MEMORANDUM FOR DEPUTY SECRETARY OF STATE
DEPUTY SECRETARY OF DEFENSE
DEPUTY ATTORNEY GENERAL
DEPUTY SECRETARY OF AGRICULTURE
DEPUTY SECRETARY OF COMMERCE
DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES
DEPUTY SECRETARY OF ENERGY
DEPUTY SECRETARY OF HOMELAND SECURITY
DEPUTY ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY
PRINCIPAL DEPUTY DIRECTOR OF NATIONAL INTELLIGENCE
ADMINISTRATOR OF THE UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT
VICE CHAIRMAN OF THE JOINT CHIEFS OF STAFF
DEPUTY DIRECTOR OF THE FEDERAL BUREAU OF INVESTIGATION

SUBJECT: Fiscal Year 2016 Budget Guidance for Countering Biological Threats Resource Priorities

Countering Biological Threats and promoting the Global Health Security Agenda (GHSA) continue to be high priorities for the President and his Administration. The attached list of Countering Biological Threats priorities was developed by the National Security Council staff, in coordination with the Office of Management and Budget (OMB) and the Office of Science and Technology Policy, and is consistent with the objectives and focus of the United States National Strategy for Countering Biological Threats and the GHSA.

The purpose of this resource guidance for the Fiscal Year (FY) 2016 budget process is to enable your department or agency to allocate appropriate resources to implement United States Government priorities to counter biological threats. While developing budget submissions, your department or agency should focus on programs and activities highlighted in the attached priorities memorandum (Tab A).

In your FY 2016 budget submissions to OMB in early September 2014, please identify which programs, projects, and activities align to each of the priorities in the attached guidance. Your department’s or agency’s submission to OMB
should also include a brief narrative explaining how its activities to counter biological threats support the FY 2016 policy priorities. We all have a critical role in fulfilling these priorities, and we look to each of you to budget for those priorities relevant to your department or agency within available resources in FY 2016.

As you are well aware, in a time of constrained resources, departments and agencies should continue to direct resources to high-priority activities and identify potential reductions or eliminations in less effective, lower quality, or lower priority programs. Departments and agencies should explain in their budget submissions how they are redirecting available resources (within existing authorities) from lower priority areas to activities that counter biological threats and address the priorities described in the attached guidance. It is also important that departments and agencies engaged in complementary activities consult with each other during the budget planning process so that resources are coordinated to maximize their impact and avoid unnecessary duplication. Where appropriate and consistent with the law, departments and agencies should consider leveraging programs with other public and private sector institutions. Department and agency submissions should meet the requirements outlined in the FY 2016 Budget Guidance memorandum from OMB, titled “M-13-14.”

Lisa O. Monaco
Assistant to the President for Homeland Security and Counterterrorism

Brian Deese
Acting Director Office of Management and Budget

Attachment
Tab A Fiscal Year 2016 Budget Guidance for Countering Biological Threats Resource Priorities

cc:
Assistant to the President and Counsel to the President
Assistant to the President and Deputy Chief of Staff for Policy
Assistant to the President and Director of the Office of Legislative Affairs
Deputy Assistant to the President and Assistant to the Vice President for National Security Affairs
Tab A
Background. Presidential Policy Directive-2 (PPD-2) directs the Interagency Policy Committee (IPC) on Countering Biological Threats to provide policy guidance on priority areas of interest related to the National Strategy for Countering Biological Threats to inform annual department and agency budget requests. Similar to fiscal years (FY) 2012, 2013, 2014, and 2015 the Assistant to the President for Homeland Security and Counterterrorism and the Director of the Office of Management and Budget (OMB) are jointly issuing the Countering Biological Threat Resource Priorities Memo for FY 2016, while leveraging input from Federal departments and agencies without circumventing their internal budget processes.

