

under Executive Order 12963, dated June 14, 1993, and amended under Executive Order 13009, dated June 14, 1995. PACHA is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App.). The Council provides advice, information, and recommendations to the Secretary regarding programs and policies to promote effective prevention and cure of HIV disease and AIDS. The functions of the Council are solely advisory in nature.

To carry out its mission, PACHA provides advice, information, and recommendations to the Secretary regarding programs and policies to (a) Reduce HIV incidence; (b) advance research on HIV/AIDS; (c) improve health outcomes and ensure people living with HIV have access to quality health care; (d) address HIV-related health disparities; and (e) provide global leadership in responding to the HIV pandemic and expand access to treatment, care, and prevention for people infected with and affected by HIV/AIDS around the world.

On July 26, 2013, the Secretary of Health and Human Services approved for the PACHA charter to be renewed. One amendment was approved for the charter. It was approved for the subcommittee structure of the Council to be amended to authorize utilization of non-member special consultants. The use of non-member special consultants will allow for more input and involvement from stakeholders in the HIV/AIDS community in the PACHA deliberative process. The new charter was effected and filed with the appropriate Congressional offices and Library of Congress on July 27, 2013. Renewal of the PACHA charter gives authorization for the Council to continue to operate until July 27, 2015.

A copy of the PACHA charter is available on the Council Web site at www.aids.gov/pacha. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site address for the FACA database is www.fido.gov/facadatabase.

Dated: August 8, 2013.

B. Kaye Hayes,

Executive Director, Presidential Advisory Council on HIV/AIDS.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Renewal of Charter for the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services is hereby giving notice that the National Vaccine Advisory Committee (NVAC) has been rechartered.

FOR FURTHER INFORMATION CONTACT: LCDR Guillermo Aviles-Mendoza, Public Health Advisor, National Vaccine Program Office, Department of Health and Human Services, Room 739G.4, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Phone: (202) 205-2982; fax: (202) 690-4631; email: nvpo@hhs.gov.

SUPPLEMENTARY INFORMATION: NVAC is a non-discretionary Federal advisory committee. The establishment of NVAC was mandated under Section 2105 (42 U.S.C. Section 300aa-5) of the Public Health Service (PHS) Act, as amended. The Committee is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App.). NVAC advises and makes recommendations to the Director, National Vaccine Program (NVP), on matters related to the Program's responsibilities. The Assistant Secretary for Health is appointed to serve as the Director, NVP.

To carry out its mission, NVAC (1) Studies and recommends ways to encourage the availability of an adequate supply of safe and effective vaccination products in the United States; (2) recommends research priorities and other measures the Director of the NVP should take to enhance the safety and efficacy of vaccines; (3) advises the Director of the NVP in the implementation of Sections 2102 and 2103 of the PHS Act; and (4) identifies annually for the Director of the NVP the most important areas of governmental and non-governmental cooperation that should be considered in implementing Sections 2101 and 2103 of the PHS Act.

On July 23, 2013, the Assistant Secretary for Health approved for the NVAC charter to be renewed. There was one amendment recommended and approved for the charter. The Committee structure has been modified

to increase the number of non-voting liaison representatives. An invitation has been extended to the Pan American Health Organization (PAHO) to serve as a non-voting liaison representative member of the Committee. PAHO is an international public health agency with over 110 years of experience working to improve health and living standards of people of the Americas. The organization is part of the United Nations system; it serves as the Regional Office for the Americas of the World Health Organization and as the health organization of the Inter-American System. PAHO works to strengthen national and local health systems and to improve the health of peoples of the Americas. It promotes primary health care strategies, including coordination of immunization campaigns through the Americas. Expanding the NVAC structure to include PAHO will assist the Committee to accomplish its mission of identifying the most important areas of governmental and non-governmental cooperation that should be considered to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccine. The new charter was effected and filed with the appropriate Congressional committees and Library of Congress on July 30, 2013. Renewal of the NVAC charter gives authorization for the Committee to continue to operate until July 30, 2015.

A copy of the NVAC charter is available on the Web site for the National Vaccine Program Office at <http://www.hhs.gov/nvpo/nvac>. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site address for the FACA database is <http://fido.gov/facadatabase>.

Dated: August 8, 2013.

Bruce Gellin,

Deputy Assistant Secretary for Health (Vaccines and Immunization), Director, National Vaccine Program Office.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notification of a Cooperative Agreement Award to the World Health Organization

AGENCY: Department of Health and Human Services (HHS), Assistant Secretary for Preparedness and

Response (ASPR), Biomedical Advanced Research and Development Authority.

ACTION: Notification of a sole source Cooperative Agreement Award to the World Health Organization for a grant titled: "Smallpox Research Oversight Activities: WHO Advisory Committee on Variola Virus Research."

Statutory Authority: Sections 301 and 319L of the Public Health Service Act, (42 U.S.C. 241 and 247d-7e).

