



Written Testimony
Senate Foreign Relations Committee
Subcommittee on Africa and Global Health
Policy

July 24th, 2019

Statement of
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For Release on Delivery

Expected at 2:30pm

On Wednesday, July 24, 2019

INTRODUCTION

Good morning Chairman Graham, Ranking Member Kaine, and members of the Subcommittee. I am Dr. Mitch Wolfe, Chief Medical Officer of the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to testify before you on the Ebola outbreak in the Democratic Republic of the Congo (DRC), and thank you for your continued commitment to supporting CDC's work in global health security.

This is the 10th and largest outbreak in DRC, and the second largest outbreak of Ebola ever recorded since the virus was discovered in 1976 in DRC. On July 17, 2019, the World Health Organization declared the outbreak a Public Health Emergency of International Concern (PHEIC). CDC has worked since last summer, in collaboration with interagency and international partners, to end this outbreak and ensure the health and security of our country. On June 13, CDC announced the activation of its Emergency Operations Center to support the response to the ongoing Ebola outbreak in Eastern DRC, which allows CDC to provide increased operational support to meet the outbreak's evolving challenges, and provides strengthened functional continuity to meet the long term commitment needed to end the outbreak. We have comprehensive Ebola response capabilities developed over 40 years at the forefront of Ebola virus research and further refined by direct engagement in more than 20 Ebola outbreak responses globally. In the wake of the worst Ebola outbreak in history, the 2014-2016 outbreak in West Africa that claimed over 11,000 lives, CDC has made significant advancements in Ebola science, surveillance, and response. For example, we confirmed that live Ebola virus can persist in specific body fluids, such as in seminal fluids, for over a year following infection. We have also trained epidemiologists and laboratory scientists, and provided testing materials for African countries at greatest risk of an Ebola outbreak. In addition, in June 2015, we established CDC's Global Rapid Response Team, a cadre of over 500 highly-trained CDC responders ready to deploy on short notice anywhere in the world to respond to global health threats and emergencies.

As of July 17, CDC expert disease detectives and other staff had completed 313 deployments to the DRC, neighboring countries, and the World Health Organization (WHO) headquarters in Geneva to provide leadership and expertise in surveillance, laboratory testing, data analytics, vaccine implementation, emergency management, infection prevention and control, behavioral sciences, health communications, and border health. In addition, we support coordination of activities among response leaders including the DRC Ministry of Health and WHO. Our operational expertise allows us to quickly and efficiently identify the unique scientific and social variables of outbreaks and address them with proven interventions.

However, the unique challenges of this Ebola outbreak mean this fight is even more difficult than past responses. The complex security challenges in North Kivu and Ituri provinces have severely limited CDC's direct participation at the outbreak's epicenter, which is located far from the capital city of Kinshasa in an area threatened by armed conflict, crime, and civil unrest, as well as heavy cross-border movement into neighboring countries. Violence in the impacted communities has hampered Ebola disease surveillance, contact tracing, and vaccination efforts. The affected population has low levels of trust in the government and the international community. The DRC is also experiencing other serious infectious disease outbreaks, such as cholera, measles, and malaria, further stressing its health system. Additionally, disease control in the impacted area is challenging because of weak healthcare and public health infrastructure.

STATUS OF THE EPIDEMIC

On August 1, 2018, the DRC Ministry of Health and Population reported an outbreak of Ebola virus disease (EVD) in North Kivu Province. As of July 21, the number of cases reported was 2,592, with 1,737 deaths (a 67 percent fatality rate). Due to challenges in case detection and reporting posed by the security situation, CDC suspects that the true number of cases could be much larger. As of July 21, cases have been reported in 25 health zones of North Kivu and Ituri provinces. On June 11, the Ugandan Ministry of Health reported its first confirmed case of Ebola; two additional cases, from the same family who crossed into Uganda from DRC, were then confirmed on

June 12. There are currently no additional confirmed cases in Uganda, and contacts of these cases were closely monitored for 21 days (the incubation period for Ebola). More than 3,000 people were vaccinated in Uganda to help prevent disease spread from the cases in Kasese District, as well as over 4,000 frontline healthcare workers vaccinated across the country. To date, no cases of Ebola have been confirmed in any other provinces in the DRC or in the other neighboring countries. The current outbreak is, however, already the second-worst Ebola outbreak ever recorded, with case counts continuing to increase and key response indicators showing little improvement.

