

Healthier World, Safer America

A US Government Roadmap for International Action to Prevent the Next Pandemic



CONTENTS

Executive summary	3
Introduction	
US global leadership to prevent, detect, and respond to infectious disease	
Carrying forward a global health security international action plan	
Research and development today to address tomorrow's health security challenges	19
US funding and the need for dedicated, sustained financing	21
Recommendations	27
Appendix	29

Authored by

Elana Banin with support from Brandon Ball, Loren Becker, Jenny Blair, Raad Fadaak, Heather Ignatius, Jessica Li, Carolyn Reynolds, Linda Venczel, and Claire Wingfield. Edited by Kerry Gallo, Kelly Healy, Derek Ambrosino, Lindsay Pack, and John Ballenot.

Acknowledgments

Many thanks to Beth Cameron, Courtney Carson, Porter Delaney, Gabrielle Fitzgerald, Rebecca Katz, Josh Michaud, Michael Miller, John Monahan and Crystal Watson for providing valuable insights for the development of this paper.

Cover photo: PATH/Georgina Goodwin

PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health.

455 Massachusetts Avenue, NW, Suite 1000 Washington, DC 20001

info@path.org www.path.org

Copyright © 2017, PATH. All rights reserved.

The material in this document may be freely used for educational or noncommercial purposes, provided that the material is accompanied by an acknowledgment line. Suggested citation: PATH. Healthier World, Safer America: A Roadmap for International Action to Prevent the Next Pandemic. Seattle: PATH; 2017.

EXECUTIVE SUMMARY

2018 marks the centennial of the deadly influenza pandemic, which killed an estimated 50 million people worldwide—including 675,000 Americans.

Despite major advances in public health, medicine, and technology over the past century, America and the world still remain vulnerable; experts predict that a similar influenza pandemic today could kill as many as 50 to 80 million people. Population density and global interconnectedness mean that an outbreak anywhere can quickly become an outbreak *everywhere*, and the greatest risks may stem from the weakest health systems

in the poorest communities around the world. Simply put, the US government can't adequately safeguard Americans' health without the assurance that other countries have the right tools, infrastructure, policies, and systems in place to prevent future outbreaks from spiraling out of control.

The recent Ebola and Zika outbreaks illustrate the continuing threat of infectious disease to the United States and the world. The December 2014 Ebola outbreak, which originated in a remote village in West Africa, infected more than

15,000 people across 10 countries. While vital to slow the spread of the outbreak, the Ebola crises cost US taxpayers \$5.4 billion in emergency supplemental funding, forced several US cities to spend millions in containment, disrupted global business and supply chains, and required the deployment of the US military to mitigate the threat. Other governments, multilateral agencies, private-sector companies, and charities also spent billions of dollars on Ebola response and recovery. In addition, the crisis set back years of economic growth in the three worstaffected countries—Liberia, Sierra Leone, and Guinea and undermined previous US-funded efforts to foster stability, health, and economic development. As the Ebola crisis began to ebb, the Zika virus surged in Brazil and spread rapidly to 26 countries, infecting up to 1 million people, including more than 5,500 confirmed US cases as of September 2017. Thousands of pregnant American women in affected areas were put at risk of having babies with debilitating birth defects, and the threat, while lowered, has not disappeared. Congress appropriated \$1.1 billion for the Zika response, and the potential economic cost of Zika across six high-risk southern states (Alabama, Florida, Georgia, Louisiana, Mississippi, and Texas) has been estimated to be as high as \$1.2 billion in both direct medical costs and productivity losses.

The good news is that these recent outbreaks have served as a global wakeup call. Over the past three years, the international community has made significant steps to get better prepared, with US leadership and financing as a catalyst for international action. The World Health Organization (WHO) has adopted measures to step up countries' compliance with the International Health Regulations (IHRs), which commit nations to prevent, detect, and respond to international disease threats. In addition, over 60 countries have committed to the Global Health Security Agenda (GHSA), a US-initiated partnership of nations, international organizations, and

nongovernmental stakeholders to address vulnerabilities to infectious disease threats. As a result of the IHRs, the GHSA, and an estimated \$1 billion of the \$5.4 billion Ebola supplemental funding directed to global health security capacity building, the US government is helping reduce the risk of deadly and costly pandemic threats, enabling low- and middle-income countries—where the risks are highest—to stop future outbreaks at the source. This includes building and securing laboratory capacities and real-time disease surveillance

systems, training frontline health workers in outbreak preparedness, establishing stronger command structures for emergency response, and accelerating deployment of essential medicines, tools, and supplies to stop outbreaks from spreading. These US investments have already had a dramatic impact in some areas; for example, the response time to stopping recent outbreaks in Cameroon decreased from 8 weeks to just 24 hours. **This rapid response can mean the difference between an isolated outbreak and a global catastrophe.**

26 Countries
1 Million People
\$1.1 Billion US tax dollars

10 Countries
15,000 People
\$5.4 Billion US tax dollars

1918
FLU

50 Million People
Untold Economic loss

OCTOBER 2017

A pandemic like

outbreak could

million people.

kill up to 80

the 1918 influenza

Although this is laudable progress, the work to reduce global health threats with pandemic potential has only just begun. A series of post-Ebola expert assessments pointed to the serious gaps in pandemic preparedness at global and national levels. As of 2014, two-thirds of countries did not fully comply with the IHRs. For the most at-risk countries, the road to better outbreak readiness is steep, and investments that are being made in new preparedness capabilities—such as the WHO Joint External Evaluation (JEE) process to assess a

country's ability to comply with the IHRs-are either still a work in progress or are just starting to be actionable. After volunteering for a JEE, countries work with the WHO to enact multiyear action plans and financing strategies to close their preparedness gaps, and are held accountable for progress. Even in the best-prepared countries, ongoing investments and international collaboration will be required to ensure outbreak readiness, with purposeful focus on ensuring that low- and middleincome countries are committed to mobilizing political action and domestic resources to strengthen their preparedness and response capabilities.

Recognizing this ongoing threat, the 2017 National Academy of Sciences, Engineering, and Medicine report Global Health and the Future Role of the United States declared that global health

security must remain a US leadership priority and recommended that the US government take proactive measures both at home and abroad to increase readiness to infectious disease threats. Bipartisan Administration and Congressional leadership has endorsed this view. In October 2017, US Secretary of State Rex Tillerson committed to supporting the GHSA and extending it until 2024. US recommitment to the GHSA is welcome, but is only meaningful if backed by the financial and diplomatic resources necessary to the task.

As the United States and the world begin to reap the benefits of the investments in better pandemic preparedness, now is not the time to step back.

History has shown us that as outbreaks become less visible, and as infectious diseases decline due to successful public health interventions, public funding for those very programs is subsequently cut in favor of other priorities. As complacency and neglect rise, so again does the risk of disease, followed by another series of outbreaks, leading to more panic and costlier

"Containing the spread of deadly disease in the countries of origin is a vital US national security interest.... While we've made tremendous progress since GHSA was launched in 2014, considerable work remains. That is why the United States advocates extending the Global Health Security Agenda until the year 2024."

-Rex Tillerson, US Secretary of State

interventions. As the September 2019 sunset date looms for GHSA and the Ebola supplemental funding, the US government should take specific action to ensure the nascent global progress continues. The ongoing threat that pandemics pose to US health, economic, and national security interests demands dedicated and steady funding for global health security, with a concerted focus on enabling low- and middleincome countries to strengthen their capabilities in proven public health interventions. The major US government agencies performing this work—particularly the Centers for Disease Control and Prevention (CDC), US Agency for International Development (USAID), Department of Defense (DOD), and Department of State (DOS)—should be adequately supported in line with the critical capacities with which they contribute. US leadership

and catalytic financing should also be dedicated to global health research and development (R&D)—for new vaccines, drugs, diagnostics, and other technologies—that will enable the United States and the world to tackle the disease threats of today and tomorrow. Although it may be impossible to completely prevent the emergence and spread of infectious threats, the United States and the world can be much better prepared by ensuring that the poorest and most vulnerable countries have well-functioning and well-equipped health systems.



RECOMMENDATIONS

To protect the health of Americans and people around the world, US leadership to drive global health security is more important than ever. The US Administration and Congress should come together behind a comprehensive US strategy for pandemic preparedness, which requires robust investments and continued vigilance both at home and abroad.

This paper focuses on the impact of the US' global investments in outbreak preparedness in low- and middleincome countries, and urges the current US Administration and Congress to adopt the following recommendations to make America and the world safer from global health threats:

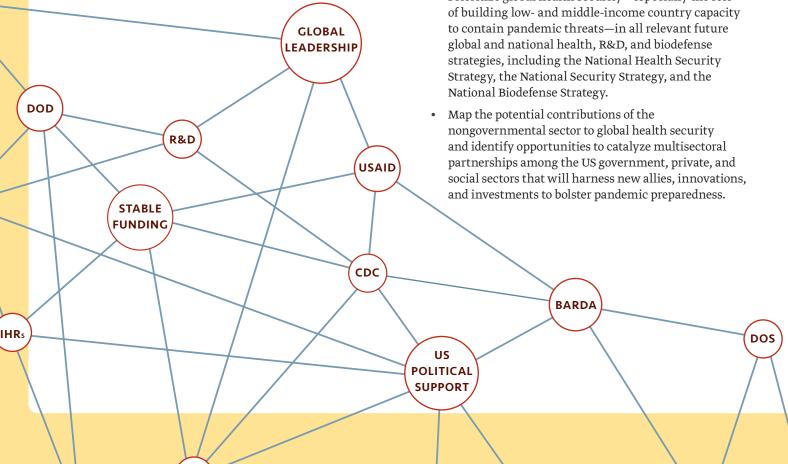
US GLOBAL HEALTH LEADERSHIP

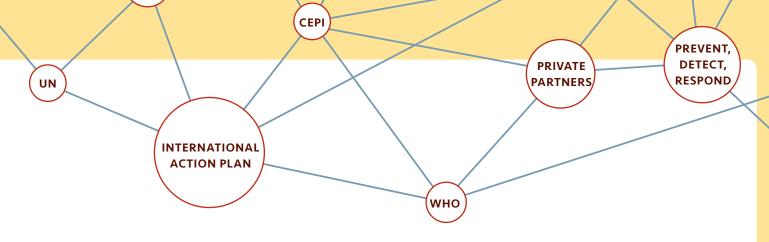
- Maintain consistent, high-level US political support for the next phase of implementation and expansion of the GHSA, taking concerted action in line with public declarations that strengthens global prevention, detection, and rapid response to emerging health threats abroad is a priority for the US government.
- Leverage available diplomatic and multilateral financing channels to motivate partner countries, specifically at-risk countries, to achieve and sustain compliance with the IHRs, using the US voice and vote at the United Nations, WHO, World Bank Group, and other relevant international health, development, and security platforms.

GHSA

AN INTERNATIONAL ACTION PLAN

- Develop and implement a US plan for international action in accordance with the structure set forth in the standing Executive Order Advancing the Global Health Security Agenda to Achieve a World Safe and Secure from Infectious Disease Threats. This action plan should prioritize and articulate the US government's role in advancing preparedness in low- and middle-income countries and catalyze R&D for disease threats, supported with clear and measurable indicators for progress.
- Designate senior-level oversight to achieve full implementation of the guidance outlined in the Executive Order and action plan, including ensuring coordinated support to US Chiefs of Mission and country teams to facilitate country preparedness for biological threats, and monitoring and evaluating progress toward global health security targets.
- Prioritize global health security—especially the role to contain pandemic threats—in all relevant future global and national health, R&D, and biodefense strategies, including the National Health Security Strategy, the National Security Strategy, and the





RESEARCH AND DEVELOPMENT

- Develop a new generation and robust pipeline of medical countermeasures—including appropriate drugs and technologies that are reflective of robust surveillance data—for infectious and emerging diseases with pandemic potential, allowing the US to quickly prevent an outbreak from becoming a pandemic.
- Enable the development and deployment of incentives
 to proactively and sustainably engage the private
 sector in medical product development for infectious
 and emerging diseases with pandemic potential to
 capitalize on the resources, expertise, and other skills
 of industry. This includes expanding governmentdriven incentive mechanisms like the Biomedical
 Advanced Research and Development Authority
 (BARDA) to financially support R&D for an expanded
 set of infectious and emerging diseases to bring
 industry partners to the table.
- Contribute US scientific and financial leadership to multilateral efforts to accelerate R&D on emerging pandemic threats, including through the Coalition for Epidemic Preparedness Innovations, the G20's R&D Collaboration Hub for antimicrobial clinical research and product development, and regional regulatory harmonization initiatives in endemic disease regions.



