U.S. Department of Health and Human Services
Assistant Secretary for Preparedness and Response

FY 2014 BUDGET YEAR IN REVIEW

An overview of ASPR's budget and accomplishments

May 2015

U.S. Department of Health and Human Services
The Office of the Assistant Secretary for Preparedness and Response (ASPR)

Fiscal Year 2014 Budget Year in Review

The Office of the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS) works to protect people's health when disaster strikes by building strong, healthy communities that are able to withstand adversity and become resilient. ASPR brings together the worlds of policy, science, and emergency management. We drive national and global policy on health preparedness and ensure that evidence-based practice is the foundation of our strategies. We work with industry to ensure that the nation has the vaccines, drugs, and medical supplies it will need during a public health emergency. When states ask for assistance during and after a disaster, we are ready with a federal health response tailored to meet their needs.

During fiscal year (FY) 2014 (October 1, 2013 through September 30, 2014), the United States faced several major public health emergencies and challenges. These events included severe weather, health screening support for the influx of thousands of unaccompanied children crossing the southern U.S. border, the outbreak of Ebola virus disease in West Africa, and other smaller, localized events.

ASPR responded to these public health challenges head on by working effectively with its partners in HHS, other federal agencies, local communities, states, and other nations and international bodies. ASPR did so while helping to maintain the nation's progress in developing medical countermeasures against pandemic influenza; emerging infectious diseases; chemical, biological, radiological, and nuclear threats; and other public health dangers such as antibiotic-resistant bacteria. Furthermore, ASPR redesigned and improved the National Disaster Medical System, strengthened community health care preparedness, and advanced policies for improving the post-disaster resilience of children, the elderly, and people who depend daily on medical devices to stay alive and thrive.

> *"Our all-hazards approach, a shift from individual planning efforts to a more comprehensive approach to all public health and medical emergencies, allows us to be flexible and nimble to both known and unknown threats, including the current Ebola crisis in West Africa that has challenged the entire global response capacity."*
>
> Nicole Lurie, MD, MSPH
> *Assistant Secretary for Preparedness and Response*

Improving Public Health Preparedness, Response and Recovery

The mission of ASPR's Office of Emergency Management (OEM) is to save and sustain lives by supporting communities as they prepare for, respond to, and recover from disasters and other public health emergencies. OEM leads HHS's disaster response and recovery efforts. During FY 2014, OEM's resources totaled $338 million. OEM awarded two-thirds of this funding to states and other jurisdictions through cooperative agreements to promote health care system preparedness. The remainder of the funding was for preparedness and emergency operations, and the National Disaster Medical System (NDMS), which is a federally-coordinated system that is available to augment local and state medical response capabilities during declared emergencies.

In the summer of 2014, OEM provided funding, personnel, and expertise to support the federal response to the influx of thousands of unaccompanied children crossing the southern U.S. border. OEM augmented health screening for these minor children as the Department of Homeland Security's (DHS) Customs and Border Protection processed them. OEM also worked at the Washington, DC headquarters of DHS's Federal Emergency Management Agency (FEMA) to enhance communication and coordinate resources with the border activities. Further, OEM coordinated with the Department of Defense (DOD) to provide surge support at four facilities and support logistics for the operations.

In addition, OEM supported efforts to contain the Ebola outbreak in West Africa and enhance domestic readiness and preparedness for Ebola. NDMS's Chief Medical Officer program developed safety guidelines for the U.S. Public Health Service mission in Africa. OEM also provided logistical support for the mission. NDMS determined what resources, including its personnel, would be needed in the event of a domestic response to Ebola. In addition, NDMS headquarters personnel developed training requirements that will enhance system readiness in the future. The training will ensure that, when NDMS is activated to provide support for any wide-scale disease outbreak, medical teams are able to provide clinical care.

During FY 2014, OEM also led ASPR's responses to several severe weather incidents, including winter storms that affected the Northeast. OEM also supported the response to a chemical release in West Virginia in January 2014, provided expertise during nationwide saline and propane shortages, and continued to provide targeted mental health support to events such as the Boston Marathon.

ASPR's National Disaster Medical System helps states and communities by providing patient care in response to declared emergencies.

OEM also continued to re-examine its resources, programs, and planning to enhance their alignment with mission and needs. OEM strengthened NDMS, which provides support through a variety of medical teams:

- Disaster Medical Assistance Teams,
- International Medical Surgical Teams,
- Disaster Mortuary Assistance Teams, and
- National Veterinary Response Teams.

