

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, roughly circular loop that starts on the left and ends on the right with a horizontal line.

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 American 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC-Wide Activities and Program Support

(Including Transfer of Funds)

For an additional amount for "CDC-Wide Activities and Program Support", \$828,000,000, to remain available until expended, to prevent, prepare for, and respond to Zika virus, other vector-borne diseases, or other infectious diseases and related health outcomes, domestically and internationally; and to carry out titles II, III, and XVII of the Public Health Service ("PHS") Act with respect to domestic preparedness and global health: *Provided*, That products purchased with these funds may, at the discretion of the Secretary of Health and Human Services, be deposited in the Strategic National Stockpile under section 319F-2 of the PHS Act: *Provided further*, That funds may be used for purchase and insurance of official motor vehicles in foreign countries: *Provided further*, That the provisions in section 317S of the PHS Act shall apply to the use of funds appropriated in this paragraph as determined by the Director of the Centers for Disease Control and Prevention ("CDC") to be appropriate: *Provided further*, That funds appropriated in this paragraph may be used for grants for the construction, alteration, or renovation of non-federally owned facilities to improve preparedness and response capability at the State and local level: *Provided further*, That funds appropriated in this paragraph may be used for acquisition of real property (including long-term ground leases) and equipment, and construction, demolition, or renovation of facilities, including construction on leased land: *Provided further*, That funds appropriated in this paragraph may be transferred by the Director of CDC to other accounts of the CDC for the purposes provided in this paragraph: *Provided further*, That such transfer authority is in addition to any other transfer authority provided by law: *Provided further*, That, upon a determination that all or part of the funds transferred from this appropriation are not necessary for the purposes provided herein, such amounts may be transferred back to this appropriation: *Provided further*, That the amount appropriated in this paragraph is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended: *Provided further*, That such amount shall be available only if the President designates such amount as an emergency requirement pursuant to section 251(b)(2)(A).

This request would provide a total of \$828.0 million to prevent, detect, and respond to the Zika virus and other vector-borne and emerging infectious diseases both domestically and internationally. This funding would expand vector control programs to reduce the ongoing transmission of *Aedes aegypti* mosquitoes and enhance laboratory, epidemiology, and surveillance capacity, and testing for the Zika virus in States and Territories, with a priority focus on areas with ongoing Zika transmission such as Puerto Rico and the U.S. Territories, as well as in areas with the mosquitos that can spread Zika. CDC would also support 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 addition to strengthening preparedness in States and Territories, CDC would

enhance international capacity for virus surveillance and expand the Field Epidemiology Training Program and laboratory testing in countries at highest risk of Zika virus outbreaks.

Currently, there is no vaccine or therapeutic available to prevent or treat Zika virus infections. CDC has found that infection by Zika virus is possibly associated with birth defects and adverse pregnancy outcomes, especially microcephaly. CDC expects the number of cases of Zika virus across the U.S. and around the world to increase in the coming months.

Mosquito control is difficult. However, States and cities that invest in mosquito control mechanisms can track and address many mosquito breeding areas to drive down the populations. These resources would maximize the use of available tools to reduce the mosquitoes that can spread the Zika virus and other diseases, and equip State and local health departments and laboratories with the tools needed to detect and mitigate the spread of the Zika virus.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENTAL MANAGEMENT

Public Health and Social Services Emergency Fund

(Including Transfer of Funds)