Past outbreaks of Ebola in the DRC typically occurred in sparsely-populated, rural areas. The current outbreak—like the 2014-2016 outbreak in West Africa—includes densely-populated urban areas, increasing the likelihood of human-to-human spread. The outbreak initially affected the Mandima health zone and then spread to the town of Beni, which has a municipal population of 340,000 and a greater area population of about one million. More recently the outbreak has been heavily affecting the adjacent North Kivu health zones of Katwa and Butembo, which together also encompass an urban area with a population of approximately one million. The highly mobile population in this area of DRC poses challenges for Ebola responders' contact tracing efforts. Affected health zones have experienced reintroduction of Ebola cases to areas where disease transmission was previously halted or slowed. The number of affected health zones is also increasing; on June 30 an Ebola case was identified in a previously unaffected health zone of Ituri Province, close to the South Sudan border. On July 14, an Ebola case was confirmed for the first time in the city of Goma, which has a population of approximately two million people and is on the border with Rwanda. CDC staff already embedded in the Goma Emergency Operations Center provided direct support to the case investigation, including interviewing contacts to establish their level of risk, performing an assessment at the health care facility visited by the patient, and strengthening the screening process at the Goma airport. In each instance, CDC experts were able to quickly identify and correct weaknesses in the response, reducing the risk of onward disease transmission.

Escalating violence in some areas has generated significant population displacement within DRC as well as across borders. Ongoing insecurity limits the effectiveness of public health interventions such as case investigation, contact tracing, and vaccination efforts. Many of the new cases that are reported each day are identified in later stages of illness, meaning that they spent much of their infectious period outside of isolation and potentially infected others. Moreover, from June 27 to July 17, among the 245 new cases with contact-related information, 61 percent were either unknown contacts (not known as contacts of previous Ebola patients) or known contacts but not being followed by responders at the time of symptom onset. This means that contact tracers may be missing chains of transmission and Ebola cases may not be identified by responders early enough to prevent further transmission.

STATUS OF RESPONSE EFFORTS

The Government of the DRC is leading the response, with strong assistance from WHO. CDC is providing technical guidance to the DRC government, bordering country governments, WHO and partners, bringing to bear decades of experience, global health investments, and lessons learned in the West Africa Ebola response. For example, CDC is working with WHO and DRC's Ministry of Health to standardize training materials and operating procedures for triage and isolation, decontamination of healthcare facilities, and routine patient care. All partners are working together toward one goal: to end this outbreak as soon as possible.

In August 2018, CDC and USAID briefly deployed Ebola experts to Beni for a few days, but they were pulled back due to security concerns. In the context of a December 2018 DRC presidential election, where several areas of the country experienced a deterioration in the overall security situation, U.S. Embassy Kinshasa went on Ordered Departure of non-emergency U.S. government staff and all eligible family members on December 14, 2018. When this was lifted on Jan. 31, CDC staff returned to DRC to directly support the DRC government, WHO, and the integrated U.S. Disaster Assistance Response Team (DART), where CDC serves as the public health lead for the DART. As of July 19, 15 CDC staff were working with Ministry of Health counterparts in DRC in the capital

of Kinshasa and especially in the North Kivu provincial capital of Goma, which has become the DRC government's base of operations to respond to the outbreak. Goma is about 300 kilometers from the main outbreak areas, and is considered to be more secure. As an example of how we work, in March, with U.S. Embassy Kinshasa concurrence, two CDC staff deployed to the town of Bunia in Ituri Province for two weeks to assist with the investigation of a newly confirmed Ebola case. CDC made local responders aware that there may be unrecognized chains of transmission in Bunia, and CDC advised local Bunia staff to better standardize and share information across vaccination and contact tracing teams. CDC works closely with the U.S. Embassy in Kinshasa to ensure the safety of deployed personnel, and routinely defers to the State Department to assess the security situation and determine access to the outbreak areas. While not currently operating within Beni, Butembo, and other outbreak areas, CDC remains prepared to return when it is deemed safe to do so by the U.S. Department of State.

