and Nonproliferation Biosecurity Engagement Program; and the U.S. contributions to 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 Defense Threat Reduction Agency (DTRA) and its Cooperative Threat Reduction Directorate's Cooperative Biological Engagement Program (CBEP); the Armed Forces Health Surveillance Branch Global Emerging Infections Surveillance and Response Program; the Army Medical Research and Development 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: 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)112

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

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (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." 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.¹¹⁹ 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)¹²⁰

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)121

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 ALLIANCE122

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 SECURITY¹²³

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)124

Launched in February 2014, the GHSA is a growing partner-ship 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. 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)126

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 Security 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 ZONE¹²⁷

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 provide 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." 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 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, dieticians, 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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- governments may have little presence, but these flexibilities pertain only to the small number of low- and middle-income countries still eligible for Gavi support. With a Geneva-based secretariat and no staff at the country level, Gavi is limited in its ability to provide on-the-ground support during an outbreak. The United States could also urge the WHO's CEF to set aside monies to prevent, rather than just respond to, emergencies, but the United States has not yet contributed to the Fund so may have limited influence.
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