DEDICATED, SUSTAINED US GOVERNMENT FINANCING

- Ensure a whole-of-government approach to global health security financing, including dedicated and sustained funding for CDC, USAID, DOD, and DOS programming and personnel.
- Starting in FY2019, increase the annual base funding for global health security-related activities at CDC and USAID to ensure these agencies can continue their programming after the Ebola supplemental funding expires. To bridge the gap between the supplemental and core appropriations, USAID's Emerging Pandemic Threats budget should increase from \$72.5 million to \$172.5 million, and CDC's Division of Global Health Protection budget should increase from \$58.2 million to \$208.2 million.
- Ensure agencies have access to an emergency reserve fund to initiate an early and rapid response to emerging pandemic threats, allowing USAID and CDC to each retain up to \$70 million if and when needed. The reserve fund should be replenished once it is used to ensure funds are available for the next outbreak, and should not be interchangeable with annual appropriations or previously allocated emergency funding, nor borrowed from other global health or development programs, which would derail progress in other critical areas.
- Maintain US support for global health programs that build core public health capabilities and bolster frontline preparedness—including the US President's Emergency Plan for AIDS Relief, President's Malaria Initiative, Global Polio Eradication Initiative, and Child and Maternal Survival programs.
- Provide sustained and predictable investment across the US government in R&D for diseases with pandemic potential, to advance both the foundational knowledge of pathogens and the development of medical countermeasures.

INTRODUCTION

2018 marks the centennial of the deadly influenza pandemic that killed an estimated 50 million people worldwide, including 675,000 Americans. Despite major advances in public health, medicine, and technology during the past century, the world remains vulnerable; experts predict that a similar influenza pandemic today could kill as many as 50 to 80 million people. Outbreaks of life-threatening infectious diseases are occurring with increasing frequency around the world, with threats stemming from the weakest health systems in the poorest communities. From Ebola in West Africa, to Zika in South America, to avian influenza in China, these outbreaks are putting Americans and others across the globe at risk. Output Despite Major Despite Ma

Even in the United States, a severe pandemic could result in twice as many deaths as all US battlefield fatalities since 1776. These global health security risks are only expanding. The number of infectious diseases discovered per decade has increased nearly fourfold during the past 60 years, and the number of outbreaks per year has more than tripled since 1980. External factors stoking the fire include the increasing resistance of pathogens to currently available drugs, increasing urbanization and mass migration, and expansion of animal-to-human transmission of disease. This is further complicated by the ever-present threat of terrorist interest in biological weapons of mass destruction. Simply put, the US government can't adequately safeguard Americans' health if other countries don't have the right tools, infrastructure, policies, and systems in place to prevent outbreaks from spiraling out of control.

The potential health consequences of disease outbreaks are immense. For example, the December 2014 Ebola outbreak affected more than 15,000 people across ten countries. ⁶ The Zika virus surged in 2014 in Brazil and spread rapidly to 26 countries, infecting up to 1 million people. ⁷ Other diseases such as cholera affect up to 4 million people a year and cause as many as 143,000 deaths. ⁸ The burden is often greatest among the poorest people, as well as in conflict zones and areas with natural disasters. Even in the United States, a severe pandemic could result in twice as many deaths as all US battlefield fatalities since 1776. ⁹ Outbreaks of infectious disease also have many harmful indirect effects on health goals and delivery, proliferating global instability. ¹⁰ For instance, health system resources devoted to outbreaks

are not available for other essential health services, which often means less access to health care needed by women, children, and other vulnerable populations. Family income spent on infectious diseases is then not available for other drivers of economic growth.

"You're a lot more likely to die in a pandemic than a terrorist attack."

- US Representative Tom Cole (R-OK)

The potential economic effects of disease outbreaks and pandemics are also staggering. In the United States alone, an estimated 40 percent of the US labor force would be unable to work due to illness during the peak weeks of a severe influenza pandemic. The World Bank has estimated that the annual global direct and indirect costs of a moderate pandemic is roughly \$570 billion, or 0.7 percent

of global income.¹² The cost of a severe pandemic, like the 1918 influenza pandemic, could be as much as 5 percent of global gross domestic product¹³ or, as estimated by the National Academy of Medicine's Global Health Risk Framework, up to \$6 trillion.¹⁴ Much of this economic impact would result from avoidance of travel and poor workforce attendance. Individual threats like Ebola cost US taxpayers a total of \$5.4 billion,¹⁵ with estimated costs of \$1 million to treat only two Ebola patients at the Nebraska Medical Center,¹⁶ and \$1.1 billion for Zika,^{a,17} with expenses estimated as high as \$1.2 billion for six states in both direct medical costs and productivity losses.¹⁸

a Despite the President's emergency request to obtain "new" appropriations for Zika, each of the Congressional proposals required significant offsets from existing sources to fund the response. The final bill did not specify that borrowed funds should be used to specifically offset Zika funding. If this is the case, the entire \$1.1 billion would be new funding, although this remains to be seen.

Despite the great risks and potential catastrophic consequences of a pandemic, the international community, including the United States, has invested relatively little to date in prevention and preparation. US defense spending amounts to more than \$640 billion, and the Department of Defense (DOD) participates in well-resourced international military alliances and regularly conducts exercises to test preparedness and response. The contrast with the amount of resources devoted to protecting humankind from potential pandemics

is striking, with the United States spending around \$450 million for global health security. This amount is minimal in spite of the fact that investments in health care capacity-building and infrastructure are among the most cost-effective interventions against crises capable of crippling communities or industries. Instead, as the havoc caused by the most recent outbreak is forgotten, we become complacent and relegate the case for investment to the back burner, only to be unprepared when the next outbreak occurs. The result is that the world remains vulnerable, unprepared for the next pandemic.

Although it is impossible to completely prevent the emergence and spread of infectious threats, we can be much better prepared by prioritizing solutions. Preparation needs to include strengthening public health capabilities in low- and middle-income countries, providing global and regional expertise and coordination, and enabling accelerated research and development (R&D). The price tag on prevention is substantially less, with one example provided by the National Academy of Medicine's Global Health Risk Framework equaling \$4.5 billion per year. 21 As stated by White House Homeland Security Adviser Thomas Bossert, "[the global problem is that the] weakest country among us with the...least preventative care capabilities are going to be the patient zero outbreak source. And they're going to end up killing and infecting the world, and so we need to put money into places that don't have the money to do it themselves to prevent loss of life here."²²

The United States has an opportunity to build on its political and financial contributions to date as well as its deep technical expertise for global health security. This work will ultimately enable the United States to protect its citizens and economy

while benefiting others around the world. Nations with healthy populations are more likely to be productive, prosperous, and peaceful. Fortifying the ability of every country to prevent, detect, and respond to global health threats is in our national interest and bolsters the health security of our interconnected world. ²³ The US government has been—and must remain—a leader in protecting global health security, preventing both outbreaks and pandemics that could kill hundreds of thousands and devastate national economies.

It could cost \$6 trillion to contain pandemics.



The US has been — and must remain — a leader in protecting global health security.



US GLOBAL LEADERSHIP TO PREVENT, DETECT, AND RESPOND TO INFECTIOUS DISEASE

US leadership around the world has driven the success of previous and ongoing global health security initiatives through longstanding bipartisan support. The US government's work to advance global health security has historically been enabled through a number of programs, including but not limited to:

- The Centers for Disease Control and Prevention's (CDC)
 Global Disease Detection and Response Program and
 Field Epidemiology Training Programs
- The US Agency for International Development's (USAID) Emerging Pandemic Threats Program
- The DOD's Cooperative Biological Engagement Program, Global Emerging Infections Surveillance and Response Program and Walter Reed Army Institute of Research
- The Department of State's (DOS) Biosecurity Engagement Program
- The National Institute of Health's (NIH) National Institute of Allergies and Infectious Diseases and Fogarty International Center^b

Collectively, these programs have resulted in a tremendous return on investment for the United States, catalyzing both multisector and multinational engagement, as demonstrated in the achievements of the past ten years.

In 2005, against the backdrop of severe acute respiratory syndrome (SARS), avian influenza, anthrax bioterrorism, and fears of a global influenza pandemic, the United States supported global action by joining with other World Health Organization (WHO) Member States in becoming a signatory to the revised International Health Regulations (IHRs). These regulations commit countries to achieving the capacities required to detect, assess, report, and respond to outbreaks of infectious diseases and other acute public health risks.²⁴

In 2009, the H1N1 influenza outbreak tested the robustness of IHRs implementation for the first time, exposing weaknesses in detection, reporting, and response. Following this outbreak, the WHO acknowledged that 80 percent of countries were not fully compliant with the 2005 IHRs. ²⁵

b These programs do not all receive direct appropriations for capacity building in low- and middle-income countries but do benefit global health security at large. See the US funding and the need for dedicated, sustained financing section for more details.

Launch of the Global Health Security Agenda

In recognition of the need to increase compliance with the IHRs, the Global Health Security Agenda (GHSA) was launched in February 2014 to help build countries' capacities to create a world safe from infectious disease threats and elevate global health security as a national and global priority. With critical bipartisan leadership from the United States and key international partners, the GHSA has grown into an alliance of more than 60 nations as well as international organizations and nongovernmental stakeholders. The GHSA pursues a multilateral, multisectoral approach to strengthen global and national capacity to prevent,

detect, and respond to human, animal, and environmental disease threats, whether naturally occurring or accidentally or deliberately spread.²⁶

The Ebola outbreak showed the world the stark consequences of inadequacy to address global health security. The United States was indispensable in stemming the Ebola crisis in West Africa, helping to halt the spread of disease. Since then, the United States has committed to assisting 31 countries and the Caribbean Community to strengthen their preparedness for future disease

"...the weakest country among us with the...least preventative care capabilities [are] going to be the patient zero outbreak source. And they're going to end up killing and infecting the world."

- Thomas Bossert, White House Homeland Security Adviser

outbreaks, including contributing \$1 billion in new funding to assist 17 priority countries, as well as 14 additional countries and the Caribbean region in building their capacity. This commitment is grounded in principles such as accountability and transparency. The GHSA has had measurable impact (see text box). This includes strengthening and securing laboratories and real-time disease surveillance systems, training frontline health workers in outbreak detection, establishing stronger command structures for emergency response, and accelerating deployment of essential medicines, tools, and supplies to stop outbreaks from spreading. These investments have already resulted in a dramatic reduction in response times; for example, response time to recent outbreaks in Cameroon decreased from 8 weeks to just 24 hours. As weeks to just 24 hours.

The GHSA has had measurable impact: strengthening laboratories and surveillance systems, training frontline workers, establishing emergency response, and accelerating essential tools to stop outbreaks.

The GHSA has

grown into an

alliance of more

from infectious

disease threats.

than 60 nations to

create a world safe

The critical US role in the GHSA

In 2014, the United States helped to launch the GHSA and committed to supporting at least 31 countries reduce vulnerabilities to public health threats. The GHSA is now a partnership of over 60 countries around the world. US investments through the GHSA have enabled countries to develop tools to address specific preparedness gaps. For example, within the 17 priority countries, these investments:

- Financed training and technical assistance activities that have strengthened laboratory performance, upgraded animal disease transmission control programs, and provided critical drugs, vaccines, diagnostics, and equipment to help respond to new outbreaks.
- Strengthened 16 countries' emergency operations centers and incident management systems and sent subject matter experts to the field to provide cutting-edge technical guidance to governments and other partner organizations.
- Supported field epidemiology training programs (FETPs) that are training new cadres of in-country disease detectives who will investigate and respond to infectious disease outbreaks before they spill over to other countries. As of 2017, all 17 priority GHSA countries have a permanent, full-time epidemiologist as a result of FETPs.
- Prevented dangerous pathogens from accidently or deliberately being released by building comprehensive biosecurity and biosafety systems across laboratories and developed a plan to minimize, consolidate, and secure pathogens, supported by staff training to avoid future infections.²⁹

Impact of US investments in building other countries' capacities in health security

US leadership within the GHSA and other initiatives pre-dating the GHSA has begun to measurably reduce global vulnerability to infectious diseases and make health security an international priority. Key areas of impact have included supporting the WHO and other countries in developing the Joint External Evaluations (JEE), a process that has helped more than 50 countries

(including the United States) identify gaps in global health security, determine a baseline, and measure progress; developing vaccines and medical countermeasures that have strengthened countries' ability to combat antimicrobial resistance, zoonotic diseases, and biosecurity risks; improving data collection systems and infrastructure, which has helped to reduce the burden of respiratory syndromes, diarrheal diseases, foodborne illnesses, and animal-borne diseases, as well as improve detection of early warning signs of outbreaks; and improving comprehensive governance by

increasing collaboration among key stakeholders across the human health, animal health, agriculture, defense, and development sectors. All of this work is done in tandem with in-country and international stakeholder partnerships.