CDC also has deployed staff to augment our existing country offices in the neighboring countries of Uganda, Rwanda, and South Sudan. As evidenced by the cross-border transmission in Uganda last month, these countries are all vulnerable to the possibility of imported cases arriving from the DRC. From August 6, 2018 through July 17, 2019, 199 CDC staff have participated in a combined 313 deployments in response to the Ebola outbreak: 98 deployments to DRC; 91 to Geneva; 55 to Uganda; 40 to Rwanda; and 29 to South Sudan.

Risk Communications and Health Education

While the context of the response still presents many challenges, efforts to improve cooperation and engagement with local communities remains a critical aspect of this Ebola response, and continues to be a focus of our work. CDC social and behavioral scientists have deployed to DRC, WHO headquarters, and several countries bordering the DRC to guide risk communication and community engagement strategies. Experts from CDC, WHO, the International Federation of Red Cross and Red Crescent Societies (Red Cross), and UNICEF

continue to work toward improving the quality of engagement activities by standardizing approaches and developing and delivering communications training to all implementing partners.

A key component of improving community engagement is fulfilling the information needs of the community by answering and addressing their questions and concerns. Since May, CDC deployers have worked with the DRC Ministry of Health and UNICEF on message development and testing, analyzing and promoting the use of community feedback data in content and strategy development, and long-term risk communication and community engagement planning. CDC has also posted multiple Ebola prevention-oriented fact sheets, posters, and flip books translated into French, Swahili, Kinande, and Kinyarwanda, and recently released a video public service announcement (PSA) video featuring Congolese native and former NBA star Dikembe Mutombo delivering Ebola prevention messages.

Contact Tracing

Contact tracing is the effort to find everyone who comes in contact with a sick Ebola patient, either directly or through contaminated materials. The goals of this process are to monitor contacts daily for signs of illness and to isolate ill persons before they can infect others. One missed contact who develops disease can keep the outbreak going. When a case is not known to be a contact, they are usually identified in a late stage of illness and may have already spread the infection to others. On July 21, a total of 17,253 out of 20,302 (85 percent) known contacts of people with Ebola were being followed. However, as noted earlier, among the new cases with contact information from June 27 to July 17, 61 percent were either unknown contacts or known but not followed at the time of symptom onset. The high proportion of cases that are not known contacts or that are lost to follow-up indicates that the quality of contact tracing must improve if the outbreak is to be contained; contact tracing efforts have been hindered by the volatile security situation. To strengthen contact tracing, CDC designed “train-the-trainers” courses for frontline response workers, focusing on contact tracing methods. CDC also created an Ebola “Exposure Window Calculator” smartphone app in use by case investigators.

Infection Prevention and Control in Healthcare Settings

Healthcare settings have played an important role in amplifying transmission in this and many prior outbreaks. Implementing proper infection control and prevention practices is critical to stopping the spread of the virus within the healthcare delivery system and to the community. Prompt identification and isolation of patients arriving at healthcare facilities with possible Ebola virus infection is essential so that they may be safely evaluated and, if necessary, transported to an Ebola Treatment Unit for further care. Infected people who are not initially recognized to have Ebola may receive care at multiple facilities before Ebola is suspected, exposing numerous patients and healthcare workers to the virus. As of July 21, 34 percent of cases identified in the preceding 21 days had visited two or more health care facilities before being confirmed with Ebola.

Unfortunately, patients often arrive at specialized Ebola Treatment Units late in their illness, and other healthcare facilities in the area are not necessarily prepared to effectively or safely care for Ebola patients. Patients are more likely to infect others during this time, and less likely to survive if treatment is started late. As of July 21, 137 local healthcare workers have contracted Ebola in the DRC. Within DRC, CDC is collaborating with WHO and the Ministry of Health to improve the use of standard procedures for correct patient assessment, triage, and infection prevention and control (IPC) practices across health facilities and to strengthen the supportive supervision and mentoring of healthcare workers.

In the bordering countries of Uganda and Rwanda, CDC is providing assistance to response partners to improve the capacity of healthcare facilities to rapidly identify and isolate suspected Ebola cases, train personnel, and improve infection prevention and control. At least 150 healthcare personnel have been trained by CDC in Uganda and Rwanda since October 2018. Using information from interviews conducted at border crossings, refugee transit centers, and district health offices, CDC identified clinics and hospitals in border districts of neighboring countries that would be most likely to receive an imported case of Ebola from the outbreak area.

CDC assessed triage practices at these facilities, interviewed and informed staff about risks of imported Ebola, and prioritized facilities for additional training and support.