FY 2016 Priorities Associated with Countering Biological Threats in support of the Global Health Security Agenda. One consequence of a more interconnected world is the increasing opportunities for human, animal, and zoonotic diseases to emerge and spread globally. Today’s health security threats arise from at least five sources: the emergence and spread of new microbes; the globalization of travel and food supply; the rise of drug-resistant pathogens; the acceleration of biological science capabilities and the risk that these capabilities may cause the inadvertent or intentional release of pathogens; and continued concerns about the acquisition, development, and use of biological agents by state and nonstate actors. The current outbreaks of Middle East Respiratory Syndrome, H7N9 influenza, and Ebola are revealing gaps in the global system for managing emerging biological threats. These outbreaks also demonstrate the need for enhanced U.S. leadership to strengthen global capabilities to prevent, detect, and respond to biological threats, whether naturally occurring, deliberate, or accidental.

In keeping with the emphasis in the National Strategy for Countering Biological Threats on promoting global health security, the FY 2016 priorities form the basis of the

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For Global Health Security Agenda objectives that are consistent with the five end-states outlined in the document, “International Engagement to Reduce Biological Threats,” this will be achieved through improving United States Government coordination and implementation of key international bioengagement activities aimed at reducing biological risks in priority countries, among other activities. The Countering Biological Threats IPC has identified the following countries as continuing national-level priorities for countering biological threats in order to better harmonize and coordinate interagency bioengagement activities toward those end-states: Afghanistan, China, Egypt,
Administration's Global Health Security Agenda (GHSA). Departments and agencies play critical roles in fulfilling these priorities and should identify these priorities, as well as programs and activities that reflect them, when building their FY 2016 budget requests.

The following priorities and targets should be prioritized in FY 2016 in support of the GHSA.

Global Health Security Agenda Objectives

1. Prevent Avoidable Epidemics; including prevention of naturally occurring outbreaks and intentional or accidental releases.

- Prevent the emergence and spread of antimicrobial drug resistant organisms and emerging zoonotic diseases, and strengthen international regulatory frameworks governing food safety. Act to reduce the individual and institutional factors that enable antimicrobial resistance and the emergence of zoonotic disease threats, increase surveillance and early detection of antimicrobial resistant microorganisms and novel zoonotic diseases; measurably enhance antimicrobial stewardship; strengthen supply chains; promote safe practices in livestock production and the marketing of animals; and promote the appropriate and responsible use of antibiotics in all settings, including developing strategies with host countries to improve food safety.

- Promote national biosafety and biosecurity systems. Promote the development of specific multisectoral approaches in countries and regions for managing biological materials to support diagnostic, research, and biosurveillance activities, including identifying, securing, safely monitoring, and storing dangerous pathogens in a minimal number of facilities while advancing global biosurveillance, and frameworks to advance safe and responsible conduct.

- Reduce the number and magnitude of infectious disease outbreaks. Countries will have in place effective programs for vaccination against epidemic-prone diseases and nosocomial infection control.

India, Indonesia, Iraq, Kenya, Mexico, Pakistan, Russia, Vietnam, and Yemen. The IPC will work to prioritize capacity needs in these countries, informed by the sub-IPC effort. It should be noted that departments and agencies prioritize programmatic efforts in a number of countries, and this list is not intended to exclude those efforts.
2. Detect Threats Early. Detect, characterize, and transparently report emerging biological threats early through real-time biosurveillance.

- Launch, strengthen, and link global networks for real-time biosurveillance. Promote the establishment of monitoring systems that can predict and identify infectious disease threats; interoperable, networked information-sharing platforms and bioinformatic systems; and networks that link to regional disease detection hubs.

- Strengthen the global norm of rapid, transparent reporting and sample sharing in the event of health emergencies of international concern. Strengthen capabilities for accurate and transparent reporting to the World Health Organization (WHO), World Organization for Animal Health (OIE), and the Food and Agriculture Organization of the United Nations (FAO) during emergencies, with rapid sample and reagent sharing between countries and international organizations.

- Develop and deploy novel diagnostics and strengthen laboratory systems. Strengthen country and regional capacity at the point-of-care and point-of-need to enable accurate, timely collection and analysis of information, and laboratory systems capable of safely and accurately detecting all major dangerous pathogens with minimal biorisk.

