

THE WHITE HOUSE

WASHINGTON

February 22, 2016

Dear Mr. Speaker:

Today, I ask the Congress to consider the enclosed FY 2016 emergency supplemental appropriations request of approximately \$1.9 billion to respond to the Zika virus both domestically and internationally. This funding would build upon ongoing preparedness efforts and provide resources for the Departments of Health and Human Services and State, and the U.S. Agency for International Development (USAID). Funding would support immediate response activities to prevent the spread of, prepare for, and respond to Zika virus transmission; fortify domestic public health systems to prevent, detect, and respond to Zika virus transmission; speed research, development, and procurement of vaccines, therapeutics, and diagnostics; provide emergency assistance to States and the U.S. Territories to combat the virus; provide additional Federal Medicaid funding in Puerto Rico and the other U.S. Territories for health services for pregnant women at risk of infection or diagnosed with Zika virus, and for children with microcephaly, and for other health care costs; and enhance the ability of Zika-affected countries to better combat mosquitoes, control transmission, and support affected populations.

The Centers for Disease Control and Prevention reports 50 laboratory-confirmed cases of the Zika virus among U.S. travelers from December 2015 - February 5, 2016. In addition, the Pan American Health Organization reports 26 countries and territories in the Americas with local Zika transmission. On February 1, 2016, the World Health Organization declared the Zika virus a Public Health Emergency of International Concern.

My foremost priority is to protect the health and safety of Americans. This request supports the necessary steps to fortify our domestic health system, detect and respond to any potential Zika outbreaks at home, and to limit the spread in other countries.

The request includes approximately \$1.9 billion to respond to Zika virus transmission across the United States and internationally. In addition, transfer authority is requested to allow for sufficient response and flexibility across the Federal Government to address changing circumstances and emerging needs related to the Zika virus.

My Administration requests that the funding described above be designated as emergency requirements pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended.

I urge the Congress to act expeditiously in considering this important request, the details of which are set forth in the enclosed letter from the Director of the Office of Management and Budget.

Sincerely,

A handwritten signature in black ink, appearing to be 'P. Ryan', written in a cursive style. The signature is enclosed within a large, hand-drawn circle.

The Honorable Paul D. Ryan
Speaker of the
House of Representatives
Washington, D.C. 20515



Estimate No. 1
114th Congress, 2nd Session
EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D. C. 20503

THE DIRECTOR

February 22, 2016

The President
The White House

Dear Mr. President:

Submitted for your consideration is an emergency supplemental appropriations request to address the Zika outbreak and other vector-borne and emerging infectious diseases both domestically and internationally. These funds are being requested to respond to the Zika virus by bolstering domestic preparedness, accelerating the procurement and testing of vaccines, diagnostics, and new mosquito control methods, and enhancing global capability to detect and respond to the Zika virus.

This request provides approximately \$1.9 billion to support immediate response activities to prevent the spread of, prepare for, and respond to Zika virus transmission; fortify domestic public health systems to prevent, detect, and respond to the Zika virus; speed the research, development, and procurement of vaccines, therapeutics, and diagnostics; provide emergency assistance to States and the U.S. Territories to combat the mosquito vector and the Zika virus; provide additional Federal Medicaid funding in Puerto Rico and the other U.S. Territories for health services for pregnant women at risk of infection or diagnosed with the Zika virus and for children with microcephaly, and for other health care costs; and enhance the ability of Zika-affected countries to better combat mosquitoes, control transmission and support affected populations.

The funding amounts proposed are requested to be designated as emergency requirements pursuant to section 251(b) (2) (A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended.

The major categories of funding are highlighted below:

Department of Health and Human Services (HHS) – \$1,509 million

The request includes funding for the immediate response to prevent, prepare for, and respond to the Zika virus and other vector-borne and emerging infectious disease threats. The request includes funding for the following HHS operating divisions:

Centers for Disease Control and Prevention (CDC) – \$828 million. This funding is requested to support prevention and response strategies through the following activities:

Grants and technical assistance to Puerto Rico and U.S. Territories (\$225 million).