Border Health

The two DRC provinces affected by this outbreak, North Kivu and Ituri, both border Uganda. North Kivu also borders Rwanda, and Ituri province has a relatively short border with South Sudan. There is substantial population movement across these country borders. The Mpondwe Border Crossing is the busiest official ground crossings on the border between Uganda and the DRC, with a peak of 35,000 travelers passing through each day. At the Rubavu District Point of Entry between Goma, DRC and Gisenyi/Rubavu City, Rwanda, an estimated 50,000 people cross daily. This high volume, which includes pedestrian, commercial car, and truck traffic, poses significant concerns for potential cross-border transmission of infectious diseases. The WHO assesses that there is a very high risk of regional spread. Preparedness activities in bordering countries are ongoing and CDC is providing technical assistance on their border health security efforts. Building on long-term in-country CDC presence as well as collaborations from the earlier 2018 outbreak, CDC is working with the DRC Ministry of Health and Population and other partners to adapt and implement screening protocols at country-prioritized airports and ground crossings, and to map population movement into and out of the outbreak zone to determine where surveillance and other public health interventions could be enhanced. As of July 22, over 77 million travelers have been screened at 80 priority ports and crossing points in the DRC since the outbreak began.

Vaccine Implementation

CDC conducted a clinical vaccine trial in Sierra Leone during the West Africa Ebola outbreak, enrolling and vaccinating nearly 8,000 healthcare and frontline workers. This and several other studies have suggested that the rVSV-ZEBOV (Merck) investigational vaccine is safe and protects against infection with the Ebola virus. While the vaccine is not yet licensed, the vaccine is being used in the current outbreak in expanded access trials,

predominantly in a ring vaccination strategy that targets contacts of Ebola case patients for vaccination as well as secondary contacts. WHO and the DRC Ministry of Health co-lead the vaccination effort, with CDC contributing expert advice. While security concerns have prevented CDC from participating in field activities, CDC staff are embedded in the DRC Vaccine Commissions in Kinshasa and Goma and at WHO headquarters to analyze data and improve the quality of ring vaccination efforts.

CDC has also collaborated with WHO colleagues in Rwanda, South Sudan, and Uganda to implement preventative vaccination of health care workers in geographic areas near the DRC border, and has provided technical assistance to these countries. To date, over 9,000 healthcare workers have been vaccinated in the border countries of Rwanda, Uganda and South Sudan. In addition, we have applied our expertise to update Ebola vaccination protocols, operating procedures, and training and communications materials for use at national and local levels, and facilitated trainings for national staff. Our work across multiple countries has helped standardize procedures and facilitate the use of best practices. As of July 17, over 164,000 individuals had been vaccinated in DRC.

On May 7, the WHO Strategic Advisory Group of Experts (SAGE) on Immunization published interim recommendations to expand Ebola vaccination strategies and address security concerns. Their recommended vaccination strategies include ring vaccination, using “pop-up vaccination” sites at a distance from the residences of contacts, and targeted geographic vaccination, where all individuals in a given village or neighborhood are invited to receive vaccine. These SAGE recommendations also include alternative dosing to help ensure vaccine continues to be available. Following the SAGE recommendation, the DRC ethical review board approved a protocol to implement vaccination for new populations (pregnant women beyond the first trimester, lactating women, and infants down to 6 months of age) and to implement vaccination at half the previous DRC dosage, which provides a similar potency to the vaccine used in the West African outbreak. These changes have been implemented in the field since early June 2019.

With expanded vaccination efforts we continue to underscore that strengthening implementation of basic public health measures, especially effective engagement and comprehensive identification of contacts, will be essential in conjunction with any vaccination strategy.

OUTLOOK OF THE EPIDEMIC

Ebola transmission can be stopped and the outbreak terminated when at least 70 percent of cases are effectively isolated; that is, moved to an Ebola Treatment Unit before they have infected anyone else, or have their contacts and secondary contacts fully vaccinated. This needs to be sustained for at least two to three months in order to end the outbreak. While we have the public health knowledge and tools to complete this task, we have not been able to fully implement these tools in the field. Neither the outbreak nor the security situation on the ground has improved in recent months and it is difficult to predict with certainty what will happen. Without substantial and continued improvements, the DRC could soon be facing an epidemic that rapidly increases; at that point, the possibility of the outbreak spreading to neighboring countries – in numbers much higher than the three confirmed cases in Uganda we have already seen - will increase. CDC is committed to leveraging its resources and global health security expertise to help end the outbreak.