The United States has also engaged with partners and other donors to target resources effectively, measurably,

and sustainably, mobilizing multilaterals and the private sector. One example of this is the Private Sector Roundtable (PSRT), which seeks to mobilize industry to help countries prevent, detect, and respond to health-related crises. Formed based on the call to action for the involvement of private-sector entities, the PSRT has launched working groups around priority areas, built critical relationships, and served as a liaison for companies seeking to coordinate. ³⁰ For instance, the

PSRT Technology & Analytics Working Group, headed by Intel Corporation, has developed an online application powered by Qlik Technologies' software to track and view JEE scoring. Using this tool, JEE reports can now be visualized in interactive charts, graphs, and maps that will make it easier to compare a country's health security capabilities over time and identify gaps and opportunities for improvement.³¹

Ultimately, US-led efforts have mitigated human suffering and loss of life, as well as reduced negative economic impact. These investments have led to more efficient

and effective global health security advancement (see text box, next page); for example, agencies such as the DOD and the CDC are collaborating with host nation partners to advance surveillance efforts, leading to the earliest known positive sample of Middle East respiratory syndrome coronavirus (MERS-CoV) and detecting the first case of pandemic H1N1 in the United States. 32

US-led efforts have mitigated human suffering and loss of life, as well as reduced negative economic impact.



/Therese Biorn Masor

Impact from US investments in global health security

- In March 2016 in Liberia and Guinea, a new Ebola outbreak was effectively controlled, minimizing the outbreak to only 13
 cases and 9 deaths. US investments had helped to increase the countries' capacities to detect and respond to
 disease outbreaks.³³
- The CDC helped Vietnam develop a network of national emergency operations centers that act as nerve centers for epidemic intelligence, bringing outbreak detection and response even closer to the source. As a result, Vietnam has been able to rapidly respond to the Zika epidemic and prevent the virus from spreading.³⁴
- The USAID's PREDICT Project, spanning 35 countries, detected more than 850 new viruses, optimized more than 60 laboratories, collected samples from more than 740,000 wild animals, and trained 3,300 field and laboratory staff.³⁵
- DOS trained 1,200 Liberian National Police in Monrovia to prevent access to and limit the spread of dangerous pathogens from the laboratory setting, and 500 Guinean law enforcement officers were trained on biosafety and biosecurity. 36
- Within the DOD, the Walter Reed Army Institute of Research moved Zika vaccine development forward, from concept to human clinical trials in less than 10 months, with the help of HIV program researchers.³⁷
- The Biomedical Advanced Research and Development Authority (BARDA) supported R&D of five late-stage pipeline candidates—three vaccines and two drugs—for Ebola and select viral hemorrhagic fevers.³⁸
- NIH is currently partnering with GlaxoSmithKline to develop several Ebola vaccine candidates and is sponsoring clinical trials in Africa, managed by a US-Liberia research partnership.³⁹
- Within the Department of Health and Human Services (HHS), the Office of Pandemics and Emerging Threats, supported by the Office of Science and Technology Policy, led the development of the National Strategy for Combating Antibiotic-Resistant Bacteria and creation of a related interagency taskforce, stemming the flow of substandard and counterfeit pharmaceuticals internationally.⁴⁰
- Working through the GHSA platform, the DOD and CDC collaborated to enable improved biosafety and biosecurity in Uganda, maximizing the use of modern diagnostics and minimizing the storage of dangerous pathogens, protecting health in East Africa and preventing further instability.⁴¹



Health security benefits of US investments in global health programs

In addition to the impact of US government investments intended to improve epidemic preparedness, investments in so-called "traditional" US global health programs—including immunization, maternal and child health, HIV/AIDS, tuberculosis, and malaria—strengthen the ability of low- and middle-income countries to enhance global health security, including bolstering health workforces, systems, and infrastructure. Under Chief of Mission authority, these programs are synergistic and

work in tandem with the programs supported by US assistance for the GHSA, functioning together to improve measurable outcomes (see text box). For example, the President's Emergency Plan for AIDS Relief (PEPFAR) is often used as a platform for addressing drivers of health epidemics, and was used during the Ebola outbreak in Uganda to support a surveillance transportation system in which motorcycle couriers traveled through rural areas to pick up blood samples, aiding quicker diagnoses. ⁴²

Health security benefits of US investments in traditional global health programs:

- Nigeria was able to respond rapidly to its 2014 Ebola outbreak because of a preexisting polio surveillance structure and emergency operations center, as well as the presence of trained field epidemiologists, supported by US funding through the Global Polio Eradication Initiative (GPEI). Nigeria rapidly shifted the target of these capabilities from polio to Ebola to contain the outbreak in Lagos, a city of 21 million people, with only 19 cases and eight deaths.⁴³
- Through the existing US PEPFAR platform—which equips countries to respond to HIV/AIDS epidemics—the DOD invested
 in a strategic initiative called the Joint West Africa Research Group to also address health threats such as Ebola, avian flu,
 and cholera. This initiative uses the DOD's existing partnership with the Nigerian military and its large network of medical
 facilities and trained personnel to conduct surveillance and clinical research on infectious disease threats for biosecurity
 preparedness.⁴⁴
- In Liberia and Guinea, maternal and child health units benefitting from US government support now have screening
 and triage services as well as staff trained for infection prevention and control standards. In addition, maternal and
 child health social mobilizers who traditionally campaign for polio, measles, and deworming are also monitoring target
 populations for outbreaks and building citizen trust.⁴⁵
- The President's Malaria Initiative (PMI) supports the CDC's field epidemiology training programs in 12 focus countries
 in Africa to build a cadre of ministry of health staff with technical skills in the collection, analysis, and interpretation of
 data for decision-making and epidemiologic investigations. For example, numerous Tanzanian government institution
 officials have now graduated from a master of science program in Applied Epidemiology and Public Health Laboratory
 Management.⁴⁶



Challenges and solutions for global progress

Despite US-supported progress in global health security in recent years, many challenges remain. Without continued political will, meaningful action, and financing strategies to enact national multiyear action plans, new pathogens will continue to spread undetected, leading to costly delays in combating outbreaks. In the past year alone, outbreaks have included Ebola in the Democratic Republic of Congo, cholera in Cameroon and Yemen, measles in Pakistan, the plague in Mozambique, and yellow fever in Angola and Brazil. As the current Administration shapes its priorities, the next phase of work in global health security offers an opportunity to further complement US leadership, leveraging available diplomatic, development, and security channels to motivate partner countries, specifically at-risk countries, to achieve and sustain compliance with the IHRs.

Countering pandemic threats is not possible without sustained international cooperation and investment. The US can demonstrate global leadership in a number of ways, taking advantage of the unique set of actors with the ability to drive progress. First, the United States should remain committed to the IHRs and GHSA principles, as well as to other international efforts that support prevention, detection, and response to emerging health threats, taking action in line with public declarations that strengthening global health security abroad is a priority for the US government. This includes building and securing the availability of collective resources and capacities such as a global health workforce, including frontline disease detectives, trained scientists, and emergency response teams as well as expanded global networks to detect and treat emerging health threats.

Secondly, the US government should continue to work closely with the United Nations, WHO, World Bank Group, and other relevant multilateral and multistakeholder health, development, and security platforms, driving innovative global initiatives to develop solutions. The US government should also take into consideration the full breadth of One Health sectors that can contribute to results with strategies such as the Tool for the Evaluation of Performance of Veterinary Services already in place under the World Organization for Animal Health. New initiatives are also emerging, including the Coalition for Epidemic Preparedness Innovations (CEPI—expanded upon further in the R&D section below), which can further bolster the US commitments.

Third, the US government should ensure that strengthening pandemic preparedness in low- and middle-income countries is, and remains, a priority for both its bilateral and multilateral foreign assistance. In addition to sustaining dedicated bilateral financing for global health security—which continues to be a



core challenge, explored in depth below—multilateral financing is an important tool to secure commitments, marshal resources from other nations, and incentivize countries to increase their own domestic resources for outbreak preparedness. The US can leverage funding mechanisms such as the Pandemic Emergency Financing Facility—an insurance-backed facility launched by the World Bank Group with support from Japan, Germany, and the WHO-to provide surge funding to enable a rapid, effective response to specific, large-scale disease outbreaks before they escalate. The US should fulfill its pledge to the World Bank's International Development Association, which supports countries to build resilient health systems and strong public health capabilities, including pandemic preparedness planning. The US should also work with partner countries to ensure that WHO has sufficient resources to implement its Emergency Response Framework, revamped in the wake of the Ebola crisis. A strong US commitment and support for these multilateral efforts plays a key signaling role to

CARRYING FORWARD A GLOBAL HEALTH SECURITY INTERNATIONAL ACTION PLAN

security and pandemic preparedness.

other nations to prioritize investments in global health

A core component of ensuring the US government remains ahead of the global outbreak curve will be advancing US and country strategies for prioritization of global health security. Many of the agency and department roles and responsibilities to counter biological threats were codified in November 2016 by an Executive Order—Advancing the Global Health Security Agenda to Achieve a World Safe and Secure from Infectious Disease Threats—which has been retained by the current Administration. 47 The Executive Order articulates how



the United States should advance GHSA targets and IHRs implementation, fueling a strong whole-of-government approach to global health security.

As directed by the Executive Order, White House leadership has empowered lead agencies to provide planning and oversight as well as technical agencies taking action in the field. Policy and coordination development is overseen by an Interagency Review Council, headed by the National Security Council. National-level coordination is supported through the Secretary of State's role to oversee programs and policies that advance the GHSA within foreign countries. Other agencies that support the direction of the council and coordination efforts include USAID, CDC, DOD, Department of Justice, Department of Agriculture, HHS, Department of Homeland Security, Office of Management and Budget, Environmental Protection Agency, and Office of Science and Technology Policy. Outside of the GHSA platform, this work is also being bolstered by adjoining US government efforts (see Table 1).

In addition to retaining these gains, the next phase of readiness will require working toward ensuring all countries meet global standards, with actionable objectives and measurable progress in compliance with the IHRs. The United States has a key role to play in supporting low- and middle-income country development of multiyear action plans, accountability mechanisms, and execution of pandemic preparedness, with an emphasis on mobilizing domestic resources to demonstrate political commitment to action. To encourage country achievements, complete coverage of IHRs capacities, and fully financed national plans, the Administration should further implement the Executive Order by developing a US-led international action plan for continued, long-term bipartisan support for the

GHSA, carried out by the White House, National Security Council staff, and Secretary of State.

This plan would need to be guided by US government objectives, define principles, and articulate how the United States seeks to drive specific progress, with an emphasis on how the US will invest in preparedness in low- and middle-income countries and R&D. Foundational to an effective plan will be specified goals supported by interim milestones measurements, retaining core principles of transparency and accountability. This plan could provide a line of sight on global health security across the US government, including directional leadership for enhancing and engaging other US-led global health initiatives, as well as the wider biodefense community, to achieve these goals.

There are also multiple existing cross-government security and foreign assistance strategies that should reflect and reinforce these priorities, including future iterations of the National Biodefense Strategy and Implementation Plan, the National Security Strategy, and the National Health Security Strategy and its Implementation Plan. These strategies should reference and be referenced by wider global health strategies set forth by the Administration.^c It is critical to note that, although national leadership is imperative, it cannot operate in a vacuum and should be supported by partnerships and cross-sector coordination of multilateral and international organizations, private stakeholders, civil society, and leaders from around the world to catalyze progress through additional funding and collective action. These partnerships will harness new allies, innovations, and investments to bolster pandemic preparedness.

This includes but is not limited to: Department of Defense Guidance for Security Cooperation; State Department Office of US Foreign Assistance Resources, Functional Bureau Strategy; State/USAID Strategic Plan; USAID's Global Health Strategic Framework: Better Health for Development; One Health Strategic Plan; US Global Development Policy; HHS Global Strategy; HHS Strategic Plan; and CDC Global Health Strategy. As it pertains to global health security, these strategies should be consolidated and reflected in the processes carried out by the Executive Order.

TABLE 1. Summarized roles of government agencies with respect to the GHSA and broader support for global health security.

Department > Agency or Office > Roles in implementing global health security

Executive Office of the President of the United States

National Security Council, Office of Management and Budget, and Office of Science and Technology Policy

Principal forum for coordinating and tracking global health security policy. Leads US advancement of the GHSA targets and implementation of the IHRs within partner countries, including convening and chairing a GHSA Interagency Review Council.

US Department of Health and Human Services

Office of Global Affairs:

Builds relationships with other nations and partners to develop, promote, and advance global policies and efforts to strengthen global health security.