During FY 2014, OEM reviewed Disaster Medical Assistance and National Veterinary Response Teams. This review aimed to strengthen team configurations to better target and meet state and local needs following a public health or medical incident. By fully implementing the review's findings, OEM will decrease costs while increasing its agility and response readiness.

OEM's Hospital Preparedness Program (HPP) also made progress in FY 2014. Every year, OEM awards cooperative agreements to states to enhance health care system preparedness and improve medical surge capacity following disasters. In FY 2014, HPP awarded $229 million to the program's 62 awardees. These awardees distributed HPP funding around their jurisdictions to support training, coalition-building and partnership, preparedness exercises, and other initiatives to enhance resilience within their communities.

ASPR's Office of Emergency Management supports exercises in real-world settings that enhance health care system preparedness at the federal, state, and local levels.

During FY 2014, HPP continued to help states and communities build local networks and sustain health care coalitions. Nationwide, the number of health care coalitions increased to approximately 11,000. These coalitions were important as the nation prepared for a potential Ebola outbreak domestically. Coalitions shared information, participated in joint training and testing exercises, and shared critical planning and supporting documents throughout their networks. Health care coalitions are continuing their preparedness activities for Ebola in 2015. These investments will help ensure that they are ready to respond safely, rapidly, and effectively not only to a potential Ebola outbreak but also to other serious communicable diseases.

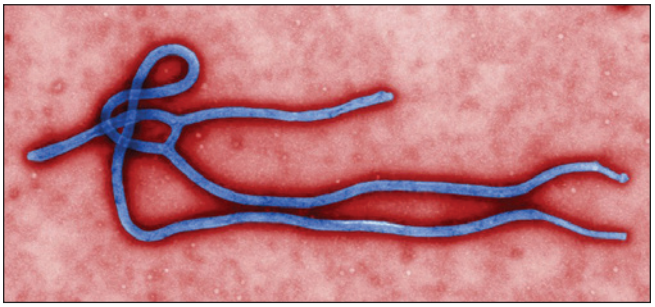
As is sometimes true with an individual's health, communities' public health challenges do not usually cease soon after a disaster is over. In fact, it can take years to rebuild not only physical structures but also health care infrastructures. In FY 2014, OEM continued to support a number of recovery initiatives to ensure communities are able to bounce back from disaster. For example, by agreement with FEMA, OEM continued supporting New York and New Jersey in their recovery from 2012's Hurricane Sandy. OEM also engaged with partners regarding the drought in California and the tornadoes in the South and Midwest, including Mississippi and Arkansas, in April 2014.

Developing Medical Countermeasures for Infectious Diseases & Other Threats

The United States and other nations work together to prepare for and respond to pandemic influenza; emerging infectious diseases such as Ebola; and chemical, biological, radiological, and nuclear (CBRN) threats. ASPR's Biomedical Advanced Research and Development Authority (BARDA) supports the advanced research, development, and procurement of novel and innovative medical countermeasures (MCM) such as vaccines, antimicrobial drugs, diagnostics, and medical devices to address the medical consequences of CBRN agents and naturally-occurring and emerging threats. Recent examples of such threats include last year's H7N9 influenza outbreak in China and the current Ebola epidemic in West Africa. In FY 2014, BARDA moved six new MCM candidates and innovations from early development into advanced development. For pandemic influenza, BARDA invested in new ways to produce more vaccine sooner and new antigen-sparing pandemic influenza vaccines. BARDA also secured adequate production capacity to meet the U.S. need for existing domestic egg-based influenza vaccines in the event of a pandemic. In addition, BARDA supported more sensitive point-of-care influenza diagnostic devices and new next-generation portable ventilators. For CBRN and other public health threats, BARDA invested in new antimicrobial drugs, Ebola monoclonal antibody therapeutics, biothreat diagnostics, and immunomodulators.

In 2014, BARDA also added a new component to America's infrastructure for MCM development and manufacturing. BARDA established its Clinical Studies Network. The network comprises five Clinical Research Organizations that provide clinical study support to MCM developers and respond in public health emergencies such as the current Ebola epidemic.

The U.S. MCM response to the Ebola outbreak in West Africa demonstrates how BARDA collaborates and coordinates effectively with a wide range of partners to achieve progress. BARDA is working with its partners in HHS, DOD, other federal agencies, other countries, and non-governmental organizations to engage industry and academia. BARDA and its partners are using public-private partnerships to mount the rapid development of candidates for Ebola vaccines and therapeutics. These MCM candidates are going through important clinical trials. If these MCMs prove to be safe and effective, then they could be manufactured on a larger scale and made available in Africa and, if needed, here in the United States.