Locally transmitted Zika virus has been reported in the Commonwealth of Puerto Rico, the U.S. Virgin Islands, and America Samoa. Puerto Rico and the U.S. Territories may

have substantial spread of the Zika virus as more than 80 percent of adults in Puerto Rico have already been infected with at least one strain of dengue, and about a quarter have been infected with the more recently introduced chikungunya. This funding is requested to expand vector control programs to reduce transmission of *Aedes aegypti* mosquitoes and enhance lab capacity for the Zika virus and other infectious disease testing in Puerto Rico and the U.S. Territories. In addition, these resources would:

- Expand surveillance and response to local transmission;
- Conduct active surveillance for Zika virus infections in pregnant women; and establish surveillance for Guillain-Barré syndrome, including a Pregnancy Cohort Study and State Maternal/Child Surveillance birth defects registry in Puerto Rico;
- Implement vector control activities in priority areas/risk populations to suppress Zika virus transmission in Puerto Rico;
- Deploy targeted prevention and education strategies with key populations and support public education efforts, with a specific emphasis on at-risk populations; and
- Improve capacity at Commonwealth and Federal laboratories in Puerto Rico to diagnose the Zika virus disease rapidly.

Domestic Response (\$453 million). This funding is requested to prevent, detect, and respond to the Zika virus and other infectious diseases; strengthen State and local response capabilities; and establish teams for rapid response to clusters in local areas of the United States. More specifically, this funding would be used to:

- Provide grants to southern and other States at risk, and Territories with known *Aedes aegypti* populations to support the following activities:
 - CDC emergency response teams that can be deployed as needed to assist affected Territories and States in vector control; and
 - Improved vector prevention and control in areas that have experienced sporadic dengue transmission, and are at risk of Zika transmission, including Florida and Texas.
- Enhance epidemiology, laboratory, and surveillance capacity to track Zika virus in people and mosquitoes. Funding would be provided through the Epidemiology and Laboratory Capacity for Infectious Diseases Program and Laboratory Reference Network.
- Deploy targeted prevention and education strategies for key populations, including health care professionals, and support public education efforts, with a specific emphasis on at-risk populations.
- Conduct surveillance of health behaviors for women before, during, and after pregnancy using the Pregnancy Risk Assessment Monitoring System (PRAMS). Building on this existing capacity, CDC would expand PRAMS for Zika-related outcomes. CDC would also provide the clinical support and enhance the ability for birth defect registries across the United States to detect adverse health outcomes related to the Zika virus.
- Improve diagnostics for Zika, including advanced methods to refine tests, and support development of a vaccine through serological assays.

- Research the potential link between Zika and microcephaly and estimate the current prevalence of microcephaly and measure change in incidence rates over time as well as the risk factors and rates of adverse health outcomes from Zika.
- Strengthen existing CDC facilities, such as the Ft. Collins laboratory, to bolster capacity to prevent, detect, and respond to the Zika virus and other infectious vector-borne diseases.
- Minimize risk from transfusion, organ transplantation, and use of other equipment. CDC would also assist partners to identify sources of blood products for transfusion within affected areas to prevent transfusion-transmitted Zika.
- Develop novel methods and conduct research to control mosquitoes and discover new compounds that are safe and effective at both killing and repelling mosquitoes.

CDC International Response Activities (\$150 million). This funding would expand the Field Epidemiology Training Program, infectious disease surveillance, and emergency response activities in Zika-affected countries. It would also provide international capacity for surveillance, laboratories, training, and vector surveillance and control in countries at highest risk of the Zika virus disease and provide support to the Pan American Health Organization's (PAHO) laboratory network for increased vigilance on Zika.

Centers for Medicare and Medicaid Services – \$246 million. Puerto Rico and the other U.S. Territories are experiencing ongoing active transmission of the Zika virus. **This request seeks a one-year increase in the Medicaid Federal Medical Assistance Percentage (FMAP), from 55 to 65 percent in Puerto Rico and the other U.S. Territories, to provide an estimated \$246 million in additional Federal assistance to support health services for pregnant women at risk of infection or diagnosed with the Zika virus and for children with microcephaly and other birth defects, and for other health care costs. This request does not make any changes to the underlying Medicaid program in the Territories, and the additional funding would not be counted toward current Medicaid allotments.** Unlike States, Medicaid funding for Territories is capped, which has limited their capacity to respond to these emerging health needs.

National Institutes of Health Research, Including Vaccines – \$130 million. This funding supports efforts that would build upon existing resources to develop a vaccine for Zika and chikungunya (including the clinical testing phases up to the time when external interests would be willing to take over commercial development). Funds would also support basic research and research on the natural history of Zika.

Food and Drug Administration (FDA) Vaccine and Diagnostics Development and Review – \$10 million. This funding would support: development of reference reagents for Zika virus RNA to validate donor screening assays; evaluation of pathogen reduction methods for reducing Zika virus transmission in blood products; characterization of antigenic sites on the Zika virus for evaluating cross-protection by immunoglobulins against arboviruses; and expansion of diagnostic "regulatory-grade" nucleic acid database to support next generation diagnostic devices. The funding would also support post-market surveillance of vaccines, therapies, and other related administrative activities.