For an additional amount for "Public Health and Social Services Emergency Fund", \$295,000,000, to remain available until expended, to prevent, prepare for, and respond to Zika virus, other vector-borne diseases, or other infectious diseases and related health outcomes, domestically and internationally; to develop necessary countermeasures and vaccines, including the development and purchase of vaccines, therapeutics, diagnostics, necessary medical supplies, and administrative activities; for carrying out titles II, III, and XVII of the PHS Act with respect to domestic preparedness and global health; and for carrying out title III of the PHS Act and title V of the Social Security Act to provide health care and related services in areas affected by Zika virus: *Provided*, That funds appropriated in this paragraph may be used to procure security countermeasures (as defined in section 319F-2(c)(1)(B) of the PHS Act, as amended by this Act): *Provided further*, That paragraphs (1) and (7)(C) of subsection (c) of section 319F-2 of the PHS Act, but no other provisions of such section, shall apply to such security countermeasures procured with funds appropriated in this paragraph: *Provided further*, That products purchased with funds appropriated in this paragraph may, at the discretion of the Secretary of Health and Human Services, be deposited in the Strategic National Stockpile under section 319F-2 of the PHS Act: *Provided further*, That funds appropriated in this paragraph may be transferred to the fund authorized by section 319F-4 of the PHS Act: *Provided further*, That funds appropriated in this paragraph may, for purposes of providing primary health services in areas affected by Zika virus, other vector-borne diseases, or other infectious diseases, be used to assign National Health Service Corps ("NHSC") members to Puerto Rico and other Territories, notwithstanding the assignment priorities and limitations in or under sections 333(a)(1)(D), 333(b), or 333A(a) of the PHS Act, and to make NHSC Loan Repayment Program awards under section 338B of such Act: *Provided further*, That funds may be awarded for projects of regional and national significance in Puerto Rico and other Territories authorized under section 501 of the Social Security Act, notwithstanding section 502 of such Act: *Provided further*, That funds may be used for the alteration or renovation of non-federally owned facilities to improve preparedness and response capability at the State and local level: *Provided further*, That funds appropriated in this paragraph may be transferred to other appropriations of the Department of Health and Human Services, as determined by the Secretary to be appropriate, to be used for the purposes specified in this paragraph: *Provided further*, That any transfers of these funds shall be made in consultation with the Office of Management and Budget: *Provided further*, That the transfer authority provided in this paragraph is in addition to any other transfer authority provided by law: *Provided further*, That, upon a determination that all or part of the funds transferred from this appropriation are not necessary for the purposes provided herein, such amounts may be transferred back to this appropriation: *Provided further*, That the amount appropriated in this paragraph is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended:

Provided further, That such amount shall be available only if the President designates such amount as an emergency requirement pursuant to section 251(b)(2)(A).

This request would provide \$295.0 million to support the development and procurement of medical countermeasures to diagnose, prevent, and treat the Zika virus and related vector-borne disease, or other emerging infectious disease. This funding would also support expanded authority in the Countermeasure Injury Compensation Fund if the PREP Act coverage is extended to manufacturers through BioShield, Advanced Development, or other vaccine research funding. This request would provide resources for public health services in Puerto Rico and other geographies affected by Zika. This request also includes language that would support health care services in affected areas through Health Centers, National Health Services Corps, Home Visiting program, and Maternal Child Health Special Projects of Regional and National Significance. Furthermore, this request also provides resources to support emerging needs related to Zika and other infectious diseases such as vaccine development and procurement, improved vector control methods, and support emerging State public health response needs. The transfer authority associated with the funds for emerging needs allows transfers of resources within the Department of Health and Human Services. As the urgent and emerging Zika virus progresses during summer months, it is necessary to have maximum flexibility to respond in a manner that is most appropriate.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases

For an additional amount for "National Institute of Allergy and Infectious Diseases", \$130,000,000, to remain available until expended, to prevent, prepare for, and respond to Zika virus, other vector-borne diseases, or other infectious diseases and related health outcomes, domestically and internationally, including expenses related to carrying out section 301 and title IV of the PHS Act: *Provided*, That such funds may be transferred by the Director of the National Institutes of Health ("NIH") to other accounts of the NIH for the purposes provided in this paragraph: *Provided further*, That such transfer authority is in addition to any other transfer authority provided by law: *Provided further*, That, upon a determination that all or part of the funds transferred from this appropriation are not necessary for the purposes provided herein, such amounts may be transferred back to this appropriation: *Provided further*, That the amount appropriated in this paragraph is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended: *Provided further*, That such amount shall be available only if the President designates such amount as an emergency requirement pursuant to section 251(b)(2)(A).

This request would provide \$130.0 million to support preclinical and clinical development of vaccines for the Zika virus, other vector-borne diseases, or other infectious diseases. Funding would also be used for basic research and research on the natural history of disease of the Zika virus and other vector-borne diseases.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

Salaries and Expenses

For an additional amount for "Salaries and Expenses", \$10,000,000, to remain available until expended, to prevent, prepare for, and respond to Zika virus, other vector-borne diseases, or other infectious diseases and related health outcomes, domestically and internationally, and to develop necessary medical countermeasures and vaccines, including the review, regulation, and post market surveillance of vaccines and therapies, and administrative activities: *Provided*, That such amount is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended: *Provided further*, That such amount shall be available only if the President designates such amount as an emergency requirement pursuant to section 251(b)(2)(A).