During 2014, ASPR's Biomedical Advanced Research and Development Authority began supporting the advanced development of medical countermeasures against Ebola virus disease.

BARDA used $25 million in FY 2014 funding to begin its support for the development of therapeutic MCMs against Ebola. To continue the important development of Ebola therapeutic and vaccine candidates, the Administration requested and Congress provided additional funding for FY 2015. In total, BARDA has received $215 million in 2015 funding for Ebola and is contributing to developing

these MCMs through the targeted advanced development, manufacturing, and testing of promising MCMs that may intervene in the current epidemic in West Africa and potentially be added to the U.S. Strategic National Stockpile (SNS) that the Centers for Disease Control and Prevention (CDC) manage. For example, BARDA is supporting the development of more of the Ebola monoclonal antibody therapeutic candidate ZMapp. BARDA is funding the production of more ZMapp using not only tobacco plants but also mammalian cells. This strategy intends both to produce MCM material for clinical trials and determine how to rapidly produce large quantities of this new Ebola therapeutic. BARDA also is working with the manufacturers of promising Ebola vaccine candidates to scale up manufacturing from pilot to commercial production scale, provide more thermostable vaccine product, and produce adequate quantities to conduct clinical trials in West Africa to determine whether the vaccines work. In addition, BARDA is engaging its Fill-Finish Manufacturing Network to fill Ebola vaccines and monoclonal antibody therapeutics into final containers for clinical studies.

ASPR's Biomedical Advanced Research and Development Authority supports advancements like cell-based vaccines and public-private partnerships that are modernizing the manufacturing of medical countermeasures.

During FY 2014, ASPR also has made significant progress in enhancing pandemic preparedness for our nation. In November 2013, the Food and Drug Administration (FDA) licensed the first pandemic influenza vaccine with an adjuvant. BARDA had supported the development of this MCM, GlaxoSmithKline's Q-PAN H5N1 pandemic vaccine with AS03 adjuvant, since 2007.

BARDA has created a robust and formidable pipeline of dozens of products that are candidates for MCMs against pandemic influenza, emerging infectious diseases such as Ebola, and CBRN threats. Between 2004 and 2013, under Project BioShield (BioShield), this development pipeline yielded 12 new MCMs against CBRN threats. These and other MCMs are in the SNS and ready in the event of a public health emergency. In FY 2014, BARDA replenished the stockpile of smallpox vaccine for immunocompromised individuals and anthrax antitoxins. By 2018, BARDA plans for this CBRN development pipeline to provide at least 12 more MCM candidates for BioShield acquisition to address CBRN threats.

As discussed above, BARDA is addressing the last material threat identified by DHS—viral hemorrhagic fever viruses—by supporting the development, manufacturing, and testing of multiple Ebola vaccine and therapeutic candidates. By FY 2016, BARDA expects that several of these Ebola MCMs will be mature and proven enough for acquisition through BioShield and will be added to the SNS.

Developing Strategies & Policies that Strengthen Health Resilience

In FY 2014, ASPR's Office of Policy and Planning (OPP) continued to lead policy, planning, and research about how to encourage greater public health resilience from disasters. These strategies and policies include plans for such things as MCMs, medical care for at-risk individuals, behavioral health care during and after disasters, and community resilience from the devastating effects of public health emergencies.

During the response to Hurricane Sandy, in FY 2013, ASPR launched a new initiative for Science Preparedness and Response Research. This initiative focuses on defining the research needs and unanswered questions in the aftermath of this disaster and how to learn from one disaster to another so that communities can be more resilient. Even as a community deals with a disaster or other public health emergency, there is a limited window of time during which researchers can identify, collect, and analyze critical and time-sensitive data and information needed to protect the health and safety of responders and communities, both immediately and long term.

ASPR's Science Preparedness and Response Research initiative is examining questions about how individuals and communities responded to and are recovering from Hurricane Sandy.

In 2013 and 2014, ASPR issued two research funding opportunities to support science preparedness research projects related to Hurricane Sandy recovery. These projects contribute to the growing knowledge base of evidence-based research, and inform national best practices in future disaster and public health emergency responses. The scientists are investigating priority research areas in community, responder, and public health system resilience; the role of social media in disaster response and recovery; mental health outcomes of affected individuals and communities; health hazards among response workers and volunteers; mold mitigation and related health issues; and the efficacy of education, training, and communication in risk management.