Centers for Disease Control and Prevention:

Division of Global Health Protection (including Global Disease Detection Centers and Field Epidemiology Training Programs); Epidemic Intelligence Service;

Emerging and Zoonotic Infectious Diseases;

Public Health Preparedness and Response Program;

Immunization and Respiratory Diseases

Leads technical implementation for health security. Uses multiple platforms to combat health threats, supporting critical disease detection networks, diagnostic tools, laboratory systems, and the public health workforce. Bolsters global health security through programming in immunization (with GPEI), HIV/AIDS, tuberculosis, malaria, and other neglected diseases.

National Institutes of Health:

National Institute of Allergy and Infectious Diseases;

the Fogarty International Center

Advances R&D on infectious diseases such as Ebola and Zika; mentors and trains scientists overseas.

Food & Drug Administration:

Implements its Emergency Use Authorization and Emergency Investigational New Drug schemes, which help promising tools not yet approved be used in emergency situations, such as the Ebola epidemic; enhances international regulatory systems for antibiotic resistance, food safety, and supply chain strengthening.

Office of the Assistant Secretary for Preparedness and Response:

The Biomedical Advanced Research and Development Authority

Coordinates the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies.

US Agency for International Development

Global Health Bureau's Emerging Pandemic Threats

Focuses on zoonotic diseases, workforce development, disease surveillance, and antimicrobial resistance, collaborating with national and community stakeholders to monitor viruses with pandemic potential, mitigating effects. Invests in R&D for new tools through Grand Challenge financing and advanced market guarantees for Ebola and Zika diagnostics. Bolsters global health security work with programming in HIV/AIDS, tuberculosis, malaria (with PMI), maternal and child health, and neglected tropical diseases.

Department > Agency or Office > Roles in implementing global health security

US Department of State

Office of International Health and Biodefense;

International Security and Nonproliferation Bureau's Biosecurity Engagement Program;

Office of Global Health Diplomacy

Engages on health security through policymaking, coordinating, planning, and implementing global biological security and defense programs in partnership with international stakeholders and diplomatic missions as well as through interagency work. Bolsters global health security work through programming in HIV/AIDs (with PEPFAR).

US Department of Agriculture

Animal and Plant Health Inspection Service;

Foreign Agricultural Service;

National Institute of Food and Agriculture;

Agriculture Research Service

The leading authority on animal diseases and agricultural production, providing technical assistance and research collaborations to help countries improve disease surveillance, enhancing biosafety and biosecurity best practices.

US Department of Defense

Cooperative Threat Reduction's Cooperative Biological Engagement Program;

Defense Threat Reduction Agency;

Army Medical Research and Material Command's Military Infectious Diseases Research Program;

Naval Medical Research Center and Naval Research Laboratory;

Walter Reed Army Institute of Research;

Congressionally Directed Medical Research Programs;

Defense Advanced Research Projects Agency;

the Armed Forces Health Surveillance Branch's Global Emerging Infections Surveillance and Response System

Enhances R&D, biosecurity, and biosurveillance in countries around the world, helping to prevent and respond to outbreaks of infectious disease that may threaten international and domestic stability. Also develops key lessons from military health operations that can be used in civilian sectors and engages with partner nations to train militaries in tactical combat medical training.

Department of Justice

Federal Bureau of Investigation

Links public health and law enforcement with INTERPOL on the GHSA. Ensures GHSA's successful implementation in coordination with other relevant FBI programs and partners.

Department of Homeland Security

Chemical and Biological Defense Division

Assesses the impacts of global health threats on homeland security operations related to global health threats at US borders and ports of entry.

RESEARCH AND DEVELOPMENT TODAY TO ADDRESS TOMORROW'S HEALTH SECURITY CHALLENGES

To effectively prevent, detect, and respond to health challenges, we need appropriate tools—including drugs, vaccines, diagnostics, and other technologies. This requires sustained investment in R&D—both for long-standing infectious diseases with pandemic potential and for a broad range of emerging diseases. Prioritization of R&D will help ensure that when an outbreak occurs, we have a foundational knowledge of the pathogen as well as the medical countermeasures we need to address it.

A core challenge the US faces is that R&D to address emerging and infectious diseases has long been

underfunded. In 2014, funding for non-Ebola neglected disease R&D was the lowest recorded since the G-FINDER survey, which tracks public funding for R&D in neglected diseases, began in 2007. d,48 This is further expanded upon in the financing section below. This gap highlights the lack of sustainable, forward-looking investment in the drugs, diagnostics, and vaccines needed to combat both known and unknown disease threats, and it reflects a disconnect between the expressed prioritization of global health security and the financial commitments to support it. It

also highlights a tendency to fund R&D for global health security with emergency, stop-gap measures instead of more cost-effective, sustained, predictable investments that prepare us for future threats.

Accordingly, the development of medical countermeasures for infectious and emerging diseases with pandemic potential has not kept pace with the increasing urgency and frequency of epidemics. This divergence was particularly evident during both the Ebola and Zika outbreaks, where there was a notable lack of appropriate tools and technologies—approved or under development—to address the crises. In both cases, under-prioritization of R&D required rapid mobilization to accelerate the development of urgently needed medical technologies. In the case of Zika, the situation was dire, as resources were needed both to improve understanding of the basic science of the disease—including sexual transmission and associated birth defects-which challenged the development of medical countermeasures. This problem is expanded by the rise of antimicrobial resistance, meaning the drugs are becoming less effective and drug-resistant versions of diseases are increasing,

rendering current tools inadequate. By 2050, \$100 trillion and 10 million lives are projected to be lost as a result of antimicrobial resistance. Disease surveillance also requires investment to make strong connections between surveillance data and the development of appropriate medical countermeasures. This will help build systems that the United States can use to forecast and schedule product development needs, build a pipeline of countermeasure candidates, and bolster our ability to quickly respond to prevent an outbreak from becoming a deadly pandemic.

History has shown us how US government R&D leadership, ongoing investment, and prioritization have helped overcome some of the biggest health challenges of our time and improve global health security. For

example, sustained R&D for diseases such as polio, measles, diarrheal disease, HIV/AIDS, malaria, and tuberculosis have led to significant gains against these diseases, protecting global and American health. This includes decades of support for polio vaccines, which have almost eliminated the debilitating disease, and US leadership to address HIV/ AIDS, including developing the first antiretroviral treatments and helping to transform AIDS from an automatic death sentence to a manageable chronic disease.

More recently, US commitment

and funding to address Ebola helped to transform Ebola

R&D. In response to the 2014 outbreak, US funding for Ebola R&D increased from negligible levels in 2013, to \$101 million in 2014, to \$298 million in 2015, 50 reflecting more dedicated funding for any disease except for HIV/ AIDS. The surge in commitment came with results. By the end of 2015, four new US-supported products for Ebola and select viral hemorrhagic fevers had been registered, and 11 new US-supported Ebola products had advanced in the product development pipeline.⁵¹ These efforts were supported by the CDC, DOD, NIH, Food and Drug Administration (FDA), and BARDA, which all played unique and critical roles in the product development process. It is important to note that because R&D is an inherently long process, even a surge of funding and commitment for Ebola did not result in tools ready for use during the 2014 outbreak. Only sustained investment prior to the 2014 outbreak would have been able to yield the tools needed to address it quickly and efficiently. However, the United States and the world are now better prepared to meet the next outbreak.

"Research into developing a

Zika virus vaccine, diagnostic

tests, and treatments must be

implemented as a part of an

effective strategy to end this

harmful epidemic and protect

Americans traveling abroad."

- US Senator Richard Blumenthal (D-CT)

d As defined by the G-FINDER report, neglected refers to diseases which disproportionately affects people in developing countries, with a need for new products, and insufficient commercial market to attract private industry.

Sustained government investment and incentives to secure ongoing commitment to R&D is key to engaging the private sector.

Harnessing the private sector and multilateral bodies

Engaging the private sector remains critical to catalyzing R&D for pandemic prevention. When effectively mobilized, private industry has been an important ally. During the Ebola outbreak, for example, more than 300 private-sector companies contributed substantial financial resources, ⁵² as well as extensive R&D of new health interventions for logistics and supply chain, health, technology, data management, and financial services. With targeted incentives from the US government, Johnson & Johnson, GlaxoSmithKline, Merck, and Novavax all used their teams, labs, and capabilities to develop and test Ebola vaccines. Other

companies conducted R&D for easier-to-use diagnostic tests, and many also partnered with public stakeholders, such as the NIH or WHO, to accelerate research and advance deployment of countermeasures in the field. 53

Sustained government investment and incentives to secure ongoing commitment to R&D for infectious and emerging diseases with pandemic potential is key to engaging the private sector. As these diseases primarily affect people in the world's poorest places, there is little market incentive for private industry to independently participate. Previous examples of private-sector commitments can provide future platforms for investment. In the response to the Ebola and Zika outbreaks, the US Congress passed legislation extending and offering new incentives to industry. As one tool, Congress extended the FDA's priority review voucher, a mechanism that awards developers of novel products for select infectious and emerging diseases with a transferrable voucher guaranteeing the expedited FDA review of another pharmaceutical product.⁵⁴

Congress also allowed BARDA, an entity predominately used to develop medical countermeasures for biological threats, to engage the private sector. BARDA is a relatively new player in the field of global health R&D, as its mission is to develop medical countermeasures against diseases that threaten US citizens; prior to the recent Ebola outbreak, it had primarily focused on domestic tools for pandemic influenza or anthrax. Through unique contracting mechanisms and grant funding for late-stage product development, BARDA successfully worked with industry to advance at least six new Ebola technologies⁵⁵ and at least five new Zika technologies, geared for global application. 56 BARDA's incentive mechanisms and external funding for product development could serve as a model for a future collaboration. However, funding cuts are already having an impact, as Sanofi Pasteur recently halted its Zika vaccine development program due to reduced BARDA investment.⁵⁷ Government incentives should help bridge this divide. To continue to capitalize on the resources, expertise, and know-how of the private sector to advance global health security, the United States must be

strategic, carefully and purposefully deploying incentives that bring industry to the table.

US government support for existing global and multilateral mechanisms could also make a substantial contribution to the advancement of global health security R&D. Many newly established initiatives support US-articulated global health security goals and could be greatly advanced with US participation, leadership, and commitment of resources. For example, CEPI—launched in January 2017 with an initial \$460 million investment from Germany, Japan, Norway, the Bill & Melinda Gates Foundation, and Wellcome Trust—is an initiative to more quickly develop and test new vaccines for emerging and reemerging infectious diseases. Although CEPI was celebrated as an important global response in the aftermath of Ebola, the United States has yet to commit resources or expertise to advance the platform. Similarly, there are avenues to cooperate with global partners through the proposed G20 R&D

"We are prepared to add four Ebola countermeasures to the stockpile whereas three years ago, very few products were even in early stages of development. This marks a pivotal moment in US and global preparedness for future public health emergencies. We reached this point at unprecedented speed, and that's a direct result of innovative approaches to product development and to partnering across the U.S. government, other nations, and private industry."

- Rick Bright, BARDA Director

US government support for existing global and multilateral mechanisms could make a substantial contribution to the advancement of global health security R&D.

Collaboration Hub for R&D on antimicrobial resistance (AMR).⁵⁹ If sufficiently supported by the US and other partners, the Collaboration Hub offers a promising mechanism to streamline and coordinate the notoriously difficult process of addressing AMR. Given the high failure rate and long pipeline time for new products to combat AMR, securing coordinated resource allocation

and collaborative research is a high priority to ensure that the US has the necessary tools. There are also regional initiatives which encourage collaboration between high-income countries and low- and middle-income countries-including regulatory harmonization efforts such as the African Vaccine Regulatory Forum and African Medicines Regulatory Harmonization—that could be bolstered through US engagement.

Creating a sustainable environment to support forward-looking R&D for infectious and emerging

diseases with pandemic potential is critical to improving global health security. This is true whether it is investing in preparedness or response. Implementing the hardlearned lessons from Ebola and Zika—in which we had no approved tools to prevent, diagnose, or treat either disease—can help to achieve this goal while ensuring the full contribution of commitments, assets, and resources from partners across sectors. The United States should pursue an approach that proactively and sustainably funds R&D for infectious and emerging diseases with pandemic potential, anticipates the need for new technologies, and strengthens collaboration across agencies, with the private sector and in conjunction with global and multilateral initiatives.

US FUNDING AND THE NEED FOR DEDICATED, SUSTAINED FINANCING

Funding for global health security is challenged by the very nature and urgency of outbreaks. The most cost-effective approach is for the United States and international stakeholders to provide funds for prevention

> and preparedness before a crisis happens, instead of spending large amounts on emergency response after an outbreak escalates to a pandemic. When pandemics have emerged in the past, Congress has been fenced into appropriating large amounts of emergency funds, despite the fact that investments in preparedness are miniscule in comparison. As each outbreak subsides, funding also declines—often significantly—and political battles may impede further progress.60 In addition to the challenges created by funding surges related to specific outbreaks, annual appropriations for global

> > 21

specific outbreaks, annual appropriations for global health security programs vary from year to year, making it difficult to adequately plan and prepare. This is further complicated by the number of programs that sit within disparate accounts across the US government. The inefficient appropriation of financing is a major concern, as are ad hoc authorizing legislation and case-by-case emergency funding appropriations that continue to put the safety of Americans and others at risk.