This request would provide \$10.0 million in funding to support highly targeted regulatory science research required for the efficient development and regulatory review of medical products and blood screening assays for Zika virus; collaboration with, and providing technical support to international partners' response efforts; and FDA staff to support the development, review, regulation, and surveillance of vaccines, diagnostics, and therapies.

GENERAL PROVISIONS—THIS ACT

(Including Transfer of Funds)

Sec. ____ . For purposes of preventing, preparing for, and responding to Zika virus, other vector-borne diseases, or other infectious diseases and related health outcomes domestically and internationally, the Secretary of Health and Human Services may use funds provided in this Act—

(1) to acquire, lease, construct, alter, renovate, equip, furnish, or manage facilities outside of the United States, as necessary to conduct such programs, in consultation with the Secretary of State, either directly for the use of the United States Government or for the use, pursuant to grants, direct assistance, or cooperative agreements, of public or nonprofit private institutions or agencies in participating foreign countries; and

(2) to enter into contracts with individuals for the provision of personal services (as described in section 104 of part 37 of title 48, Code of Federal Regulations (48 CFR 37.104)), within the United States and abroad: *Provided*, That such individuals may not be deemed employees of the United States for the purpose of any law administered by the Office of Personnel Management.

This provision would provide HHS with the authority to directly undertake certain renovations, alterations, and leasing overseas for the use of U.S. Government staff. The general provision would also provide expanded personal services contract authority for HHS to more rapidly hire/deploy staff to improve response efforts for the purposes of preventing, preparing for, and responding to the Zika virus, other vector-borne diseases, or other infectious diseases and related outcomes domestically and internationally. Currently, the CDC does not have the authority to use personal services contracts domestically. This flexibility is necessary to meet the surge in integrated workforce that is required for HHS to respond to the Zika virus and perform domestic preparedness activities.

Sec. ____ . Section 3304 of title 5, United States Code, is amended by adding a new subsection (g), to read as follows—

"(g) The heads of the Department of Health and Human Services, Department of State, and the Agency for International Development may appoint, without regard to the provisions of sections 3309 through 3319, candidates needed for positions to perform critical work in direct response to a public health threat requiring an immediate response for which—

"(1) public notice has been given; and

"(2) the Secretary of Health and Human Services has determined that such a public health threat exists."

This proposal would provide authority for HHS, State, and USAID to directly hire staff during urgent public health threats such as Zika. Current hiring processes can involve delay and make it difficult to hire individuals with needed competencies. Expedited hiring authority would allow agencies to urgently respond to public health threats.

Sec. ____ . Funds appropriated by this Act may be used to reimburse accounts administered by the Department of Health and Human Services for obligations incurred for Zika virus response prior to the enactment of this Act.

This proposal would allow funds provided in this Act to be used to reimburse accounts at the Department of Health and Human Services to address the Zika disease response that occurred prior to the enactment of this appropriation.

Sec. ____ . TRANSFER AUTHORITY. Funds appropriated to the Department of Health and Human Services in this Act may be transferred to and merged with other Federal accounts for purposes specified in this Act following consultation with the Office of Management and Budget: *Provided*, That such transfer authority shall be in addition to any other transfer authority provided by law: *Provided further*, That, upon a determination that all or part of the funds transferred from an appropriation are not necessary, such amounts may be transferred back to that appropriation.

This proposal would allow the transfer of certain resources provided in this Act to other Departments and agencies, including the Department of Defense, the Environmental Protection Agency, and the Department of Agriculture. This authority would allow the Federal Government the flexibility to address the changing circumstances of the Zika virus.

Sec. ____ . Section 319F-2(c)(1)(B) of the Public Health Service Act (42 U.S.C. 247d-6b(c)(1)(B)) is amended—

(1) in clause (i)(III)(bb), by striking "; or" and inserting a semicolon;

(2) in clause (ii), by striking the period and inserting "; or"; and

(3) by adding the following new clause:

"(iii)(I) the Secretary determines to be a necessary countermeasure to diagnose, mitigate, prevent, or treat harm from any infectious disease that may pose a threat to the public health; and

"(II)(aa) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act, or licensed under section 351 of this Act; or

"(bb) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within 10 years after the date of a determination under subclause (I)."