RISK TO THE UNITED STATES

CDC understands that an international outbreak of Ebola puts the United States at risk and we appreciate the trust placed in CDC to keep Americans safe from public health threats both at home and abroad. At this time, we believe the direct risk to the United States remains low based on the travel volume and patterns from the outbreak areas to the United States and the implementation of border screening measures at key airports and ports in the DRC and neighboring countries. CDC helped organize exit screening workshops in Kinshasa and Goma in DRC to bolster screening efforts and prevent spread of disease. On average, of the approximately

325,000 air travelers arriving in the United States daily, about 43 travelers are from the DRC, largely from regions unaffected by the Ebola outbreak.

CDC continues to implement routine border health security measures at U.S. Ports of Entry and has issued a Level 2 (Practice Enhanced Precautions) travel health notice for the DRC that informs travelers and clinicians about the outbreak and what types of precautions they should take if traveling to the affected areas of the DRC. CDC has been in regular contact with the non-governmental organizations operating in the outbreak areas, and we provide recommendations on monitoring and pre-departure health assessments for healthcare workers. In addition, the U.S. Department of State has identified the outbreak area as a “do not travel” zone because of armed conflict, crime, and civil unrest. Current CDC guidance for managing Ebola cases in U.S. healthcare settings has been reviewed and communicated to healthcare facilities as part of domestic preparedness efforts. CDC’s Laboratory Response Network stands ready to perform testing on Ebola specimens should any need arise, with testing kits deployed across the United States.

BIG PICTURE: GLOBAL HEALTH SECURITY

The ongoing response to Ebola in DRC and surrounding countries demonstrates CDC’s continued commitment to strengthen global health security. CDC has been engaged in global health security work for over seven decades and is able to leverage the essential public health assets developed by notable initiatives like the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), the President’s Malaria Initiative, and global polio eradication to support core global health security programs and ensure the safety of Americans. With an understanding of the increasing threats posed by infectious diseases globally and in the context of the West Africa Ebola outbreak, CDC received \$582 million in supplemental funding for a five-year effort in support of the Global Health Security Agenda (GHS). GHS was launched by a growing partnership of nations, international organizations, and non-governmental stakeholders in 2014 with a stated vision of a world safe and secure from global health threats posed by infectious diseases. Since GHS’s launch, CDC’s global health security work has helped partner

countries build and improve their public health system capacity. With CDC's support, partner countries were able to effectively contain meningitis in Liberia, Marburg virus in Uganda, multidrug-resistant tuberculosis in India, and vaccine-preventable diseases including measles and pertussis in Pakistan and diphtheria in Vietnam, among other threats across the globe. These outbreaks were stopped at their source, saving lives and reducing the amount of time it takes to effectively respond from months and weeks to days.

We appreciate the continued commitment of Congress to global health security. Support for global health security enables CDC to continue protecting Americans by detecting and preventing infectious disease threats before they reach our borders. We are seeing progress in the 17 priority countries where we have invested our global health security resources: all 17 have improved rapid response to disease threats through established or expanded public health workforce training of field-based epidemiologists, 13 have improved prevention of vaccine-preventable diseases through increased community immunization coverage, 15 have ensured effective public health emergency operation centers through training of emergency management officials, and 9 have increased their ability to identify country-prioritized pathogens through improved national laboratory testing capacity.

The DRC serves as an example of a country where CDC investments have built capacity since program operations began in 2002, including activities specifically to prepare for an Ebola outbreak. These efforts have also fostered strong relationships with the DRC and surrounding countries' ministries of health that have proved critical in times of crisis. The May-July 2018 outbreak of Ebola in the Equateur province of the DRC raised international concern due to logistical challenges caused by the large and remote area. That outbreak ultimately led to 53 cases and 29 deaths. The swift response, which included CDC and other U.S. government personnel in the field, ensured it was quickly controlled. Without a doubt, our global health security activities in the DRC enabled a faster, more effective and successful response to the May-July 2018 outbreak, and provide an important

foundation in the current Ebola response, even considering the complex security situation and special difficulties posed by this outbreak.