Also in FY 2014, OPP's MCM Strategy and Requirements division developed HHS's Secretarial declaration that circumstances exist to justify the authorization of emergency use of *in vitro* diagnostics for detecting the Ebola virus. Following this declaration, unapproved medical products or unapproved uses of approved medical products can be used in an emergency to diagnose, treat, or prevent serious life-threatening diseases or conditions caused by Ebola when there are no adequate, approved, and available alternatives. This action enhances health security by allowing laboratory personnel to more rapidly and accurately detect Ebola virus in individuals exhibiting signs and symptoms, thus preventing further transmission of this deadly disease and helping to identify which patients need treatment.

OPP also produced an important product-specific requirement that outlines product attributes for MCMs against Ebola and Marburg fever disease.

Because of the relative developmental immaturity of candidate MCMs in the pipeline, this document focuses on broad classes of MCMs (e.g., vaccines, monoclonal antibodies, antivirals, and RNA interference therapeutics). This document enhances national preparedness by providing the policy justifications for future acquisitions of MCMs into the SNS.

ASPR's OPP also continues to lead policy development to ensure that vulnerable populations are considered in preparedness, response, and recovery. During FY 2014, OPP led an innovative initiative to target populations who depend on medical devices and technology that can become inoperable during a power outage associated with a disaster. OPP also hosted exercises in Louisiana and New York about using data from the Centers for Medicare and Medicaid Services to improve health care providers' ability to identify, locate, and reach out to at-risk populations. During FY 2014, OPP also launched the National Advisory Committee on Children and Disasters, and developed frameworks that the United States uses to respond to international requests for MCMs and other assistance, including during the global responses to the H7N9 influenza strain, Ebola, and Middle East Respiratory Syndrome coronavirus (MERS-CoV).

ASPR's Science Preparedness and Response Research initiative is examining questions about how individuals and communities responded to and are recovering from Hurricane Sandy.

OPP's Division of International Health Security continued leading critical international partnerships. These partnerships include the Global Health Security Initiative and the North American Plan for Animal and Pandemic Influenza. The division also developed and exercised policy frameworks for the United States to provide international assistance during a disaster or other public health emergency. The United States used these frameworks to provide financial resources, MCMs, laboratory sample sharing, and public health and medical personnel during the responses to the H7N9 influenza strain, MERS-CoV, and most recently, the Ebola outbreak.

ASPR's OPP also leads the U.S. International Health Regulations Program in monitoring potential public health emergencies of international concern under the World Health Organization framework. To date, the program has notified stakeholders about 66 potential events of international concern since the regulations entered into force in the United States in 2007. OPP also continues to manage cooperative agreements to support 12 countries across four continental regions: Central/Latin America, Eastern Caribbean, Sub-Saharan Africa and Southeastern Asia. These partnerships are enhancing these nations' core capacities to detect, assess, communicate, and respond to public health emergencies.

Investing in ASPR's Most Important Resource: Its People

ASPR is successful in achieving its goals not only because it invests in MCMs, disaster medical assistance, and research but also because it has a dedicated staff of federal employees and contractors. Some of these people are scientists, emergency responders, and policy developers. Other staff work on administrative operations, information technology, communications, legislation, contracts, grants, human resources, budgeting, and finance.

During FY 2014, ASPR strengthened initiatives to promote a leadership and mentoring culture. By developing its staff's skills and abilities, ASPR can ensure it is capable of addressing evolving threats and emerging challenges to public health. Furthermore, staff can better develop and implement innovative solutions in the face of future disasters.

ASPR also launched new quality-improvement initiatives in FY 2014 and took actions to mitigate risk and improve financial management. For example, ASPR obligated 99.9 percent of its annual funding for FY 2014, leaving just $2,500 unobligated at the end of the fiscal year. ASPR also awarded 47 percent of total eligible contract dollars to small businesses, closed out 85 grants, and reduced late-payment penalties it pays to just 0.01 percent of total contract funding awarded. ASPR also substantially expanded its public outreach using innovative communication tools and technologies. Using Vine, Facebook, Twitter, and phe.gov, ASPR is enhancing community connectedness and empowering individuals to take action during public health and medical emergencies.

These are just a few of ASPR's accomplishments. To learn more about ASPR's work to protect our nation's health security, how to prepare for disasters, and how to build resilient communities:

- Visit our website at **www.phe.gov**;
- Find us on Facebook at **facebook.com/phegov** or
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