This provision would expand the definition of a security countermeasure for the purpose of procurement under BioShield, such that countermeasures meeting the new definition are not required to be associated with a Material Threat Determination. Countermeasures meeting the new definition are countermeasures the HHS Secretary determines to be necessary to diagnose, mitigate, prevent, or treat harm from any infectious disease that may pose a threat to the public health.

Sec. ____ . EMERGENCY INCREASE IN TERRITORIAL FMAP.

(a) IN GENERAL.—

(1) For purposes of title XIX of the Social Security Act, for the one year period beginning with the first day of the first full fiscal quarter following enactment of this section, the Federal medical assistance percentage ("FMAP") under section 1905(b) of such Act for the Territories specified in paragraph (2) shall be raised from 55 percent to 65 percent. Any net increase in payment to such a territory under section 1903(a) of such Act, which is attributable to such raised FMAP, shall be disregarded in applying sections 1108(f) and 1108(g) of such Act to the territory.

(2) The Territories specified in this paragraph are the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(b) AVAILABILITY OF APPROPRIATIONS FOR IMPLEMENTING INCREASED FMAP.—With respect to the amount needed for purposes of implementing the raised FMAP under subsection (a) for each of fiscal years 2016 and 2017, such amount is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended, and such amount shall be available only if the President designates such amount as an emergency requirement pursuant to section 251(b)(2)(A).

This request would increase the Medicaid Federal Medical Assistance Percentage (FMAP), from 55 to 65 percent, in Puerto Rico and the other U.S. Territories for one year to provide additional Federal assistance to support health services for pregnant women at risk of infection or diagnosed with 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 towards current Medicaid allotments. Puerto Rico and the other U.S. Territories are experiencing ongoing active transmission of the Zika virus. Unlike States, Medicaid funding for Territories is capped, which has limited their capacity to respond to these emerging health needs. This is being requested as a change in a mandatory program impacting both FY 2016 and FY 2017.

DEPARTMENT OF STATE AND OTHER INTERNATIONAL PROGRAMS

ADMINISTRATION OF FOREIGN AFFAIRS

Diplomatic and Consular Programs

For an additional amount for "Diplomatic and Consular Programs", \$14,594,000, to remain available until September 30, 2017, for necessary expenses to support response efforts related to the Zika virus and related health outcomes, other vector-borne diseases, or other infectious diseases: *Provided*, That up to \$2,419,000 may be made available for medical evacuation costs of any other Department or agency of the United States under the Chief of Mission authority, and may be transferred to any other appropriation of such Department or agency for such costs: *Provided further*, That such amount is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended: *Provided further*, That such amount shall be available only if the President designates such amount as an emergency requirement pursuant to section 251(b)(2)(A).

This request would provide a total of \$14.6 million for immediate support to address the Zika virus. Of this amount, \$8.4 million would support the Office of Medical Services to enable additional medical evacuations for employees facing increases risk due to the virus including authority to provide evacuation services to other agencies under Chief of Mission authority. The remaining \$6.2 million of the request would support coordination efforts in the region, public diplomacy outreach, and related U.S. efforts.

DEPARTMENT OF STATE AND OTHER INTERNATIONAL PROGRAMS

ADMINISTRATION OF FOREIGN AFFAIRS

Emergencies in the Diplomatic and Consular Service

For an additional amount for "Emergencies in the Diplomatic and Consular Services", \$4,000,000 for necessary expenses to support response efforts related to the Zika virus and related health outcomes, other vector-borne diseases, or other infectious diseases, to remain available until expended: *Provided*, That such amount is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended: *Provided further*, That such amount shall be available only if the President designates such amount as an emergency requirement pursuant to section 251(b)(2)(A).

This request would provide a total of \$4.0 million in funding to support potential costs for evacuation of U.S. citizens from Zika-affected countries.