Other HHS Activities – \$295 million. This funding would be available to support urgent needs related to the Zika virus and other infectious diseases, such as rapid advanced development and commercialization of new vaccines, diagnostic tests, and vector control methods for the Zika virus, force health protection, and support for State public health response needs. These resources would also expand programs to support additional capacity in health centers operating in Puerto Rico to support health services, including prevention, screening, and treatment for the Zika virus. This funding would also expand home visiting services targeting low-income pregnant women diagnosed with, or at risk of infection from the Zika virus, and families with children born with microcephaly and other birth defects. In addition, HHS would place additional clinicians in Puerto Rico, as well as provide targeted assistance related to the Zika virus to Puerto Rico's Maternal and Child Health program. There are also resources requested to respond to emerging and unanticipated needs including funding that could be transferred to other Federal agencies as needed, such as the Department of Defense, the Environmental Protection Agency, U.S. Department of Agriculture, and others. This funding would provide the Federal Government the flexibility to address the changing circumstances of the Zika virus infections.

U.S. Agency for International Development (USAID) – \$335 million

The request includes investments to support affected countries' ability to control mosquitoes and the transmission of the virus, support maternal health, expand public education on prevention and response, and to create new incentives for the development of vaccines and diagnostics. The request would also provide flexibility in the use of remaining USAID Ebola funds. Activities would focus particularly on South America, Central America, and the Caribbean, and would:

- Leverage the successful strategies from the President's Malaria Initiative to implement integrated vector management activities in countries affected by or at risk of the Zika virus;
- Stimulate private sector research and development of vaccines, diagnostics, and vector control innovations through public-private partnerships and mechanisms to provide incentives, such as advance market commitments, volume guarantees, milestone payments, or incentive prizes;
- Support training of health care workers in affected countries including providing information about best practices for supporting children with microcephaly and providing support for pregnant women, including helping them access repellent to protect against mosquitoes.
- Establish education campaigns to empower communities in affected countries to take actions to protect themselves from the Zika virus as well as other mosquito-borne diseases; and
- Issue Global Health Security Grand Challenges calling for groundbreaking innovations in Zika diagnostics, vector control, personal protection, community engagement, and surveillance for Zika and other infectious diseases.

Department of State – \$41 million

The funding request includes support for U.S. citizens in affected countries, medical support for State Department employees in affected countries, public diplomacy, communications, and other operations activities. The Department would also support the World

Health Organization (WHO) and its regional arm, the Pan American Health Organization (PAHO), to minimize the Zika threat in affected countries while reducing the risk of further spreading the virus. These resources would support critical public health actions underway, including preparedness, surveillance, data collection, and risk communication. Activities would also include support for the UN Children's Fund's (UNICEF) Zika response efforts in Brazil, activities to bolster diagnostic capabilities through deployment of equipment, and specialized training. The request would also provide flexibility in the use of remaining State Ebola funds.

General Provisions

The request includes provisions that would, for example, provide the authority to transfer certain funding made available in the Act to allow the Federal Government the flexibility to address the changing circumstances of the outbreak. This funding would be transferred to address emerging needs including funding across other Federal agencies as needed, such as the Department of Defense, the Environmental Protection Agency, and U.S. Department of Agriculture. The request also would provide HHS the authority to undertake certain renovations, alterations, and leasing of buildings overseas. In addition, the request includes language for HHS, State, and USAID to receive direct hiring authority for necessary Federal workers as well as the ability to enter into personal services contracts with qualified individuals to improve response efforts and to enable quicker response. This request further proposes new authority to expand HHS's ability to develop countermeasures for emerging infectious diseases and other threats to public health, and permit USAID to make multi-year funding commitments to incentivize the development of global health technologies.

Recommendation

I carefully reviewed this request and I am satisfied that it is necessary at this time. Without emergency funding, agencies would not have sufficient resources to address the Zika virus adequately. In particular, without these resources, HHS, State, and USAID would have fewer resources needed to effectively control the Zika virus from further spread, develop safe and effective treatments and vaccines, or urgently expand international capacity to prevent, detect, and rapidly respond to outbreaks.

Therefore, I join the heads of the affected Departments and agencies in recommending you transmit the proposals to the Congress.

Sincerely,



Shaun Donovan
Director

Enclosures