- Train and deploy an effective biosurveillance workforce. Build country capacity for a trained and functioning biosurveillance workforce, with trained disease detectives and laboratory scientists.

3. Respond Rapidly and Effectively to biological threats of international concern.

- Develop an interconnected global network of Emergency Operations Centers and multisectoral response to biological incidents. Promote establishment of Emergency Operations Centers and trained, functioning, multisectoral rapid response teams, with access to a real-time information system. Promote capacity to attribute the source.

- Improve global access to medical and non-medical countermeasures during health emergencies. Increase country and regional capacity to produce or procure personal protective equipment, medications, vaccines, and technical expertise, as well as the capacity to plan for and deploy nonmedical countermeasures. The United States will develop and strengthen policies and operational frameworks to share
public and animal health and medical personnel and countermeasures with partners.

Global Health Security Agenda Target

Overarching Target: Over the next 5 years, the United States commits to working with at least 30 partner countries (containing at least 4 billion people) to prevent, detect, and effectively respond to infectious disease threats, whether naturally occurring or caused by accidental or intentional releases of dangerous pathogens. We call on other countries to join in this effort to realize the vision of a world where all 7 billion people are effectively protected against infectious disease threats.

We will work with partner countries on specific objectives to prevent, detect, and effectively respond to infectious disease threats, and will measure our own progress through the following metrics and milestones. We invite partner countries to use metrics appropriate to their own situations, including these and others:

Prevent: Countries will have systems, policies, and procedures in place to prevent or mitigate avoidable outbreaks. Considering their own vulnerabilities, countries should prioritize and implement the following:

• Surveillance to monitor and slow antimicrobial resistance, with at least one reference laboratory capable of identifying at least three of the seven WHO priority antimicrobial resistant pathogens using standardized, reliable detection assays, and reporting these results when appropriate to international or International Health Regulations (IHR) focal points.

• A whole-of-government national biosecurity system is in place that ensures collections of especially dangerous pathogens are identified, held, secured, and monitored in a minimal number of facilities with biosafety and biosecurity best practices in place; biorisk management training and educational outreach is conducted to promote a shared culture of responsibility, reduce dual use biological risks, and ensure safe transfer of biological agents; and country-specific biosecurity legislation, laboratory certification, and pathogen control measures are in place as appropriate.

• Adopted behaviors, policies and practices that minimize the spillover of zoonotic diseases into human populations.
• Immunization of at least 90 percent of the country’s one-year-old population with at least one dose of measles-containing vaccine as measured by coverage surveys or administrative data.

Detect: Countries will have real-time biosurveillance and effective modern diagnostics in place that are able to reliably conduct at least five of the 10 core tests (including point-of-care and laboratory-based diagnostics) on appropriately identified and collected outbreak specimens transported safely and securely to accredited laboratories from at least 80 percent of districts in the country. The United States will also support countries in substantially accomplishing:

• Surveillance for three core syndromes indicative of potential public health emergencies conducted according to international standards;

• Country and regional capacity to analyze and link data toward real-time biosurveillance systems, including interoperable, interconnected electronic reporting systems within the country, which can include clinical, laboratory, environmental testing, product safety and quality, and bioinformatics data;

• Timely and accurate disease reporting according to WHO, OIE, and FAO requirements;

• A workforce including physicians, veterinarians, biostatisticians, laboratory scientists, and at least 1 trained field epidemiologist per 200,000 population, who can systematically cooperate to meet relevant IHR and Performance of Veterinary Services core competencies.

Respond: Countries will have a public health Emergency Operation Center (EOC) functioning according to minimum common standards maintaining trained, functioning, multisectoral rapid response teams and real-time biosurveillance laboratory networks and information systems, and trained EOC staff capable of activating a coordinated emergency response within 120 minutes of the identification of a public health emergency. The United States will also support countries in substantially accomplishing:

• In the event of a suspected or confirmed biological attack, have the capacity to link public health and law enforcement for the purpose of attribution;

• A national framework for sending and receiving medical countermeasures and public health and medical personnel from
and to international partners during public health emergencies.