DEPARTMENT OF STATE AND OTHER INTERNATIONAL PROGRAMS

ADMINISTRATION OF FOREIGN AFFAIRS

Repatriation Loans Program Account

For an additional amount for "Repatriation Loans Program Account" for the cost of direct loans, \$1,000,000, to support the response efforts related to the Zika virus and related health outcomes, other vector-borne diseases, or other infectious diseases, to remain available until expended: *Provided*, That such costs, including the cost of modifying such loans, shall be as defined in section 502 of the Congressional Budget Act of 1974: *Provided further*, That such funds are available to subsidize an additional amount of gross obligations for the principal amount of direct loans not to exceed \$1,880,406: *Provided further*, That such amount is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended: *Provided further*, That such amount shall be available only if the President designates such amount as an emergency requirement pursuant to section 251(b)(2)(A).

This request would provide \$1.0 million to enable financing of \$1.9 million in repatriation loans to U.S. citizens who are seeking to leave Zika-affected areas or who have been exposed to or contracted Zika.

DEPARTMENT OF STATE AND OTHER INTERNATIONAL PROGRAMS

OTHER

Global Health Programs

For an additional amount for "Global Health Programs", \$325,000,000, to remain available until expended, for necessary expenses for assistance or research to prevent, treat, or otherwise respond to the Zika virus and related health outcomes, other vector-borne diseases, or other infectious diseases: *Provided*, That funds appropriated under this heading may be made available for multi-year funding commitments to incentivize the development of global health technologies: *Provided further*, That such amount is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended: *Provided further*, That such amount shall be available only if the President designates such amount as an emergency requirement pursuant to section 251(b)(2)(A).

The request would provide a total of \$325.0 million for investments to support affected countries' ability to implement vector management and control programs and reduce transmission of the Zika virus; support maternal and child health; expand public communication and behavior change efforts; and create new incentives for the development of vaccines, diagnostics, vector control innovations, and other global health technologies. Activities would focus particularly on affected and at-risk countries, which are currently in South America, Central America, and the Caribbean. While specific allocations would be refined as country needs are assessed, the following are preliminary anticipated allocations:

- \$100 million to implement integrated vector management and control activities in countries affected by and at risk of the Zika virus and other vector-borne diseases;
- \$100 million to 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 or volume guarantees;
- \$50 million to provide support for maternal and child health in affected and at risk countries, including training of health care workers, ensuring access to voluntary family planning information, services, and methods, providing information about best practices for supporting children with microcephaly, and helping pregnant women and their partners access appropriate personal protection including repellent to protect against mosquitoes;
- \$25 million to establish public health communication and behavior change campaigns to empower communities in affected and at-risk countries to take actions to protect themselves from the Zika virus and other vector-borne diseases; and
- \$50 million to issue Global Health Security Grand Challenges calling for groundbreaking innovations in diagnostics, vector control, personal protection, community engagement and surveillance or other tools to address Zika and other infectious diseases, or develop other public-private partnerships designed to accelerate the introduction of innovative tools and practices.

INTERNATIONAL ASSISTANCE PROGRAMS

INTERNATIONAL SECURITY ASSISTANCE

Nonproliferation, Anti-Terrorism, Demining and Related Programs

For an additional amount for "Nonproliferation, Anti-Terrorism, Demining and Related Programs", \$8,000,000, to remain available until September 30, 2017, for necessary expenses to support response and research efforts related to the Zika virus and related health outcomes, other vector-borne diseases, or other infectious diseases: *Provided*, That such amount is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended: *Provided further*, That such amount shall be available only if the President designates such amount as an emergency requirement pursuant to section 251(b)(2)(A).

This request would provide a total of \$8.0 million for necessary expenses for a United States voluntary contribution to the International Atomic Energy Agency (IAEA) for Zika response and research efforts. U.S. funding will support the IAEA's work to develop and deploy nuclear techniques to help accelerate diagnosis, including related specialized training, and to implement sterile insect projects that help suppress mosquito populations.

INTERNATIONAL ASSISTANCE PROGRAMS

MULTILATERAL ASSISTANCE

International Organizations and Programs

For an additional amount for "International Organizations and Programs", \$13,500,000, to remain available until September 30, 2017, for necessary expenses to support response and research efforts related to the Zika virus and related health outcomes, other vector-borne diseases, or other infectious diseases: *Provided*, That such amount is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended: *Provided further*, That such amount shall be available only if the President designates such amount as an emergency requirement pursuant to section 251(b)(2)(A).

This request would provide a total of \$13.5 million to support activities undertaken by the WHO and its regional arm, PAHO, UNICEF, and the Food and Agriculture Organization related to Zika virus response.