Current US financing of global health security programs

PATH estimates that \$449.70 million included in the FY2017 Omnibus Appropriation is dedicated to internationally focused health security programs, directly supporting global health security capacity-

FIGURE 1. Core appropriated funds for FY2017 enacted without Ebola supplemental funding (amounts in millions)

"As the Ebola epidemic showed,

targeted investments in global health

infrastructure and pandemic response

deliver huge returns on investment,

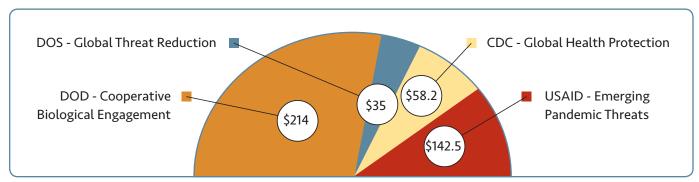
particularly when we consider the

potential cost of a pandemic that

its way to the United States."

- US Senator Chris Coons (D-DE)

crosses borders or oceans and makes



The most cost-effective approach is to provide funds for prevention and preparedness before a crisis happens.

building in low- and middle-income countries. This total includes funding for USAID's Emerging Pandemic Threats Program, CDC's Division of Global Health Protection, DOD's Cooperative Biological Engagement Program under the Cooperative Threat Reduction Program, and the DOS's Global Threat Reduction Program. Together these funding line items are less than 0.1 percent of the total non-defense discretionary budget, ⁶¹ with DOD's portion representing a little less than half of all funding allocated to global health security (Figure 1). ^e These programs will likely experience a decline in funding averaging 10 percent from FY2017 to FY2018 if the draft House and Senate bills are enacted. See Appendix A for agency-specific appropriations for FY2017-FY2018 funding line items.

Since FY2015, agency appropriations—specifically for USAID and CDC—have been augmented, a result of the \$5.4 billion allocated to combat the outbreak of Ebola. ⁶² Of the \$5.4 billion, \$1 billion was redirected to address the evolving nature of the threat. The infusion of financing meant agency budgets surged, driving an influx of capital for programmatic work outside the normal appropriations process. The \$1 billion represented a 239 percent increase over the approximately \$417.1 million in global health security appropriations in the FY2015 omnibus appropriation. This funding is currently financing the majority of GHSA efforts and is set to expire in FY2019.

In FY2017, Congress made a welcome step to augment USAID's core funding by including an additional \$70 million (see Figure 2) for an Emergency Reserve Fund to respond to exigent

"Epidemic preparedness is critical in order to ensure economic, social, and political security, as well as the stability of all nations, including the US. We can pay now, or we can pay a lot more later."

 Garrett Grigsby, Director of the Office of Global Affairs at the US Department of Health and Human Services contagious infectious disease outbreaks. This funding is separate from base monies in that it is not tied to fiscal years, is available until expended, and is only unlocked if the Secretary of State determines "that it is in the national interest to respond to an emerging health threat that poses severe threats to human health. ⁶³ This reserve fund is an effective mechanism to enable an early and rapid response to a severe outbreak, before it escalates. However, the fund as currently structured is not sufficient for all core agencies to respond, and it is not a replacement for annual appropriations for the types of global health security capacity-building efforts discussed earlier in this paper.

In addition to the agencies identified in Figure 1, other agencies and programs conduct activities that indirectly benefit global health security even though they do not receive specific appro-

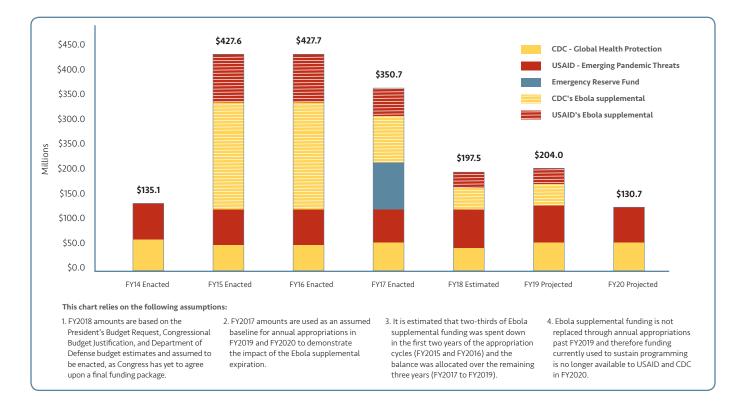
priations for this purpose. These programs are designed to provide protection for American citizens by fortifying research, surveillance, and medical countermeasures. Although not contributing to capacity-building in low- and middle-income countries in a targeted manner, these programs provide tools and expertise that enable agencies receiving direct global health security appropriations to bolster their impact, benefiting the global effort. Many of these programs are captured in a Johns Hopkins University annual federal funding report for health security. ⁶⁴ (Refer back to Table 1 for a detailed list of many contributing programs.)

In conjunction with both direct and indirect funding for infectious disease prevention activities, many US global health programs—in particular PEPFAR, PMI, GPEI, Maternal and Child Survival programs, as well as general R&D to address these diseases and conditions—are of fundamental importance in building a comprehensive approach to strong health systems and infrastructure, as well as in developing and introducing new tools to prevent, detect, and treat disease. Thus, consistent funding for these global health programs should also be seen as a critical and complementary investment for continued progress in global health security. Fluctuations in financing to meet other global health goals means that these programs are caught in a stop-start environment and are unable to maximize their potential contributions to global health security. It must be recognized that global health programs and pandemic preparedness are both critical to increasing security and each should be funded sufficiently to reflect these complementary roles.

Inconsistent financing cripples our ability to prevent, detect, and respond to outbreaks.

e While the Cooperative Biological Engagement budget is significant in relation to partner agency amounts, this funding amount has declined significantly in recent years, with a high of \$320 million in FY2014. This amount equates to almost half of the global health security total budget, so its sustainment is imperative.

FIGURE 2. USAID and CDC funding spikes as a result of the Ebola supplemental funding (amounts in millions)



FINANCIAL CHALLENGES

To ensure sustained funding for health security efforts, the US government should address two critical long-term challenges:

- 1. **Financing is inconsistent across and within agencies.** As demonstrated in Table 1 and Figure 1, a number of federal agencies and offices consistently lead the charge to prevent, detect, and respond to outbreaks, with each playing an important role. Nonetheless, global health security financing is ad hoc. Sustained progress will require that agencies leading this work—including the CDC, USAID, DOD, and DOS—are adequately funded to perform the activities for which they have critical capacities, including policy coordination, technical knowledge, R&D, regulatory capacity, in-country operations, One Health approaches, logistics, and overall authority. The current lack of transparent funding coordination and reporting across the US government also makes tracking and allocating funding extremely difficult.
- 2. **Funding for global health security has been driven by reacting to crises in real time rather than prioritizing future and preventive investments in preparedness.** Outside of regular appropriations, Congress provides funding for emergency and disaster assistance efforts that can be used to respond to health emergencies, such as the Ebola and Zika outbreaks. In FY2015, the US government allocated more in one year for surge financing than the total amount invested in the previous five years for prevention systems and tools. Moreover, two years after the Ebola outbreak, Congress appropriated \$1.1 billion for Zika, with the original intention of repurposing Ebola funding (\$117 million), the nonrecurring expenses fund at HHS (\$100 million), and Affordable Care Act funding (\$543 million). However, when funding is derived from other programs, there can be severe implications, such as the resurgence of infectious diseases that had previously been under control. A short-term funding response can never fully substitute for long-term stable investments in prevention and response systems.

US legislation addressing global health security and public health emergencies

Since 2015, multiple pieces of legislation have been introduced to address US government funding and program authorization. Although it is clear that Congress is interested in pursuing health security legislation, other than Ebola and Zika emergency supplemental funding, all standalone authorizing bills have only sought to address emergency reserve funding and few have passed. The many attempts listed below also demonstrate that most legislative proposals have only provided partial solutions and have failed to capture the full scope of commitment across departments and agencies required to effectively address the challenges at hand. The following list includes both enacted and proposed legislation to demonstrate the differing attempts at addressing the public health emergency challenges.

- Consolidated and Further Continuing Appropriations Act, 2015 [Public Law 113-235], H.R. 83, passed in December 2014. The funding package provided \$5.4 billion in emergency supplemental spending to respond to the Ebola outbreak in West Africa, for nonemergency appropriations, and to bolster domestic preparedness, most of which has expired or is set to expire in September 2019. The emergency supplemental appropriation was accompanied by a request for the authority to transfer the included funds to any federal agency to help meet Ebola or other infectious disease-related needs, both domestically and overseas.
- Infectious Diseases Rapid Response Reserve Fund, H.R. 5926, was introduced by Rep. Tom Cole (R-OK) on July 22, 2016. This bill proposed a new \$300 million reserve fund for CDC to prevent, prepare for, or respond to an infectious disease emergency while funding is allocated for a larger response. It was not included in the final enacted package for the fiscal year.
- Centers for Disease Control and Prevention Emergency Response Act, S. 3302, was introduced by Sen. Barbara Boxer (D-CA) on September 8, 2016. This bill would have established and provided \$2 billion for a CDC Emergency Response Fund. In contrast to the \$300 million Infectious Diseases Rapid Response Reserve Fund temporary funding, the \$2 billion in this bill was meant to provide a comprehensive approach for an emergency.
- Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act, 2016 [Public Law 114-223], H.R. 5325, passed in September 2016. The funding package provided \$1.1 billion in emergency supplemental spending and nonemergency appropriations to control the spread of the Zika virus throughout the Americas.
- Consolidated Appropriations Act, 2017 [Public Law 115-31], H.R. 244, passed in May 2017. This annual appropriations bill established a new \$70 million Emergency Reserve Fund at USAID to respond to exigent contagious infectious disease outbreaks.
- Public Health Emergency Response and Accountability Act, S. 196, was re-introduced by Senators Bill Cassidy, MD (R-LA) and Brian Schatz (D-HI) on January 24, 2017. This bill would provide additional funding for an HHS-specific Public Health Emergency Fund (PHEF) that was created in 1983 [Public Law 98-49]. The PHEF has only been refilled twice since its creation, with a current balance of \$57,000. Under this proposal, the Treasury would release money into the PHEF equal to the average yearly funding for public health emergencies over the past 14 years. After funding is released, agencies involved in response efforts would be obligated to pay between 0.2 and 0.5 percent of it back until the Treasury received 50 percent of the original amount. The remaining 50 percent would be designated as "emergency spending." The bill would also require HHS to convene a group of federal officials to prepare monthly reports on the spending of the funding, collaboration, and best practices specific to the emergency declared.
- Public Health Emergency Preparedness Act, H.R. 3579, is reintroduced annually by Rep. Rosa DeLauro (D-CT), most recently on July 28, 2017. It would inject \$5 billion into the HHS Public Health Emergency Fund (as described above).

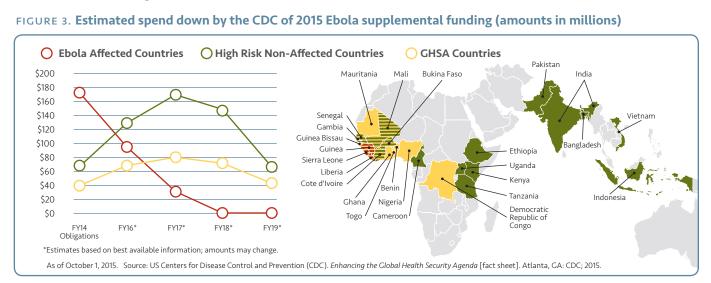
The implications of the FY2019 Ebola supplemental sunset

In FY2019, one of the core challenges facing the US government will be the contingency of many global health security programs built on the \$1 billion dwindling and expiring five-year Ebola supplemental appropriation. The affected US agencies are facing a vast downscaling of resources, and many programs supporting our health security infrastructure will be slashed in FY2020. The influx in funding in 2015 (see Appendix B for FY2015 Ebola appropriations) gave agencies the opportunity to augment their investments in global health security, using remaining resources after the epidemic was controlled to help address some of the systemic challenges to preventing future outbreaks. These investments have already had a tremendous impact, building essential capacities in the world's least developed countries in only a five-year period. However, there is much more to do, and there is a huge opportunity cost to halting the progress that has been achieved. For these programs to continue to have as much progress at a time when risks are only increasing, US government agency core budgets need to reflect the tools, infrastructure, and systems required to ensure longlasting change.