Estimated Amount of Award: \$290,000 USD.

Project Period: September 30, 2013 to September 29, 2014.

SUMMARY: A natural re-emergence of smallpox is not deemed possible, but if it were to occur as a result of a terrorist or deliberate event, it would be a potentially devastating threat to public health worldwide and would constitute a public health emergency of international concern (PHEIC) under the International Health Regulations (IHR) (2005). A case of smallpox detected by a member state requires notification to World Health Organization (WHO) as soon as possible, and any confirmed smallpox case would generate an immediate global public health response.

WHO must rely on fast and reliable laboratory diagnostic capacity worldwide to be able to identify a re-emergence of smallpox, particularly in countries where systemic orthopoxvirus infections, such as monkeypox, vaccinia virus infection or cowpox, and other non-pox viral rash illnesses, such as chicken pox, may cause clinical diagnostic confusion.

Over the past 10 years, clinical virology laboratory diagnostics has been evolving and increasingly relies on molecular techniques. This is also true with laboratory diagnoses of poxvirus infections. Precise and consistent identification of orthopoxviruses, in particular variola viruses, is now achievable using such molecular techniques as real-time Polymerase Chain Reaction (PCR), unlike earlier techniques that may have relied on direct virus isolation and identification.

WHO must be alerted when there is a potential or actual smallpox infection. Early detection and confirmation of smallpox cannot rely solely on the two WHO Collaborating Centres for smallpox and other poxvirus infections. In order to facilitate and support a prompt and effective response to mitigate the spread of the disease, these two Centres should be supported by a worldwide network of reliable laboratories able to perform PCR and real-time PCR diagnostics enabling

initial detection and identification of smallpox events.

Additionally, the U.S. Government supports the development of other medical products, including vaccines and drugs, for use within the U.S. upon verification of a smallpox case. The U.S. Government, through the Office of the Assistant Secretary for Preparedness and Response (ASPR), has successfully developed vaccine products, and is actively engaged in the development of several drug candidates for smallpox therapies, which require access to the Variola virus to satisfy regulatory requirements for product approvals.

Justification: WHO is the only eligible applicant; it is the only organization that is allowed by international agreements to address the issues outlined in this proposal. WHO is the directing and coordinating authority for health within the United Nations (U.N.) system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends. In the 21st century, health is a shared responsibility, involving equitable access to essential care and collective defense against transnational threats. States Parties to the U.N. have agreed to international standards on reporting public health incidents of concern under IHR (2005). Additionally, a majority of States Parties have also agreed to specific work-frames for pathogens such as smallpox under the Biological Weapons Convention.

Since May 1999, when the 52nd World Health Assembly (WHA) resolved to postpone the destruction of the Variola virus to allow for essential research (WHA 52.10), WHO has been charged with convening a group of experts to advise on the need for continuing such research, to review proposals for research involving viable Variola virus, to review the progress of such research, and to report to the WHA each year. The need to support the activities described in this project has not changed. In fact, WHO Member States continue to exert pressure for the WHO Secretariat to carry out this work.

The WHO Advisory Committee on Variola Virus Research (ACVVR) was established in 1999 to determine what essential research, if any, must be carried out with live Variola virus. The ACVVR monitored the research progress in order to reach global consensus on the timing for the destruction of existing Variola virus stocks. In 2007, the WHA requested the ACVVR undertake a thorough review of the approved

research program with a report presented in 2010. The results were presented at the 64th WHA meeting in May of 2011. The ACVVR continues to serve a critically important function for global public health, and to oversee research requested specifically by the U.S. to complete its national strategic goals. This includes convening a group of experts, the ACVVR, to advise on the need for continuing such research, to review proposals for research involving viable Variola virus, and to review the progress of such research.

Additional Information: The agency program contact is George Korch, who can be contacted by phone at (202) 690-5760 or via email at George.Korch@hhs.gov.

Dated: August 8, 2013.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notification of an Expansion to the Cooperative Agreement Award to the World Health Organization

AGENCY: Biomedical Advanced Research and Development Authority (BARDA), Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notification of an expansion to the Cooperative Agreement Award to the World Health Organization for a grant titled: "Smallpox Research Oversight Activities: WHO Advisory Committee on Variola Virus Research"

Statutory Authority: Sections 301 and 319L of the Public Health Service Act, (42 U.S.C. 241 and 247d-7e)

Estimated Amount of Award: \$175,000 USD.

Project Period: September 30, 2012 to September 29, 2013.

SUMMARY: A natural re-emergence of smallpox is not deemed possible, but if it were to occur as a result of a terrorist or deliberate event, it would be a potentially devastating threat to public health worldwide and would constitute a public health emergency of international concern (PHEIC) under the International Health Regulations (IHR) (2005). A case of smallpox detected by a member state requires notification to World Health Organization (WHO) as soon as possible, and any confirmed smallpox case would generate an