INTERNATIONAL ASSISTANCE PROGRAMS
AGENCY FOR INTERNATIONAL DEVELOPMENT

Operating Expenses

For an additional amount for "Operating Expenses", \$10,000,000, to remain available until September 30, 2017 for necessary expenses to support response efforts related to the Zika virus and related health outcomes, other vector-borne diseases, or other infectious diseases: *Provided*, That such amount is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended: *Provided further*, That such amount shall be available only if the President designates such amount as an emergency requirement pursuant to section 251(b)(2)(A).

This request would provide \$10.0 million for additional operating costs to support Zika virus response.

GENERAL PROVISIONS - DEPARTMENT OF STATE AND OTHER INTERNATIONAL PROGRAMS

Use of Ebola Balances for Other Infectious Diseases

Sec. ____ . Unobligated balances of amounts appropriated under title IX of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2015 (division J of Public Law 113–235) shall also be available for necessary expenses for operations, assistance, or research to prevent, treat, or otherwise respond to the Zika virus and related health outcomes, other vector-borne diseases, or other infectious diseases: *Provided*, That amounts repurposed pursuant to this section are designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended: *Provided further*, That such amounts shall be available only if the President designates such amounts as an emergency requirement pursuant to section 251(b)(2)(A).

This provision would allow unobligated balances of amounts provided to the Department of State and USAID in FY 2015 to address the Ebola disease to also be used to respond to the Zika virus or other infectious diseases as needed.

Transfer Authority

Sec. ____ . (a) Funds appropriated by this Act under the headings "Global Health Programs", "Nonproliferation, Anti-Terrorism, Demining and Related Programs", "International Organizations and Programs", and "Operating Expenses" may be transferred to, and merged with, funds appropriated by this Act under such headings to carry out the purposes of this Act.

(b) Funds appropriated by this Act under the headings "Diplomatic and Consular Programs", "Emergencies in the Diplomatic and Consular Service", and "Repatriation Loan Programs" may be transferred to, and merged with, funds appropriated by this Act under such headings to carry out the purposes of this Act.

(c) The transfer authorities provided by this section are in addition to any other transfer authority provided by law.

(d) Upon a determination that all or part of the funds transferred pursuant to the authorities provided by this section are not necessary for such purposes, such amounts may be transferred back to such appropriations.

This proposal would allow transfers of resources between the accounts in this title at the Department of State and USAID in order to provide the flexibility to address the changing circumstances of the Zika virus.

Reimbursement Authority

Sec. ____ . Funds appropriated by this Act may be used to reimburse accounts administered by the United States Agency for International Development and the Department of State for obligations incurred for Zika virus response prior to the enactment of this Act.

This proposal would allow funds provided in this Act to be used to reimburse accounts at the Department of State and USAID for obligations to address the Zika virus response that occurred prior to the enactment of this appropriation.

Availability of Funds for International Organizations

Sec. ____ . Section 307(a) of the Foreign Assistance Act of 1961 shall not apply to funds appropriated by this Act.

This proposal would allow any voluntary contributions to international organizations for Zika virus response using funds provided in this Act to be made without regard to the "pariah state" withholding of section 307 of the Foreign Assistance Act.

Notwithstanding Authority

Sec. ____ . Funds appropriated or otherwise made available under this Act and prior Acts making appropriations for the Department of State, Foreign Operations, and Related Programs that are made available to support Zika virus response and related activities may be made available notwithstanding any other provision of law.

This proposal would allow funds from this or prior Acts that are made available to support Zika virus response to be used notwithstanding any other provision of law, to ensure that Zika virus response activities can be undertaken where restrictions might otherwise impede or prevent the U.S. Government response.

Personal Service Contractors

Sec. ____ . Funds available in this Act to support response efforts related to the Zika virus and related health outcomes, other vector-borne diseases, or other infectious diseases may be used to enter into contracts with individuals for the provision of personal services (as described in section 104 of part 37 of title 48, Code of Federal Regulations (48 CFR 37.104)) in the United States or abroad: *Provided*, That such individuals may not be deemed employees of the United States for the purpose of any law administered by the Office of Personnel Management.

This proposal would allow the Department of State and USAID to quickly hire additional experts, such as global health practitioners, infectious disease physicians, and other medical staff, to support assistance programs and assist with the high volume of inquiries and requests for assistance from posts overseas.