The first example is USAID, which received approximately \$300 million in additional funding between FY2015 and FY2019 to support its programming for global health security. USAID reported that FY2015 Ebola outbreak-control activities accounted for the largest share of additional USAID disbursements, with two-thirds of this funding likely spent in the first two years. As the outbreak waned, the proportion of USAID's spending devoted to general global health security activities increased by 30 percent, as remaining resources were allocated to response, preparedness, and capacity-building from FY2017 to FY2019. ⁶⁶ In conversations with USAID officials (September 2017), PATH learned

that core funding before FY2015 was allocated for the aforementioned efforts, predominantly in Africa. When funding was augmented by the supplemental, the additional money was restricted to being used in Africa, which allowed the agency to shift its other core programming to the Middle East and Asia. This will present a serious dilemma in FY2020, as USAID's overall program funding will be significantly skewed. By FY2019, 80 percent of USAID's supplemental funding will have been spent down or obligated, meaning that most programs in the 17 GHSA Phase 1 countries will either be shut down or core funding will be shifted, meaning programs in the Middle East and Asia will be shut down.

A second example is CDC, which received approximately \$600 million in additional funding from FY2015 to FY2019 to augment its programming for global health security. 67 Two-thirds of this funding was likely spent in the first two years to ensure the Ebola outbreak was controlled, with the remainder being spent from FY2017 to FY2019. The CDC currently holds 51 cooperative agreements in 24 countries to implement GHSA and Ebola preparedness activities that will be halted. 68 In conversations with CDC officials (September 2017), PATH learned that in FY2019, CDC will have to pull back 80 percent of direct hire staff as well as most local staff in up to 35 countries. The number of CDC offices conducting global health security will also decrease to about ten, meaning public health and diplomatic engagement as well as trusted relationships with ministries of health will diminish. This will have tremendous negative impacts on the strides gained; for example, Sierra Leone has built systems for identifying diseases, with 95 percent of counties reporting outbreaks, but this connection could be lost if the CDC is no longer able to continue mentoring public health officials to send, interpret, or share data. By the end of FY2019, 100 percent of its supplemental funding will have been spent down or obligated (see Figure 3).



Without the emergency Ebola investments, current US investments in global health R&D would be the lowest ever since tracking began in 2007.

A third example is the financing gap for R&D. The 2015 G-FINDER shows that excluding emergency investments in Ebola R&D in 2014, public funding has been flat or declining for the past several years. The United States has cut funding for neglected disease R&D in five of the past six years and in FY2015 appropriated \$250 million less than it did in 2012 (see Figure 4). This downward trend was masked by the Ebola supplemental funding. After the supplemental funding is no longer available, the gap between increasing global health risks and decreasing funding for solutions will continue to grow. ⁶⁹

As a result of the inconsistent prioritization of funding distributions, taking full advantage of the individual strengths of agencies and implementing a whole-of-government approach is currently unrealistic. A shift in approach will be required before a comprehensive US framework can be realized. To reinforce and sustain American and global preparedness, sustainable funding should be instituted, prioritizing resources for programs that have the most impact. Both Congress and the Administration must maintain annual appropriations for global infectious disease programs, as well as provide robust support for traditional global health programs. If USAID and CDC are to continue to sustain the impact that was previously supported by the Ebola supplemental, base appropriations must reflect this need. CDC's Division of Global Health Protection should retain the current \$58.2 million annual appropriations, with an increase of \$150 million over the next three years, totaling \$208.2 million, to bridge the gap emerging as a result of the supplement expiration. Similarly, for USAID's Emerging Pandemic Threats program, the agency should retain the \$72.5 million with an increase of \$100 million over three years, totaling \$172.5 million. In addition to capacity-building, funding can also be allocated to help low-income countries develop self-financing

plans, opportunities for engaging with the private sector, and collaboration with development bank assistance.

Sustained funding must also be supplemented by accessible emergency response appropriations when necessary, ideally supported by an emergency reserve fund that can be accessed and distributed in real time to agencies. An appropriate amount to enable an early and rapid response to a severe outbreak will require that USAID and CDC each have access to at least \$70 million. Overall, annual appropriations and emergency funding must take advantage of the unique capabilities that each agency provides, and should not be reallocated from other critical global health and development programs.



Available at http://www.ghtcoalition.org/resources-item/return-on-innovation-why-

global-health-r-d-is-a-smart-investment-for-the-united-states

FIGURE 4. Trends in US government funding for global

health R&D by agency 2007-2015 (amounts in millions)





RECOMMENDATIONS

Pandemics can emerge quickly and rapidly, resulting in catastrophic loss of life, billions and even trillions in economic losses, and global instability which transcends sovereign borders. Too often we fall into the trap of addressing pandemic threats only after they become crises, repeating the cycle of global panic and emergency spending, followed by waning interest as the outbreak subsides, ultimately leading to inaction and complacency. The international efforts that have been launched with strong US leadership and financing in the wake of the Ebola crisis have begun to show results. Experts and leaders around the world have agreed that prioritizing strategic initiatives that sustainably bolster pandemic preparedness and global health security is needed to ensure that recent gains are not lost and that progress is maintained. To truly protect Americans and populations worldwide, the United States should continue to assert its global leadership and expertise to accelerate international progress on pandemic preparedness; build and implement a wholeof-government global health security strategy; invest in

R&D for emerging disease threats; and provide dedicated and sustained funding for these efforts. Commitment to global health security mean will the next local outbreak will be stopped, before the headlines carry the news of another deadly, costly, and unnecessary pandemic.

US GLOBAL HEALTH LEADERSHIP

- Maintain consistent, high-level US political support for the next phase of implementation and expansion of the GHSA, taking concerted action in line with public declarations that strengthens global prevention, detection, and rapid response to emerging health threats abroad is a priority for the US government.
- Leverage available diplomatic and multilateral financing channels to motivate partner countries, specifically at-risk countries, to achieve and sustain compliance with the IHRs; using the US voice and vote at the United Nations, WHO, World Bank Group, and other relevant international health, development, and security platforms.

AN INTERNATIONAL ACTION PLAN

- Develop and implement a US plan for international action in accordance with the structure set forth in the standing Executive Order Advancing the Global Health Security Agenda to Achieve a World Safe and Secure from Infectious Disease Threats. This action plan should prioritize and articulate the US government's role in advancing preparedness in low- and middle-income countries and catalyze R&D for disease threats, supported with clear and measurable indicators for progress.
- Designate senior-level oversight to achieve full implementation of the guidance outlined in the Executive Order and action plan, including ensuring coordinated support to US Chiefs of Mission and country teams to facilitate country preparedness for biological threats, and monitoring and evaluating progress toward global health security targets.
- Prioritize global health security—especially the role
 of building low- and middle-income country capacity
 to contain pandemic threats—in all relevant future
 global and national health, R&D, and biodefense
 strategies, including the National Health Security
 Strategy, the National Security Strategy, and the
 National Biodefense Strategy.
- Map the potential contributions of the nongovernmental sector to global health security and identify opportunities to catalyze multisectoral partnerships among the US government, private, and social sectors that will harness new allies, innovations, and investments to bolster pandemic preparedness.

RESEARCH AND DEVELOPMENT

- Develop a new generation and robust pipeline of medical countermeasures—including appropriate drugs and technologies that are reflective of robust surveillance data—for infectious and emerging diseases with pandemic potential, allowing the US to quickly prevent an outbreak from becoming a pandemic.
- Enable the development and deployment of incentives
 to proactively and sustainably engage the private
 sector in medical product development for infectious
 and emerging diseases with pandemic potential to
 capitalize on the resources, expertise, and other skills
 of industry. This includes expanding governmentdriven incentive mechanisms like the BARDA to
 financially support R&D for an expanded set of
 infectious and emerging diseases to bring industry
 partners to the table.

 Contribute US scientific and financial leadership to multilateral efforts to accelerate R&D on emerging pandemic threats, including through CEPI, the G20's R&D Collaboration Hub for antimicrobial clinical research and product development, and regional regulatory harmonization initiatives in endemic disease regions.

DEDICATED, SUSTAINED US GOVERNMENT FINANCING

- Ensure a whole-of-government approach to global health security financing including dedicated and sustained funding for CDC, USAID, DOD, and DOS programming and personnel.
- Starting in FY2019, increase the annual base funding
 for global health security-related activities at CDC and
 USAID to ensure these agencies can continue their
 programming after the Ebola supplemental funding
 expires. To bridge the gap between the supplemental
 and core appropriations, USAID's Emerging Pandemic
 Threats budget should increase from \$72.5 million to
 \$172.5 million, and CDC's Division of Global Health
 Protection budget should increase from \$58.2 million
 to \$208.2 million.
- Ensure agencies have access to an emergency reserve fund to initiate an early and rapid response to emerging pandemic threats, allowing USAID and CDC to each retain up to \$70 million if and when needed. The reserve fund should be replenished once it is used to ensure funds are available for the next outbreak, and should not be interchangeable with annual appropriations or previously allocated emergency funding, nor borrowed from other global health or development programs, which would derail progress inother critical areas.
- Maintain US support for global health programs that build core public health capabilities and bolster frontline preparedness—including PEPFAR, PMI, GPEI, and Child and Maternal Survival programs.
- Provide sustained and predictable investment across the US government in R&D for diseases with pandemic potential, to advance both the foundational knowledge of pathogens and the development of medical countermeasures.

APPENDIX A. Agency-specific appropriations for FY2018 funding line items

Department/ Agency	Program	FY2017 Continuing Resolution	FY2017 enacted	OMB's FY2018 proposal	Changes from FY2017 enacted levels	Notes
Centers for Disease	Control and Prevent	ion				
Centers for Global Health	Division of Global Health Protection		\$58.2 million ⁷⁰	\$50 million ⁷¹	14% decrease	This funding includes two programs: Global Disease Detection & Emergency Response, which tracks outbreaks, and Global Public Health Capacity Development, which builds a cadre of trained health workers to respond to outbreaks.
IIS Agency for Inter	national Developme	nt				
Bureau of Global Health	Emerging Pandemic Threats (formerly Pandemic Influenza and Other Emerging Threats)		\$142.5 million ⁷²	\$72.5 million ⁷³	Remains flat	In the FY2017 Omnibus, Congress provided \$72.5 for USAID's core programs, and \$70 million for an Emergency Reserve Fund, for a total of \$142.5 million. In FY2018, the Administration proposed maintaining funding for USAID's health security programs at \$72.5 million by repurposing unobligated Ebola funding from the 2015 supplemental, which will expire in FY2019. It did not factor in the FY2017 Omnibus, and therefore does not include the \$70 million for the Reserve Fund.
Department of Stat	te					
Nonproliferation, Anti-Terrorism, Demining and Related Programs	Global Threat Reduction Program		\$35 million ^{74,75}	\$32.5 million ^{76,77}	7% decrease	This funding amount reflects only half of GTR's total appropriation, the estimated amount that is internally allocated for global health security capacity building activities each year.
Department of Def	ence					
Defense Threat Reduction Agency	Cooperative Threat Reduction Program's Cooperative Biological Engagement Program		\$214 million ⁷⁸	\$172.8 million ^{79,80}	19% decrease	

APPENDIX B. Ebola supplemental funding allocated to agencies in FY2015 (in millions)⁸¹

Agency / Department / Account	Total Funding (in millions)		
INTERNATIONAL RESPONSE			
Department of State	\$41.7		
Diplomatic & Consular Programs	\$36.4		
International Security Assistance	\$5.3		
US Agency for International Development	\$2,484.7		
Operating expenses	\$19.0		
Office of Inspector General	\$5.6		
Global Health Programs account	\$312.0		
International Disaster Assistance account	\$1,436.3		
Economic Support Fund account	\$711.7		
Centers for Disease Control and Prevention	\$1,200.0		
International response activities	\$603		
Global health security	\$597		
Department of Defense	\$17.0		
Equipment procurement	\$17.0		
TOTAL INTERNATIONAL RESPONSE	\$3,743.4		
RESEARCH AND DEVELOPMENT			
Health and Human Services	\$420.0		
National Institutes of Health	\$238.0		
Biomedical Advanced Research and Development Authority	\$157.0		
Food & Drug Administration	\$25.0		
Department of Defense	\$95.0		
Defense Advanced Research Projects Agency	\$45.0		
Chemical and Biological Defense Program	\$50.0		
TOTAL RESEARCH AND DEVELOPMENT	\$515.0		
DOMESTIC RESPONSE	44470		
Health and Human Services	\$1,147.0		
Centers for Disease Control & Prevention	\$571.0		
Assistant Secretary for Preparedness and Response	\$576.0		
TOTAL DOMESTIC RESPONSE	\$1,147.0		
TOTAL EBOLA FUNDING	\$5,405.4		
	1-1		

Definitions of key terms

Biological risk – encompassing frame for disease risks that includes naturally occurring disease outbreaks at national and international levels, accidental exposure to pathogens in the context of biomedical diagnostics and research, or intentional use of pathogens for harmful purposes.