The DRC Field Epidemiology Training Program (FETP), developed with assistance from CDC and modeled after CDC's own training programs, has trained around 260 frontline and advanced disease detectives who are crucial to accurately detecting and identifying outbreaks. The DRC graduated its first cohort of FETP residents in 2015. These disease detectives are supporting the current Ebola outbreak and serve as an example of how CDC supports sustainable capacity development of countries to respond to outbreaks within their own borders. There are presently 42 FETP-trained staff deployed in nine outbreak health zones. Training programs like these work effectively because they are complemented by decades of field experience that CDC experts bring, teaching new epidemiologists how to rapidly identify diseases and respond effectively to prevent spread. CDC maintains long-standing collaborations in the DRC for priority diseases, including monkeypox virus response and prevention, building capacity and skills that have been beneficial for Ebola response. Sustainable investments, such as resources and expertise to train laboratory technicians, renovate and upgrade two laboratories, and establish a National Emergency Operations Center in the DRC, are all being leveraged in the current Ebola response.

Our global health security work is enhancing the world's ability to respond to other emerging health threats. More than 70 countries have an FETP program, resulting in more than 12,000 graduates around the world. In Liberia, improved laboratories, epidemiology training, surveillance, and surge capacity resulted in the identification of an April 2017 meningitis outbreak within one day of the first discovery of a case. By comparison, it took 90 days for the country to recognize the first Ebola case in 2014. The Uganda Virus Research Institute has emerged as a regional reference laboratory for viral hemorrhagic fevers thanks to collaboration with CDC and its subject matter experts. In addition, Uganda's Public Health Emergency Operations Center, established with CDC support in 2013, is a model for other global health security program countries. This center has been activated

for over 75 outbreaks and public health events. With this improved capacity, Uganda has detected 16 viral hemorrhagic fever outbreaks as of July 2018, and responded quickly to keep outbreaks small and contained, including the three Ebola cases identified in June 2019. They also detected a yellow fever outbreak in spring of 2016 in only four days, compared to over 40 days that it took to identify the yellow fever outbreak of 2010.

Another important component of CDC's global health work is the agency's ability to monitor threats globally and to provide rapid response through deployment of staff from across the agency. CDC's Global Emergency Alert and Response Service (GEARS) closely monitors 35 to 45 outbreaks a day through event-based surveillance and supports emergency deployments to respond to selected outbreaks. GEARS brings together the Global Disease Detection Operations Center (CDC's electronic surveillance analysis and response system for global threats) and the Global Rapid Response Team, which has trained over 500 CDC personnel who have provided nearly 22,000 person-days of response support.

One way that CDC ensures our domestic preparedness is through building global capacity in health security. As we saw during the West Africa Ebola epidemic, the current measles outbreak, and the Middle East Respiratory Syndrome (MERS) outbreak, infectious disease threats do not respect borders. An outbreak that starts in another country could reach us in a matter of hours; this is why CDC works globally to stop health threats before they enter the United States.

CONCLUSION

CDC's number one priority during any public health emergency is to save lives. CDC never loses sight of its primary mission to protect the health and safety of the American people, and we know that global health security is national security. CDC works overseas to ensure that health threats do not reach the U.S., most importantly by working to stop these threats where they start. CDC works to protect the United States from direct health threats, protect U.S. interests in global economic security, and ensure that lessons learned

overseas can be applied here to increase the strength of the U.S. public health system. While significant progress has been made, we know that we will continue to see the emergence of both known and unknown threats that will require the laboratory and surveillance infrastructure that CDC continues to support. The current Ebola outbreak remains a particular challenge for DRC and the global health community, and there are no signs that the outbreak is slowing. However, CDC's global health programs have allowed us to build strong working relationships with the DRC and surrounding countries' ministries of health, and we will continue to work with USAID and our sister agencies in the Department of Health and Human Services, as well as WHO and other international partners, until we stop this particularly challenging outbreak.

The ability to rapidly detect and effectively respond to threats to the public's health is a top priority for CDC. CDC works around the clock to not only ensure its readiness but the readiness of those on the front lines. CDC remains vigilant, because at any given moment, thousands of infectious diseases are circulating in the world. We don't know exactly which outbreak or potential pandemic threat is coming next, but we know it is coming. The work we do now ensures that, when the next major outbreak or pandemic threat does arrive, we are able to protect the health of Americans and save lives.