Epidemic – a widespread occurrence of an infectious disease in a community at a particular time.

Global health security – the capacity to prevent, detect, and respond to public health threats and reduce or prevent their spread across borders. This is accomplished through strong health systems with the resources and personnel required to identify solutions against the spread of infectious diseases.

Infectious diseases – diseases that are caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi; this type of disease can be spread, directly or indirectly, from one person to another.

Medical countermeasures – lifesaving medicines and medical supplies that can be used to diagnose, prevent, protect from, or treat conditions.

Outbreak – occurrence of disease cases in excess of what would be normally expected in a defined community, geographic area, or season.

One Health – an approach to improving health outcomes that recognizes that the health of people is connected to the health of animals and the environment. The goal of One Health is to encourage the collaborative efforts of multiple disciplines—working locally, nationally, and globally—to achieve the best health for people, animals, and the environment.

Pandemic – an epidemic that has spread over several countries or continents, usually affecting a large number of people.

Prevent, detect, and respond – preventing and reducing the likelihood of outbreaks, whether natural, accidental, or intentional; detecting threats early to save lives; and responding rapidly and effectively using multisectoral, international coordination and communication.

Zoonotic diseases – a disease spread between animals and people. Zoonotic diseases can be caused by viruses, bacteria, parasites, and fungi.

Definitions of key acronyms

AMR - Antimicrobial Resistance

BARDA - Biomedial Advanced Research and Development Authority

CARB - Combating Antibiotic Resistant Bacteria

CDC - Centers for Disease Control and Prevention

CEPI - Coalition for Epidemic Preparedness Innovations

DOD - Department of Defense

DOS - Department of State

FDA - Food and Drug Administration

FETP - Field Epidemiology Training Program

GHSA - Global Health Security Agenda

GPEI - Global Polio Eradication Initiative

HHS - Health and Human Services

IHR - International Health Regulations

JEE - Joint External Evaluation

NIH - National Institutes of Health

PEPFAR - US President's Emergency Plan for AIDS Relief

PMI - President's Malaria Initiative

PSRT - Private Sector Roundtable

USAID - US Agency for International Development

WHO - World Health Organization



PATH/Georgina Goo

REFERENCES

- 1 Taubenberger JK, Morens DM. 1918 influenza: the mother of all pandemics. *Emerging Infectious Diseases*. 2006;12(1):15–22. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3291398.
- 2 Crosby A. America's Forgotten Pandemic. Cambridge, England: Cambridge University Press; 1989.
- 3 Murray CJL, Lopez AD, Chin B, Feehan D, Hill KH. Estimation of potential global pandemic influenza mortality on the basis of vital registry data from the 1918–20 pandemic: a quantitative analysis. *The Lancet*. 2006;368(9554):2211–2218. Available at http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(06) 69895-4/abstract.
- 4 World Health Organization. State of Health Security. Report to the United Nations General Assembly. A/71/598. New York: United Nations; 2016. Available at http://www.un.org/ga/search/view_doc.asp?symbol=A/71/598.
- 5 Smith KF, Goldberg M, Rosenthal S, et al. Global rise in human infectious disease outbreaks. *Journal of the Royal Society Interface*. 2014;11(101). DOI: 10.1098/rsif.2014.0950. Available at http://rsif.royalsocietypublishing.org/content/11/101/20140950.
- 6 2014 Ebola outbreak in West Africa outbreak distribution map page. US Centers for Disease Control and Prevention website. Available at https://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html.
- 7 Petersen, E., et al. Rapid spread of zika virus in the Americas—implications for public health preparedness for mass gatherings at the 2016 Brazil Olympic games. International Journal of Infectious Diseases. 2016; 44:11-15.
- 8 Cholera fact sheet page. World Health Organization website. Available at http://www.who.int/mediacentre/factsheets/fs107/en/.
- 9 US Government Accountability Office (GAO). Defense Civil Support: DOD, HHS, and DHS Should Use Existing Coordination Mechanisms to Improve Their Pandemic Preparedness. Washington, DC: GAO; 2017. Available at http://www.gao.gov/assets/690/682707.pdf.
- 10 Center for Strategic and International Studies (CSIS). Global Health as a Bridge to Security: Interviews with U.S. Leaders. Downie R, ed. Washington, DC: CSIS; 2012. Available at https://csis-prod.s3.amazonaws.com/s3fs-public/legacy_files/files/publication/120920_Downie_GlobalHealthSecurity_Web.pdf.
- 11 US Government Accountability Office (GAO). Defense Civil Support: DOD, HHS, and DHS Should Use Existing Coordination Mechanisms to Improve Their Pandemic Preparedness. Washington, DC: GAO; 2017. Available at http://www.gao.gov/assets/690/682707.pdf.
- 12 International Working Group on Financing Preparedness (IWG). From Panic and Neglect to Investing in Health Security: Financing Pandemic Preparedness at a National Level. Washington, DC: World Bank/IWG; 2017. Available at http://documents.worldbank.org/curated/en/979591495652724770/pdf/115271-REVISED-PUBLIC-IWG-Report-Conference-Edition-8-10-2017-low-res.pdf.
- 13 Ibid
- 14 National Academy of Medicine. *The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Crises*. Washington, DC: The National Academies Press; 2016. Available at https://doi.org/10.17226/21891.
- 15 Kates J, Michaud J, Wexler A, Valentine A. The U.S. Response to Ebola: Status of the FY2015 Emergency Ebola Appropriation [issue brief]. Menlo Park, CA: Kaiser Family Foundation; 2015. Available at http://www.kff.org/global-health-policy/issue-brief/the-u-s-response-to-ebola-status-of-the-fy2015-emergency-ebola-appropriation/.
- 16 Sun LH. Cost to treat Ebola in the U.S.: \$1.16 million for 2 patients. Washington Post. November 18, 2014. Available at https://www.washingtonpost.com/news/post-nation/wp/2014/11/18/cost-to-treat-ebola-in-the-u-s-1-16-million-for-2-patients/?tid=a_inl&utm_term=.426fc39ea5bf.
- 17 Wexler A, Oum S, Kates J. The Status of Funding for Zika: The President's Request, Congressional Proposals, & Final Funding [issue brief]. Menlo Park, CA: Kaiser Family Foundation; 2016. Available at https://www.kff.org/global-health-policy/issue-brief/the-status-of-funding-for-zika-the-presidents-request-congressional-proposals-final-funding/.
- 18 Lee BY, Alfaro-Murillo JA, Parpia AS, et al. The potential economic burden of Zika in the continental United States. PLOS Neglected Tropical Diseases. 2017;11(4):e0005531. Available at http://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0005531.
- 19 Office of the Under Secretary of Defense (Comptroller) Chief Financial Officer. Defense Budget Overview: United States Department of Defense Fiscal Year 2018 Budget Request. Arlington, VA: Department of Defense; 2017. Available at http://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2018/fy2018_Budget_Request_ Overview Book.pdf.
- 20 National Academy of Medicine. *The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Crises*. Washington, DC: The National Academies Press; 2016. Available at https://doi.org/10.17226/21891.
- 21 Ibid
- 22 Bossert, T. No room for error: Advising the president on homeland security and counterterrorism. Presented at: The Aspen Security Forum, July 20, 2017; Colorado, USA. Available at: http://aspensecurityforum.org/wp-content/uploads/2017/07/No-Room-for-Error_Advising-the-President-on-Homeland-Security-and-Counterterrorism.
- 23 National Academies of Sciences, Engineering, and Medicine. *Global Health and the Future Role of the United States*. Washington, DC: The National Academies Press; 2017. Available at http://nationalacademies.org/hmd/reports/2017/global-health-and-the-future-role-of-the-united-states.aspx.
- 24 International Health Regulations page. World Health Organization website. Available at http://www.who.int/topics/international_health_regulations/en
- 25 Armstrong KE, McNabb SJN, Ferland LD, et al. Capacity of public health surveillance to comply with revised International Health Regulations, USA. *Emerging Infectious Diseases*. 2010;16(5);804–808. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2953987//
- 26 Global Health Security Agenda website. Available at https://www.ghsagenda.org/about.
- 27 Global Health Security Agenda (GHSA) Advancing the Global Health Security Agenda: Progress and Early Impact from US Investment. GHSA; 2016. https://www.ghsagenda.org/docs/default-source/default-document-library/ghsa-legacy-report.pdf.
- 28 Ibid.
- 29 Ibid.
- 30 Global Health Security Agenda (GHSA). *Private Sector Roundtable: Mobilizing Industry for Action.* GHSA; 2017. Available at http://rabinmartin.com/wp-content/uploads/2017/07/PSRT-Program-Update.pdf.
- 31 Tennenberg, A and Barash, D. The Private Sector Role in Sustainable Change for Global Health Security [blog post]. JEE Alliance. Available at https://www.jeealliance.org/blogposts/the-private-sector-role-in-sustainable-change-for-global-health-security.
- 32 Centers for Disease Control and Prevention. International influenza report FY2014 & 2015. Atlanta: U.S. Department of Health and Human Services; 2015. Available at: https://www.cdc.gov/flu/pdf/international/program/2014-15/2014-2015-intl-program-report_061416.pdf.
- 33 Enhanced Ebola detection and response in Guinea and Liberia page. Centers for Disease and Control and Prevention website. Available at https://www.cdc.gov/globalhealth/healthprotection/fieldupdates/winter-2016/two-ebola-outbreaks.html.
- 34 CDC's Contribution to the Global Health Security Agenda [fact sheet]. Atlanta, GA: Centers for Disease Control and Prevention; 2017. Available at https://www.cdc.gov/globalhealth/healthprotection/resources/pdf/CDC-contribution-GHSA-infographic.pdf.

- 35 Global Virome Project. The Beginning of the End of the Pandemic Era. 2017. Available at http://sph.hku.hk/images/news/events2017/2017-09-07 SPH-presentation.pdf.
- 36 Global Health Security Agenda (GHSA). Advancing the Global Health Security Agenda: Progress and Early Impact from U.S. Investment. GHSA; 2016. Available at https://www.ghsagenda.org/docs/default-source/default-document-library/ghsa-legacy-report.pdf.
- 37 Human Trials Begin for Army-Developed Zika Vaccine. Department of Defense website. Available at https://www.defense.gov/News/Article/Article/999584/human-trials-begin-for-army-developed-zika-vaccine/
- 38 Global Health Technologies Coalition (GHTC), Policy Cures Research. Return on Innovation: Why Global Health R&D Is a Smart Investment for the United States. Washington, DC: GHTC; 2017. Available at http://www.ghtcoalition.org/pdf/Return-on-innovation-Why-global-health-R-D-is-a-smart-investment-for-the-United-States.pdf.
- 39 National Institute of Allergies and Infectious Diseases (NIAID). Ebola vaccine trial opens in Liberia [press release]. February 2, 2015. Available at https://www.niaid.nih.gov/news-events/ebola-vaccine-trial-opens-liberia.
- 40 The White House. National Strategy for Combating Antibiotic-Resistant Bacteria. Washington, DC; 2014. Available at https://www.cdc.gov/drugresistance/pdf/carb_national_strategy.pdf
- 41 Global Health Security Agenda (GHSA). Advancing the Global Health Security Agenda: Progress and Early Impact from U.S. Investment. GHSA; 2016. Available at https://www.ghsagenda.org/docs/default-source/default-document-library/ghsa-legacy-report.pdf
- 42 Frieden T. Uganda makes impressive progress on health [blog post]. Our Global Voices. August 19, 2013. Available at https://blogs.cdc.gov/global/2013/08/19/uganda-makes-impressive-progress-on-health.
- 43 Successful Ebola responses in Nigeria, Senegal and Mali page. World Health Organization website. Available at http://www.who.int/csr/disease/ebola/one-year-report/nigeria/en/.
- 44 Joint West Africa Research Group to foster biopreparedness page. Walter Reed Program-Nigeria website. Available at http://www.wrp-n.org/joint-west-africa-research-group-foster-biopreparedness/.
- 45 Streifel C. How Did Ebola Impact Maternal and Child Health in Liberia and Sierra Leone? Washington, DC: Center for Strategic & International Studies; 2015. Available at https://csis-prod.s3.amazonaws.com/s3fs-public/legacy_files/files/publication/151019_Streifel_EbolaLiberiaSierraLeone_Web.pdf.
- 46 U.S. President's Malaria Initiative (PMI). U.S. President's Malaria Initiative (PMI) Approach to Health Systems Strengthening. Washington, DC: PMI; 2013. Available at https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/pmi-and-health-systems-strengthening, final.pdf?sfvrsn=4.
- 47 Executive Order-Advancing the Global Health Security Agenda to Achieve a World Safe and Secure from Infectious Disease Threats. November 4, 2016. Available at https://obamawhitehouse.archives.gov/the-press-office/2016/11/04/executive-order-advancing-global-health-security-agenda-achieve-world.
- 48 G-FINDER, Policy Cures. Neglected Disease Research and Development: The Ebola Effect. Sydney NSW, Australia: Policy Cures; 2016. Available at http://www.policycuresresearch.org/downloads/Y9%20GFINDER%20full%20report%20web.pdf
- 49 Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations, 2014. Available at https://amr-review.org.
- 50 G-FINDER, Policy Cures. Neglected Disease Research and Development: The Ebola Effect. Sydney NSW, Australia: Policy Cures; 2016. Available at http://www.policycuresresearch.org/downloads/Y9%20GFINDER%20full%20report%20web.pdf. /
- 51 Global Health Technologies Coalition (GHTC). Return on Innovation: Why Global Health R&D Is a Smart Investment for the United States. Washington, DC: GHTC; 2017. Available at http://www.ghtcoalition.org/resources-item/return-on-innovation-why-global-health-r-d-is-a-smart-investment-for-the-united-states.
- 52 Protecting Humanity from Future Health Crises: Report of the High-Level Panel on the Global Response to Health Crises [advance unedited copy]. New York: United Nations; 2016.
- 53 World Economic Forum and Boston Consulting Group. Managing the Risk and Impact of Future Epidemics: Options for Public-Private Cooperation. Geneva: World Economic Forum;" June 2015. Accessed December 5, 2016. Available at https://www.weforum.org/reports/managing-risk-and-impact-future-epidemics-options-public-private-cooperation.
- 54 Global Health Technologies Coalition (GHTC). Return on Innovation: Why Global Health R&D Is a Smart Investment for the United States. Washington, DC: GHTC; 2017. Available at http://www.ghtcoalition.org/resources-item/return-on-innovation-why-global-health-r-d-is-a-smart-investment-for-the-united-states. USAID, HHS. Quarterly Progress Report on Ebola Response. Available at https://oig.usaid.gov/sites/default/files/other-reports/oig_ebola_quaterly_06302016.pdf.
- 55 United States Agency for International Development (USAID), Department of Health and Human Services (HHS). Quarterly Progress Report on U.S. Government International Ebola Response and Preparedness Activities. Washington, DC: USAID/HHS; 2015. Available at https://oig.usaid.gov/sites/default/files/other-reports/oig_ebola_quarterly_fy16_021720126.pdf.
- 56 Global Research Collaboration for Infectious Disease Preparedness. *Zika Vaccine Working Group Overview*. November 2016. Available at https://www.glopid-r.org/wp-content/uploads/2016/12/zika_working_group_vaccines_overview_november_2016.pdf.
- 57 Sanofi statement on Zika vaccine license [press statement]. Bridgewater, NJ: Sanofi; September 1, 2017. Available at http://www.news.sanofi.us/Sanofi-Statement-on-Zika-Vaccine-License.
- 58 Kelland K. Global coalition aims to outpace epidemics with new vaccines. Reuters Health News. January 18, 2017. Available at http://www.reuters.com/article/us-davos-meeting-vaccines/global-coalition-aims-to-outpace-epidemics-with-new-vaccines-idUSKBN15231Y.
- 59 G20 Leaders' Declaration: Shaping an Interconnected World. Hamburg, Germany; July 7–8 2017. Available at https://www.g20.org/Content/EN/_Anlagen/G20/G20-leaders-declaration.pdf? blob=publicationFile&v=11.
- 60 Reichman LB. The U-shaped curve of concern. American Review of Respiratory Disease. 1991;144(4);741–742. Available at http://www.atsjournals.org/doi/pdf/10.1164/ajrccm/144.4.741.
- 61 Summary of FY2017 Omnibus Appropriations Act. Washington, DC: US House of Representatives Committee on Appropriations Democrats; May 1, 2017. Available at http://democrats.appropriations.house.gov/news/press-releases/summary-of-fy2017-omnibus-appropriations-act.
- 62 Consolidated and Further Continuing Appropriations Act, 2015, Public Law No. 113-235, Title VI, 113th Congress.
- 63 State, Foreign Operations and Related Programs Appropriations Bill, 2017 Omnibus Agreement Summary. Available at https://www.appropriations.senate.gov/imo/media/doc/FY17%20State%20Foreign%20Operations%20Conference%20Agreement%20Summary%20-%20Final.pdf.
- 64 Watson C, Watson M, Kirk Sell T. Federal funding for health security in FY2018. Health Security. 2017;15(4):351–372. Available at http://online.liebertpub.com/doi/abs/10.1089/hs.2017.0047?journalCode=hs
- 65 Wexler A, Oum S, Kates J. The Status of Funding for Zika: The President's Request, Congressional Proposals, & Final Funding [issue brief]. Menlo Park, CA: Kaiser Family Foundation; 2016. Available at http://www.kff.org/global-health-policy/issue-brief/the-status-of-funding-for-zika-the-presidents-request-congressional-proposals-final-funding/
- 66 United States Agency for International Development (USAID), Department of Health and Human Services (HHS). Quarterly Progress Report on U.S. Government International Ebola Response and Preparedness Activities. Washington, DC: USAID/HHS; 2015. Available at https://oig.usaid.gov/sites/default/files/other-reports/ oig_ebola_quarterly_fy16_021720126.pdf.

- 67 US Centers for Disease Control and Prevention (CDC). FY 2015–2019 Emergency Funding [fact sheet]. Atlanta, GA: CDC; 2015. Available at https://www.cdc.gov/budget/documents/ebola/fv-2015-2019-ebola-fact-sheet-overview.pdf.
- 68 US Centers for Disease Control and Prevention (CDC). Enhancing the Global Health Security Agenda [fact sheet]. Atlanta, GA: CDC; 2015. Available at https://www.cdc.gov/budget/documents/ebola/cdc-enhancing-the-global-health-security-agenda.pdf.
- 69 Global Health Technologies Coalition (GHTC). Return on Innovation: Why Global Health R&D Is a Smart Investment for the United States. Washington, DC: GHTC; 2017. Available at http://www.ghtcoalition.org/resources-item/return-on-innovation-why-global-health-r-d-is-a-smart-investment-for-the-united-states.
- 70 US FY2017 Omnibus. Division H—Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2017, p 23. Available at https://rules.house.gov/sites/republicans.rules.house.gov/files/115/OMNI/DIVISION%20H-%20LABORHHS%20SOM%20OCR%20FY17.pdf.
- 71 US Department of Health and Human Services, Centers for Disease Control and Prevention (CDC). Fiscal Year 2018 CDC Justification of Estimates for Appropriation Committees, p 173. Available at https://www.cdc.gov/budget/documents/fy2018/fy-2018-cdc-congressional-justification.pdf.
- 72 US FY2017 Omnibus. Division J—Department of State, Foreign Operations, and Related Programs Appropriations Act, 2017, p 17. Available at https://rules.house.gov/sites/republicans.rules.house.gov/files/115/OMNI/DIVISION%20J%20-%20STATEFOPs%20SOM%20OCR%20FY17.pdf.
- 73 US Department of State. Fiscal Year 2018 Congressional Budget Justification, United States Agency for International Development, p 255. Available at https://www.state.gov/documents/organization/271013.pdf.
- 74 US Department of Defense, Defense Health Program. Fiscal Year 2018 Budget Estimates. May 2017, p 245. Available at http://comptroller.defense.gov/Portals/45/Documents/defbudget/FY2018/budget justification/pdfs/09_Defense_Health_Program/DHP_PB18_Vol_I-II.pdf.
- 75 US FY2017 Omnibus. Division J—Department of State, Foreign Operations, and Related Programs Appropriations Act, 2017, p 24. Available at https://rules.house.gov/sites/republicans.rules.house.gov/files/115/OMNI/DIVISION%20J%20-%20STATEFOPs%20SOM%20OCR%20FY17.pdf.
- 76 US Department of Defense, Defense Health Program. Fiscal Year 2018 Budget Estimates. May 2017, p 245. Available at http://comptroller.defense.gov/Portals/45/Documents/defbudget/FY2018/budget justification/pdfs/09 Defense Health Program/DHP PB18 Vol I-II.pdf.
- 77 US Department of State. Fiscal Year 2018 Congressional Budget Justification, United States Agency for International Development, p 347. Available at https://www.state.gov/documents/organization/271013.pdf.
- 78 FY2017 Omnibus. Division C—Department of Defense Appropriations Act, 2017, p 71A40. Available at https://rules.house.gov/sites/republicans.rules.house.gov/files/115/OMNI/DIVISION%20C%20-%20DEFENSE%20SOM%20%20OCR%20FY17.pdf.
- 79 US Department of Defense. Fiscal Year 2018 Budget Estimates. Defense Advanced Research Projects Agency. May 2017, p 71. Available at https://www.darpa.mil/attachments/DARPA_FY18_Presidents_Budget_Request.pdf.
- 80 US Department of Defense. Fiscal Year 2018 President's Budget: Operations and Maintenance. June 2017, p 51. Available at http://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2018/fy2018 OM Overview.pdf.
- 81 Kates J, Michaud J, Wexler A, Valentine A. The U.S. Response to Ebola: Status of the FY2015 Emergency Ebola Appropriation [issue brief]. Menlo Park, CA: Kaiser Family Foundation; 2015. Available at http://www.kff.org/global-health-policy/issue-brief/the-u-s-response-to-ebola-status-of-the-fy2015-emergency-ebola-appropriation/.



WHAT PATH IS DOING TO ADDRESS GLOBAL HEALTH SECURITY CHALLENGES

PATH brings extensive expertise and capacity to the challenge of global health security. PATH draws on 40 years of experience working in more than 70 countries, in-depth understanding of the needs of vulnerable populations in low-resource settings, and proven approaches to address gaps left by weak markets. We work to close these gaps by assembling and managing effective multisectoral collaborations that align partners' needs and best leverage their expertise and contributions. Our work advances global health security by applying core capabilities in:

- Improving global, national, and local capacity to prevent, detect, and respond to public health emergencies, while strengthening health systems in low- and middle-income countries.
- Integrating upstream (product development) and downstream (health systems) advancements in vaccines, diagnostics, digital health and information systems, and health systems strengthening (including surveillance and laboratory capacity).
- Creating enabling environments through advocacy and public policy work, supporting healthy and equitable markets, and fostering monitoring, evaluation, and learning.

PATH partners with several US government agencies to advance global health security. In collaboration with HHS, PATH protects and improves health in developing countries—including joint efforts with the CDC, the National NIH, and BARDA. With HHS, PATH works to develop and deploy new strategies and technologies to prevent, detect, and control epidemic and emerging diseases. For example:

- PATH joined with the CDC to strengthen public health systems in the Democratic Republic of the Congo, India, Senegal, Tanzania, and Vietnam, furthering progress on the Global Health Security Agenda. In these countries, PATH supports national governments and partners to expand infectious disease surveillance, strengthen laboratory capacity, and develop effective information systems.
- During the 2017 Ebola outbreak in the DRC, PATH worked with the Ministry of Health to establish rapidresponse data-sharing procedures and deploy teams to investigate the outbreak. PATH engaged partners including the NIH, University of California at Los Angeles, DigitalGlobe, Vodacom, Mountain Safety Research, and WeRobotics—to map, survey, communicate, and advise on technical support, aiding government efforts to curtail the outbreak.
- Through a cooperative agreement with BARDA, in coordination with WHO, PATH is working with emerging-market vaccine manufacturers in countries such as Vietnam, Serbia, Brazil, India, and China to improve access to influenza vaccines in low- and middle-income countries. This work has supported manufacturers in readying vaccine-production facilities and advancing pandemic and seasonal vaccine candidates in preclinical and clinical studies.

PATH also collaborates with the DOD to adapt, test, and expand access to technologies, vaccines, drugs, and diagnostics. For example, following the agreement between PATH and GlaxoSmithKline in 2001 to develop RTS,S (also known as Mosquirix™ malaria vaccine) for use in young children, the Kenya Medical Research Institute/ Walter Reed in Kenya became one of the eleven Phase 3 trial sites.

Through its partnership with the USAID and the DOS, PATH helps drive the development of cost-effective global health technologies that deliver measurable results, strengthen health systems, and encourage healthy behaviors. For example, through PMI and PEPFAR, PATH provides comprehensive technical assistance, implementation support, and leadership to help low- and middle-income countries build capacity and scale up programs that provide diagnosis and treatment for HIV, malaria and other infectious diseases.





www.path.org

PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at www.path.org.

455 Massachusetts Ave NW, Suite 1000 Washington, DC 20001